

IEC 60601-1
IEC 60601-1标准

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Edition 3.1 2012-08
版本3.1 2012-08

INTERNATIONAL STANDARD
国际标准

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Medical electrical equipment –
医疗电气设备-

Part 1: General requirements for basic safety and essential performance
第1部分：基本安全和基本性能的一般要求



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INTERNATIONAL
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COMMISSION
国际电工委员会

ICS 11.040
0331-6
ICS 11.040国际标准书号978-2-8322-0331-6

ISBN 978-2-8322-

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Publication IEC 60601-1 (Third edition – 2005) I-SH 01
出版物IEC 60601-1（第三版-2005）I-SH 01

MEDICAL ELECTRICAL EQUIPMENT –
医疗电气设备-
Part 1: General requirements for basic safety and
essential performance
第1部分：基本安全和基本性能的一般要求

INTERPRETATION SHEET 1
解释表1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice
本解释表由SC 62A：医疗实践中使用的电气设备的共同方面编制

The text of this interpretation sheet is based on the following documents:
本解释表的文本基于以下文件：

ISH 依什	Report on voting 表决报告
62A/599/IS H 62A/599/IS H标准	62A/613/RV D 62A/613/RV D型

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.
批准本解释表的投票情况详见上表中的投票报告。

Subclause 1.1
第1.1款

This subclause is clarified by the following:
本款规定如下：

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.
IEC 60601-1不适用于ISO 7396-1《医用气体管道系统-第1部分：压缩医用气体和真空管道系统》所涵盖的医用气体管道系统。

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.
注：ISO 7396-1第6.3款将IEC 60601-1-8的要求应用于某些监测和报警信号。

This clarification will remain valid until a new version of IEC 60601-1 is published.
本澄清在新版IEC 60601-1发布之前仍然有效。

April 2008
2008年4月

Publication IEC 60601-1 (Third edition – 2005) I-SH 02
出版物IEC 60601-1（第三版-2005）I-SH 02

MEDICAL ELECTRICAL EQUIPMENT –
医疗电气设备-

Part 1: General requirements for basic safety and
essential performance

第1部分：基本安全和基本性能的一般要求

INTERPRETATION SHEET 2

解释表2

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

本解释表由IEC技术委员会62：医疗实践中的电气设备第62A分条款：医疗实践中使用的电气设备的共同方面编制。

The text of this interpretation sheet is based on the following documents:

本解释表的文本基于以下文件：

ISH 依什	Report on voting 表决报告
62A/634/IS H 62A/634/IS H型	62A/640/RV D RVD/620年

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

批准本解释表的投票情况详见上表中的投票报告。

Subclause 11.3

第11.3款

This subclause is clarified by the following:

本款规定如下：

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) and a significant source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

如本款基本原理所述，防火罩仅适用于由于火源（如本款所述）和重要燃料源而导致火灾的可能性很大的情况。医用电气设备制造中使用的大多数材料不被视为燃料来源，除非它们处于富氧环境中。制造商应通过风险管理文件中记录的分析，确定医用电气设备是否含有足够数量的可燃材料（燃料），以支持

燃烧和火源（能够释放超过900焦耳）。

Subclause 13.1.2

第13.1.2款

This subclause is clarified by the following:

本款规定如下：

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition. 如第4.7款所述，制造商的风险分析根据相关风险确定哪些部件需要进行故障测试。如果相关火灾风险超过制造商的风险可接受性标准，则应接受制造商的模拟分析（如FMEA）代替物理测试。如4.7所述，在此类失效模拟分析中应考虑部件可靠性和额定值。不应考虑使用过可能引起火灾的电子设备。

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from the ENCLOSURE not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where 如果本款将“危险量的火焰、熔融金属、有毒或易燃物质的排放”确定为危险情况，则指的是外壳而非部件本身的排放物。如果确定“超出表22中确定的‘其他部件和材料’的允许值乘以1.5减去12.5°C”，则仅适用于这样做会导致不可接受风险的情况（如制造商根据4.7进行的风险分析中确定的）。通常情况下

January 2009

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ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion. 基本性能将无法保持，或在存在可维持燃烧的易燃材料的情况下释放的能量超过900 J。

The first exemption to fault analysis or testing identified in subclause 13.1.2 ("The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.") is intended to apply where the component design itself ("The construction") or fusing (or other current limiting devices) in the supply circuit ("or the supply circuit") assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit. 第13.1.2款（“结构或供电电路将单个故障条件下的功耗限制在15 W以下，或将能量耗散限制在900 J以下”）中确定的故障分析或测试的第一个豁免适用于部件设计本身（“结构”）或熔断（或其他电源电路（“或电源电路”）中的限流装置确保故障期间释放的能量不会超过限值。对于额定工作在5瓦以下的最常见信号电平元件，输出短路释放的能量不会超过900 J的极限。

This clarification will remain valid until a new version of IEC 60601-1 is published. 本澄清在新版IEC 60601-1发布之前仍然有效。

January 2009
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MEDICAL ELECTRICAL EQUIPMENT –

医疗电气设备-

Part 1: General requirements for basic safety and essential performance

第1部分：基本安全和基本性能的一般要求

INTERPRETATION SHEET 3

解释表3

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

本解释表由IEC技术委员会62：医疗实践中电气设备的共同方面第62A小组委员会编制。

The text of this interpretation sheet is based on the following documents:

本解释表的文本基于以下文件：

ISH 依什	Report on voting 表决报告
62A/858/IS H 62A/858/IS H	62A/875/RV D 62A/875/RV D型

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

批准本解释表的投票情况详见上表中的投票报告。

Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)

第13.1.2款第四行（排放、外壳变形或超过最高温度）

This subclause states the following:

本款规定如下：

The following HAZARDOUS SITUATIONS shall not occur:

不得出现以下危险情况：

☐

☐

- temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;
当按照11.1.3所述进行测量和调整时，医用电气设备非应用部件但有可能接触的部件的温度超过表23中的允许值；

This is clarified by the following:

这一点可以通过以下方式加以澄清：

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

如果满足以下条件，则根据第4.5款外壳表面温度，上述要求视为满足：

- The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and
单一故障条件下，操作员可触及表面的最高允许温度为105°C；以及
- the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (indicate the surface of concern) could get hot and there is a possible RISK of a burn if touched, and
使用说明包含一个警告，在某些单一故障条件下，温度：（指示问题表面）可能会变热，如果触摸可能会有烧伤的风险，以及
- if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018) shall be used on or adjacent to the hot spot on the ENCLOSURE; and
如果风险分析表明需要在外壳上设置警告符号，则应在外壳上的热点上或附近使用安全标志ISO 7010-W018）；以及
- the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and
风险评估表明，在单一故障条件下获得的温度是可接受的，并且
- the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.
风险评估表明，采用本解释表中的替代风险控制措施会产生与应用本标准要求产生的剩余风险相当的剩余风险。

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

注1：本解释表适用于IEC 60601-1第3.0版和第3.1版。

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

注2：以下是一个分析示例，表明发生伤害的概率很低。

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Example RISK ASSESSMENT:

风险评估示例:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = $1\text{E-}9/\text{h}$) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn. 根据标准MIL-HDBK-217F，可能使XYZ设备外壳零件表面温度升高至表23所示值以上的零件的总故障率计算为60配合（1配合= $1\text{E-}9/\text{h}$ ），其中FIT代表“及时故障”。如果发生此类故障，设备将发出气味，不再正常工作。据估计，只有3种情况下，设备不会立即关闭，热表面会导致烧伤。

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability 如果使用说明中提供了足够的警告，并结合警告标志ISO 7010 W018，则产生此类损害的总概率为：概率

= $1/3 * 60 \text{ FIT} = 2 \text{ E-}8/\text{h} \approx 0,0002 \text{ per year.}$

= $1/3*60$ 配合= $2 \text{ E-}8/\text{h}$ =每年约00002。

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable. 在本例中，WXW公司的风险接受标准要求，该严重程度的危害每年的概率必须小于00003，相关风险才能被视为可接受。根据该风险接受标准，由电路中单个故障引起的外壳过热风险是可以接受的。

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INTERNATIONAL ELECTROTECHNICAL COMMISSION 国际电工委员会

MEDICAL ELECTRICAL EQUIPMENT – 医疗电气设备-

Part 1: General requirements for basic safety and essential performance 第1部分：基本安全和基本性能的一般要求

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This consolidated version of IEC 60601-1 consists of the third edition (2005) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012) [documents 62A/805/FDIS and 62A/820/RVD], its corrigenda of December 2006 and 2007, the corrigendum of its amendment 1 of July 2014, and the interpretations sheets of April 2008, January 2009 and May 2013. It bears the edition number 3.1.
IEC 60601-1的合并版本包括第三版（2005年）[文件62A/505A/FDIS和62A/512/RVD]、第1次修订（2012年）[文件62A/805/FDIS和62A/820/RVD]、2006年12月和2007年12月的勘误表、2014年7月修订1的勘误表以及2008年4月的解释表，2009年1月和2013年5月。它的版本号是3.1。

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.
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国际标准iec60601-1是由IEC技术委员会62：医疗实践中的电气设备的共同方面的第62A小组委员会编制的。

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

本第三版取消并取代1988年出版的第二版、第1次修正案（1991年）和第2次修正案（1995年）、2000年出版的第二版IEC 60601-1-1和1996年出版的第一版IEC 60601-1-4及其修正案1（1999年）。本版为技术修订版。这个版本已经进行了重大调整。电气部分的要求与IEC 60950-1所涵盖的信息技术设备的要求进一步一致，并增加了包含风险管理过程的要求。关于本修订的详细说明，见附录A.3。

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2. In this standard the following print types are used:

本出版物根据ISO/IEC指令第2部分起草。本标准使用以下打印类型：

- Requirements and definitions: in roman type.
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In referring to the structure of this standard, the term
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- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
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In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.
在本标准中，连词“or”用作“inclusive or”，因此如果条件的任何组合为true，则语句为true。

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- “may” is used to describe a permissible way to achieve compliance with a requirement or test.
“可”用于描述实现符合要求或测试的允许方法。

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

星号（*）作为标题的第一个字符或段落或表格标题的开头，表示附件a中与该项目有关的指南或理由。

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The content of the corrigendum of November 2012 have been included in this copy.
2012年11月勘误表的内容已包含在本副本中。

IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

INTRODUCTION

简介

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, Basic aspects of the safety philosophy for electrical equipment used in medical practice. The first edition of IEC/TR 60513 provided the basis for developing: 1976年，IEC 62A小组委员会出版了第一版IEC/TR 60513《医疗实践中使用的电气设备安全原理的基本方面》。第一版IEC/TR 60513为开发：

- the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);
第一版IEC 60601-1（医用电气设备的母级安全标准）；
- the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;
IEC 60601-1-xx系列医用电气设备并行标准；
- the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and
IEC 60601-2-xx特殊类型医疗电气设备专用标准系列；以及
- the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.
IEC 60601-3-xx系列特殊类型医用电气设备的性能标准。

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

大多数国家委员会意识到制定医疗实践中使用的电气设备的标准的必要性和紧迫性，在1977年投票赞成第一版的IEC 60601-1，其基础是当时代表该问题的第一种方法的草案。范围之广、有关设备的复杂性、某些保护措施的具体性质以及为验证这些措施而进行的相应试验，都需要多年的努力才能编制出这第一个标准，现在可以说，该标准自出版以来已成为普遍的参考。

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication. 然而，第一版的频繁应用显示出了改进的空间。鉴于本标准自发布以来取得了相当大的成功，这些改进更为可取。

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995. 1988年第二版的修订工作在以后的几年里继续进行。这个版本包含了所有可以合理预期到那时的改进。进一步的发展仍在不断研究中。第二版于1991年修订，然后在1995年再次修订。

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, "The ability of an electric kettle to boil water is not critical to its safe use!" 最初的IEC方法是为医疗电气设备制定单独的基本安全和性能标准。这是国家和国际一级对其他电气设备标准（如国内设备标准）采取的历史方法的自然延伸，其中基本安全是通过强制性标准来规范的，而其他性能规范是由市场压力来规范的。在这种情况下，有人说，“电水壶烧开水的能力对它的安全使用并不重要！”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL

EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

现在人们认识到，许多医疗电气设备并不是这种情况，责任组织必须依靠标准来确保基本性能和基本安全。这些领域包括设备控制向患者输送能量或治疗物质，或处理和显示影响患者管理的生理数据的准确性。

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

这种认识意味着，将基本安全和性能分离在处理因医疗电气设备设计不当而造成的危害时有些不恰当。IEC 60601-2-xx系列中的许多特殊标准涉及一系列基本性能要求，如果不采用这些标准，责任组织将无法直接评估这些要求。（但是，当前的IEC 60601系列对基本性能的要求比基本安全要求少）。

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12]) in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series. 为迎接第三版IEC 60601-1，IEC小组委员会62A于1994年编制了第二版IEC/TR 60513[12]）。第二版IEC/TR 60513将为本版IEC 60601-1的开发以及IEC 60601-1-xx和IEC 60601-2-xx系列的进一步开发提供指导。

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles: 为了实现国际标准的一致性，满足卫生保健界目前的期望，并与IEC 60601-2-xx的发展保持一致，IEC/TR 60513的第二版包括两个主要的新原则：

- the first change is that the concept of “SAFETY” has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance”; 第一个变化是“安全”的概念已经从第一版和第二版IEC 60601-1的基本安全考虑因素扩展到包括基本性能问题（例如生理监测设备的准确性）。本原则的应用导致本出版物的标题从第二版的“医用电气设备，第1部分：安全的一般要求”改为“医用电气设备，第1部分：基本安全和基本性能的一般要求”；
- the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2). 第二个变化是，在制定最低安全要求时，如果设计过程是评估某些技术（如可编程电子系统）安全性的唯一实际方法，则应规定评估设计过程的充分性。这一原则的应用是导致引入执行风险管理流程的一般要求的因素之一。在制定第三版iec60601-1的同时，与ISO/tc210的联合项目导致了医疗器械风险管理通用标准的发布。符合本版IEC 60601-1要求制造商制定符合ISO 14971部分要求的风险管理流程（见4.2）。

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone. 一般来说，电气设备的基本安全要求和基本要求适用于本标准。对于某些类型的医用电气设备，这些要求可通过附带或特定标准的特殊要求进行补充或修改。如果存在特定标准，则不应单独使用本标准。

Amendment 1 to this standard is intended to address:

本标准修改件1旨在解决：

- issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005; 自IEC 60601-1:2005发布以来，国家委员会和其他相关方发现的问题；
- the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

在IEC 60601-1:2005中引入风险管理的方式；以及

- the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.
IEC 60601-1:2005中使用基本性能概念的方式。

1) Figures in square brackets refer to the Bibliography.
方括号内的数字指参考书目。

INTRODUCTION TO THE AMENDMENT

修正案简介

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties. IEC 60601-1第三版于2005年出版。在出版时，有94个国家委员会关于第二个CDV和FDI的评论被推迟到将来的修正/修订中。SC 62A秘书处在议题单中记录了他们推迟发表的每一条意见。截至2008年4月奥克兰会议时，各小组委员会已编制了两份口译单，SC 62A秘书处还从国家委员会和其他有关方面收到了另外15个问题。

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to: 在奥克兰会议上，IEC/TC 62批准了一个项目，根据当时悬而未决的问题制定IEC 60601-1:2005第1修正案。技术委员会批准制定第1修正案，以解决悬而未决的问题，包括但不限于：

- those listed in 62A/593/DC and 62A/602/INF;
第62A/593/DC和62A/602/INF所列者；
- the way in which risk management has been introduced into IEC 60601-1:2005; and
在IEC 60601-1:2005中引入风险管理的方式；以及
- the way the concept of essential performance is used in IEC 60601-1:2005.
IEC 60601-1:2005中使用基本性能概念的方式。

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

自奥克兰会议以来，秘书处从国家委员会或其他有关方面收到了73份额外问题，共计182份议题单。本修正案旨在解决这些问题。

MEDICAL ELECTRICAL EQUIPMENT – 医疗电气设备-

Part 1: General requirements for basic safety and essential performance

第1部分: 基本安全和基本性能的一般要求

1 Scope, object and related standards

范围、对象和相关标准

1.1 * Scope

***范围**

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS. 本国际标准适用于医用电气设备和医用电气系统（以下简称医用电气设备和医用电气系统）的基本安全和基本性能。

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant. 如果某一条款或子条款仅适用于医用电气设备，或仅适用于医用电气系统，则该条款或子条款的标题和内容将予以说明。如果不是这样，该条款或子条款适用于医用电气设备和医用电气系统（如相关）。

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 本标准范围内医用电气设备或医用电气系统预期生理功能所固有的危害不在本标准的具体要求中，除非

7.2.13 and 8.4.1.

7.2.13和8.4.1。

NOTE 1 See also 4.2.

注1另见4.2。

This standard can also be applied to equipment used for compensation or alleviation of disease, injury or disability.

本标准也适用于用于补偿或减轻疾病、伤害或残疾的设备。

In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT is covered by the IEC 61010 series). This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1). IEC 61010系列涵盖了不属于医用电气设备定义范围的体外诊断设备）。本标准不适用于ISO 14708-1所涵盖的有源植入式医疗器械的可植入部分。

The IEC 60601 series does not apply to:

IEC 60601系列不适用于:

- in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series
不属于IEC 61010系列医用电气设备定义范围内的体外诊断设备
- implantable parts of active implantable medical devices covered by the ISO 14708 series or
ISO 14708系列或
- medical gas pipeline systems covered by ISO 7396-1
ISO 7396-1涵盖的医用气体管道系统

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

注2 ISO 7396-1将IEC 60601-1-8的要求应用于某些监测和报警信号。

1.2 Object **对象**

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

本标准旨在规定一般要求，并作为特定标准的基础。

1.3 * Collateral standards ***抵押标准**

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:
在IEC 60601系列中，附带标准规定了基本安全的一般要求
and ESSENTIAL PERFORMANCE applicable to:
基本性能适用于：

- a subgroup of ME EQUIPMENT (e.g. radiological equipment);
医用电气设备的一个子组（如放射设备）；
- a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.
所有医用电气设备在本标准中未完全说明的具体特性。

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

适用的担保标准自发布之日起即为规范性标准，应与本标准一起适用。

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- 2) IEC 61010 (all parts), Safety requirements for electrical equipment for measurement, control, and laboratory use
IEC 61010（所有部分），测量、控制和实验室用电气设备的安全要求
 - 3) ISO 14708-1, Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1，外科植入物-有源植入式医疗器械-第1部分：安全、标记和制造商提供信息的一般要求

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.
注1：在评估是否符合IEC 60601-1时，允许独立评估是否符合附带标准。

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.
注2：当声明符合IEC 60601-1时，声明人应特别列出已应用的附带标准。这使声明的读者能够了解哪些抵押品标准是评估的一部分。

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. Members of The IEC maintains a register catalogue of valid International Standards. Users of this standard should consult this register catalogue at "to determine which collateral standards have been published."
注3 IEC 60601系列中的附带标准编号为IEC 60601-1-xx。国际电工委员会（IEC）成员保留有效国际标准的注册目录。本标准的用户应在“确定已发布的附属标准”处查阅本注册目录。

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.
如果附属标准适用于存在特定标准的医用电气设备，则该特定标准优先于附属标准。

1.4 * Particular standards *特殊标准

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.
在IEC 60601系列中，特定标准可修改、替换或删除本标准中包含的适用于特定医用电气设备的要求，并可添加其他基本安全和基本性能要求。

NOTE Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published. Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at " and "" to determine which particular standards have been published.
注：国际电工委员会和国际标准化组织的成员保留有效国际标准的登记册。本标准的使用者应查阅这些登记册，以确定已发布的特定标准。IEC委员会制定的IEC 60601系列中的特殊标准编号为IEC 60601-2-xx。此外，由国际标准化组织和国际电工委员会联合制定的特定标准可以编号为iec80601-2-xx或iso80601-2-xx，具体取决于管理该项目的委员会。国际电工委员会和国际标准化组织保存有效的国际标准目录。本标准的用户应在“和”处查阅这些目录，以确定已发布的特定标准。

A requirement of a particular standard takes priority over this standard.
特定标准的要求优先于本标准。

2 * Normative references *规范性引用文件

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
以下文件是本申请所必需的参考文件。凡是注日期的引用文件，仅引用的版本适用。凡是不注日期的引用文件，其最新版本（包括任何修改件）适用。

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 396.

注：参考文献见第396页参考书目。

IEC 60065:2001, Audio, video and similar electronic apparatus – Safety requirements)

IEC 60065:2001，音频、视频和类似电子设备-安全要求

Amendment 1:2005

修正案1:2005

Amendment 2:2010

修正案2:2010

IEC 60068-2-2:1974 2007, Environmental testing – Part 2-2: Tests – Test B: Dry heat

IEC 60068-2-2:1974 2007，环境试验—第2-2部分：试验—试验B：干热

Amendment 1 (1993)

修正案1（1993年）

Amendment 2 (1994)

修正案2（1994年）

IEC 60079-0, Electrical apparatus for explosive gas atmospheres – Part 0:

General requirements

IEC 60079-0，爆炸性气体环境用电气设备—第0部分：一般要求

IEC 60079-2, Electrical apparatus for explosive gas atmospheres – Part 2:

Pressurized enclosures “p”

IEC 60079-6002 《爆炸性气体环境用电气设备》

IEC 60079-5, Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling “q”

IEC 60079-5，爆炸性气体环境用电气设备—第5部分：粉末填充“q”

IEC 60079-6, Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion “o”

IEC 60079-6，爆炸性气体环境用电气设备—第6部分：油浸“o”

IEC 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC

IEC 60083，IEC成员国标准化的家用和类似用途的插头和插座

4) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

有一个合并版本7.2，包括IEC 60065:2001及其修正案1（2005）和修正案2（2010）。

IEC 60085, Electrical insulation – Thermal classification
IEC 60085, 电气绝缘-热分类

IEC 60086-4, Primary batteries – Part 4: Safety of lithium batteries
IEC 60086-4, 原电池—第4部分：锂电池的安全性

IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials
IEC 60112, 固体绝缘材料的验证和比较跟踪指数的测定方法

IEC 60127-1, Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links
IEC 60127-1, 微型熔断器—第1部分：微型熔断器的定义和微型熔断器的一般要求

IEC 60227-1:1993 2007, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements)
IEC 60227-1:1993 2007, 额定电压450/750V及以下聚氯乙烯绝缘电缆-第1部分：一般要求)
Amendment 1 (1995)
修正案1（1995年）
Amendment 2 (1998)
修正案2（1998年）

IEC 60245-1:2003, Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements
IEC 60245-1:2003, 额定电压450/750V及以下的橡胶绝缘电缆第1部分：一般要求
Amendment 1:2007
修正案1:2007

IEC 60252-1, AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation
IEC 60252-1, 交流电动机电容器—第1部分：总则—性能、试验和额定值—安全要求—安装和操作指南

IEC 60320-1, Appliance couplers for household and similar general purposes – Part 1: General requirements
IEC 60320-1, 家用和类似用途的电器耦合器-第1部分：一般要求

IEC 60335-1:2001 2010, Household and similar electrical appliances – Safety – Part 1: General requirements
IEC 60335-1:2001 2010, 家用和类似用途电器-安全-第1部分：一般要求

IEC 60364-4-41, Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock
IEC 60364-4-41, 建筑物电气装置-第4-41部分：安全防护-电击防护

IEC 60384-14:2005, Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains
IEC 60384-14:2005, 电子设备用固定电容器-第14部分：分规范：电磁干扰抑制和电源连接用固定电容器

IEC 60417-DB:2002 , Graphical symbols for use on equipment)
IEC 60417-DB:2002, 设备用图形符号)

IEC 60417, Graphical symbols for use on equipment. Available from: < >
IEC 60417, 设备用图形符号。提供地点：<>

IEC 60445, Basic and safety principles for man-machine interface, marking and identification

IEC 60445, 人机界面、标记和标识的基本和安全原则

– Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system

设备终端和某些指定导体终端的标识，包括字母数字系统的一般规则

IEC 60447, Basic and safety principles for man-machine interface, marking and identification

IEC 60447, 人机界面、标记和标识的基本和安全原则

– Actuating principles

执行原理

IEC 60529:1989, Degrees of protection provided by enclosures (IP Code))

IEC 60529:1989, 外壳防护等级（IP代码）

Amendment 1 (1999)

修正案1（1999年）

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2, 医用电气设备-第1-2部分：安全的一般要求-附带标准：电磁兼容性-要求和试验

5) There exists a consolidated edition 2.2 including IEC 60227-1:1993 and its Amendment 1 (1995) and Amendment 2 (1998).

有一个合并版本2.2，包括IEC 60227-1:1993及其修正案1（1995）和修正案2（1998）。

6) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007). 7) "DB" refers to the joint ISO-IEC on-line database.

有一个合并版4.1，包括IEC 60245-1:2003及其修正案1（2007）。7）“DB”是指ISO-IEC联合在线数据库。

8) There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999). 有一个合并版本2.1，包括IEC 60529:1989及其修正案1（1999）。

IEC 60601-1-3, Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance. Collateral standard: General requirements for Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3, 医用电气设备—第1-3部分: 基本安全和基本性能的一般要求。并列标准: 诊断X射线设备辐射防护的一般要求

IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability

IEC 60601-1-6, 医用电气设备-第1-6部分: 安全的一般要求-附带标准: 可用性

IEC 60601-1-8, Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8, 医用电气设备——第1-8部分: 安全性的一般要求——附带标准: 医用电气设备和医疗电气系统中报警系统的一般要求、试验和指南

IEC 60664-1:1992 2007, Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests)

IEC 60664-1:1992 2007, 低压系统内设备的绝缘配合-第1部分: 原则、要求和试验)

Amendment 1 (2000)

修正案1 (2000)

Amendment 2 (2002)

修正案2 (2002年)

IEC 60695-11-10, Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods

IEC 60695-11-10, 火灾危险试验—第11-10部分: 试验火焰—50W水平和垂直火焰试验方法

IEC 60730-1:1999 2010, Automatic electrical controls for household and similar use – Part 1: General requirements)

家用自动控制装置的一般要求

Amendment 1 (2003)

修正案1 (2003)

IEC 60825-1:1993 2007, Safety of laser products – Part 1: Equipment classification and requirements and user's guide)

IEC 60825-1:1993 2007, 激光产品的安全-第1部分: 设备分类、要求和用户指南)

Amendment

1

(1997)

修正案1 (1997年)

Amendment

2

(2001)

修正案2 (2001年)

IEC 60851-3:1996 2009, Winding wires – Test methods – Part 3: Mechanical properties)

IEC 60851-3:1996 2009, 绕组线-试验方法-第3部分: 机械性能)

Amendment

1

(1997)

修正案1 (1997年)

Amendment

2

(2003)

修正案2 (2003年)

IEC 60851-5:1996 2008, Winding wires – Test methods – Part 5: Electrical properties)

IEC 60851-5:1996 2008, 绕组线-试验方法-第5部分: 电气性能)

Amendment

1

(1997)

修正案1 (1997年)

Amendment

2

(2004)

修正案2 (2004年)

IEC 60851-6:1996, Winding wires – Test methods – Part 6: Thermal properties

IEC 60851-6:1996, 绕组线-试验方法-第6部分: 热性能

IEC 60878:2003, Graphical symbols for electrical equipment in medical practice
IEC 60878:2003, 医疗实践中电气设备的图形符号

IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements

IEC 60884-1, 家用和类似用途插头和插座-第1部分：一般要求

IEC 60950-1:2001, Information technology equipment – Safety – Part 1: General requirements

IEC 60950-1:2001, 信息技术设备-安全-第1部分：一般要求

IEC 61058-1:2000, Switches for appliances – Part 1: General requirements)

IEC 61058-1:2000, 电器开关—第1部分：一般要求)

Amendment

1:2001

修正案1:2001

Amendment

2:2007

修正案2:2007

9) There exists a consolidated edition 1.2 including IEC 60664-1:1992 and its Amendment 1 (2000) and Amendment 2 (2002).

有一个合并版本1.2，包括IEC 60664-1:1992及其修正案1（2000）和修正案2（2002）。

10) There exists a consolidated edition 3.1, including IEC 60730-1:1999 and its Amendment 1 (2003)

有一个合并版本3.1，包括IEC 60730-1:1999及其修正案1（2003）

11) There exists a consolidated edition 1.2, including IEC 60825-1:1993 and its Amendment 1 (1997) and Amendment 2 (2001).

有一个合并版本1.2，包括IEC 60825-1:1993及其修正案1（1997）和修正案2（2001）。

12) There exists a consolidated edition 2.1, including IEC 60851-3:1996 and its Amendment 1 (1997).

存在合并版2.1，包括IEC 60851-3:1996及其修正案1（1997）。

13) There exists a consolidated edition 3.2, including IEC 60851-5:1996 and its Amendment 1 (1997) and Amendment 2 (2004).

有一个合并版本3.2，包括IEC 60851-5:1996及其修正案1（1997）和修正案2（2004）。

14) There exists a consolidated edition 3.1 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

有一个合并版本3.1 3.2，包括IEC 61058-1:2000及其修正案1（2001）和修正案2（2007）

IEC 61558-1:1997, Safety of power transformers, power supply units and similar – Part 1: General requirements and tests)

IEC 61558-1:1997, 电力变压器、电源装置和类似装置的安全-第1部分：一般要求和试验)

Amendment 1 (1998)

修正案1（1998年）

IEC 61558-2-1, Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use

IEC 61558-2-1, 安全变压器、电源装置和类似装置——第2部分：一般用途隔离变压器的特殊要求

IEC 61672-1, Electroacoustics – Sound level meters – Part 1: Specifications

IEC 61672-1, 电声学—声级计—第1部分：规范

IEC 61672-2, Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests

IEC 61672-2, 电声学—声级计—第2部分：模式评估试验

IEC 61965, Mechanical safety of cathode ray tubes

IEC 61965, 阴极射线管的机械安全

IEC 62133, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

IEC 62133, 含有碱性或其他非酸性电解质的二次电池和电池——便携式密封二次电池及其制成的电池的安全要求，用于便携式应用

IEC 62304:2006, Medical device software – Software lifecycle processes

IEC 62304:2006, 医疗器械软件-软件生命周期过程

ISO 31 (all parts), Quantities and units

ISO 31（所有部分），数量和单位

ISO 780, Packaging – Pictorial marking for handling of goods

ISO 780, 包装——货物搬运图示标志

ISO 1000, SI units and recommendations for the use of their multiples and of certain other units

ISO 1000, 国际单位制及其倍数和某些其他单位的使用建议

ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity

ISO 1853, 硫化或热塑性导电和耗散橡胶-电阻率测量

ISO 2878, Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance

ISO 2878, 硫化橡胶-抗静电和导电产品-电阻测定

ISO 2882), Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits

ISO 2882), 硫化橡胶-医院用抗静电和导电产品-电阻限值

ISO 3746, Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane

ISO 3746, 声学-使用声压测定噪声源的声功率级-在反射平面上使用包络测量表面的测量方法

ISO 3864-1:2002, Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas

ISO 3864-1:2002, 图形符号-安全颜色和安全标志-第1部分：工作场所和公共区域安全标志的设计原则

ISO 5349-1, Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements

ISO 5349-1, 机械振动-人体接触手传振动的测量和评估-第1部分：一般要求

ISO 7000-DB:2004), Graphical symbols for use on equipment – Collection of symbols

ISO 7000-DB:2004), 设备用图形符号-符号集

ISO 7010:2003 2011, Graphical symbols – Safety colours and safety signs – Registered safety signs used in workplaces and public areas

ISO 7010:2003 2011, 图形符号-安全颜色和安全标志-工作场所和公共区域使用的注册安全标志

ISO 9614-1, Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points

ISO 9614-1, 声学-使用声强测定噪声源的声功率级-离散点测量

ISO 10993 (all parts), Biological evaluation of medical devices

ISO 10993 (所有部分), 医疗器械的生物学评价

ISO 11134, Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization

ISO 11134, 保健品灭菌-验证和常规控制要求-工业湿热灭菌

ISO 11135, Medical devices – Validation and routine control of ethylene oxide sterilization

ISO 11135, 医疗器械-环氧乙烷灭菌的验证和常规控制

¹⁵⁾ There exists a consolidated edition 1.1, including IEC 61558-1:1997 and its Amendment 1 (1998).
有一个合并版本1.1, 包括IEC 61558-1:1997及其修正案1 (1998)。

¹⁶⁾ ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.
ISO 2882已于2005年2月1日撤销, 尚未确定替代标准。

¹⁷⁾ "DB" refers to the joint ISO-IEC on-line database.
“DB”是指ISO-IEC联合在线数据库。

ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11135-1:2007, 医疗保健产品灭菌-环氧乙烷-第1部分：医疗器械灭菌过程的开发、验证和常规控制要求

ISO 11137, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization

ISO 11137, 保健品灭菌-验证和常规控制要求-辐射灭菌

ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-1:2006, 医疗器械灭菌-辐射-第1部分：医疗器械灭菌过程的开发、验证和常规控制要求

ISO 13852, Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs

ISO 13852, 机械安全-防止上肢触及危险区域的安全距离

ISO 13857:2008, Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs

ISO 13857:2008, 机械安全-防止上肢和下肢触及危险区域的安全距离

ISO 14971:2000 2007, Medical devices – Application of risk management to medical devices

ISO 14971:2000 2007, 医疗器械-医疗器械风险管理的应用

ISO 15223, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

ISO 15223, 医疗器械——与医疗器械标签、标签和信息一起使用的符号

ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

ISO 15223-1:2012, 医疗器械——与医疗器械标签、标签和信息一起使用的符号——第1部分：一般要求

ISO 17665-1:2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17665-1:2006, 保健品灭菌-湿热-第1部分：医疗器械灭菌过程的开发、验证和常规控制要求

ISO 23529, Rubber – General procedures for preparing and conditioning test pieces for physical test methods

ISO 23529, 橡胶-物理试验方法用试样制备和调节的一般程序

ISO 80000-1:2009, Quantities and units – Part 1: General

ISO 80000-1:2009, 数量和单位-第1部分：总则

3 * Terminology and definitions

***术语和定义**

For the purposes of this document, the following terms and definitions apply.
以下术语和定义适用于本文件。

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the

r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

注1：除非另有说明，否则本文件中使用的术语“电压”和“电流”是指交流、直流或复合电压或电流的均方根值。

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

注2：术语“电气设备”指医用电气设备（见3.63）或其他电气设备。本标准还使用术语“设备”来表示医用电气设备或其他电气或非电气设备（见3.64）。

NOTE 3 When the term “safety” is used in this document in roman or italic type, it does not mean “safety” as defined in ISO 14971, but rather is used to mean “the state of being protected from or guarded against hurt or injury; freedom from danger”.

注3：当本文件中以罗马或斜体字体使用“安全”一词时，它并不意味着ISO 14971中定义的“安全”，而是指“受到保护，免受伤害或伤害的状态；免于危险”。

NOTE 3 4 An index is found beginning on page 402.

注3 4索引从第402页开始。

3.1

3.1

ACCESS COVER

检修盖

part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

外壳或防护装置的一部分，为调整、检查、更换或修理提供了接近电气设备部件的可能性

3.2

3.2

ACCESSIBLE PART

可触及部分

part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

可通过标准测试指接触的电气设备部件，而非应用部件

NOTE See also 5.9.2.1.

注：另见5.9.2.1。

3.3

3.3

ACCESSORY

附件
additional part for use with equipment in order to:
与设备一起使用的附加部件，以便：

- achieve the INTENDED USE,
达到预期用途，
- adapt it to some special use,
让它适应一些特殊用途，
- facilitate its use,
方便使用，
- enhance its performance,
提高其性能， 或
- enable its functions to be integrated with those of other equipment [IEC 60788:2004, rm-83-06 modified]
使其功能与其他设备的功能相集成[IEC 60788-2004， rm-83-06修改]

3.4

3.4

ACCOMPANYING DOCUMENT

随附文件

document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE
医用电气设备、医用电气系统、设备或附件的随附文件，包含负责组织或操作员的信息，特别是有关基本安全和基本性能的信息

3.5

3.5

AIR CLEARANCE

空气间隙

shortest path in air between two conductive parts
两个导电部件之间空气中的最短路径

NOTE Adapted from IEC 60664-1:2007, definition 1.3.2.
注释改编自IEC 60664-1:2007， 定义1.3.2。

3.6

3.6

APPLIANCE COUPLER

电器耦合器
means enabling the connection of a flexible cord to electrical equipment without the use of a
指在不使用
TOOL, consisting of two parts: a MAINS CONNECTOR and an
APPLIANCE INLET NOTE See Figure 1.
工具， 由两部分组成： 一个电源连接器和一个电器插座注见图1。

- ①
- ②
- ③ APPLIANCE COUPLER
- ④ 电器耦合器
- 5 APPLIANCE INLET
- 5 器具入口
- 6 DETACHABLE POWER SUPPLY CORD
- 6 可拆卸电源线
- 7 ME EQUIPMENT
- 7 医用电气设备
- FIXED mains socket-outlet/
固定电源插座/
MULTIPLE
SOCKET-OUTLET
(MSO) MAINS
CONNECTOR
多插座（MSO）电
源连接器
- MAINS PLUG
电源插头

IEC 2384/05
IEC 2384/05标准

Figure 1 – Detachable mains connection
图1-可拆卸电源连接
(see definitions)
(见定义)

3.7

3.7

APPLIANCE INLET

器具入口

part of an APPLIANCE COUPLER either integrated in or FIXED to electrical equipment

电器耦合器的一部分，集成在或固定在电气设备上

NOTE See Figure 1 and Figure 2.

注：见图1和图2。

3.8

3.8

*** APPLIED PART**

*应用部分

part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the

在我身体上的正常使用必然会用到这些设备

PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

医用电气设备或医用电气系统执行其功能的患者

NOTE 1 See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

注1：见图3、图4和图A.1至图A.7（含）。

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

注2：关于不属于应用部件定义范围，但由于应用风险管理过程而需要作为应用部件处理的部件，参见4.6。

NOTE 3 See also 3.78 for the definition of the associated term PATIENT CONNECTION.

注3：关于相关术语“患者联系”的定义，参见3.78。

3.9

3.9

*** BASIC INSULATION**

*基本绝缘

insulation providing basic protection against electric shock [IEV

826-12-14, modified]

提供基本电击防护的绝缘材料[IEV 826-12-14，修改]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.

注：基本绝缘提供了一种保护方法。

Key
钥匙

APPLIANCE INLET

(see also Figure 1)

PATIENT

CONNECTION

器具入口（参见图1）

患者连接

Conduit
管道

DETACHABLE POWER SUPPLY CORD
可拆卸电源线

ENCLOSURE
圈地

FIXED wiring
固定布线

FUNCTIONAL

EARTH

CONDUCTOR

FUNCTIONAL

EARTH

TERMINAL

SIGNAL

INPUT/OUTPUT

PART MAINS

CONDUCTOR

CONNECTOR

MAINS PART

功能接地导体功能

接地端子信号输入/

输出部分电源导体

连接器电源部分

MAINS TERMINAL DEVICE

电源终端设备
POWER SUPPLY
CORD
PROTECTIVE
EARTH
CONDUCTOR
PROTECTIVE
EARTH
TERMINAL MAINS
PLUG
电源线保护接地导
体保护接地端子电
源插头

POTENTIAL EQUALIZATION CONDUCTOR
电位均衡导体
Terminal for the connection of a
用于连接a的端子
POTENTIAL EQULIZATION CONDUCTOR
电位均衡导体

IEC 2385/05
IEC 2385/05标准

Figure 2 – Example of the defined terminals and conductors
图2-定义的端子和导体示例
(see definitions)
(见定义)



Figure 3 – Example of a CLASS I ME EQUIPMENT
图3—一类医用电气设备示例
(see definitions)
(见定义)

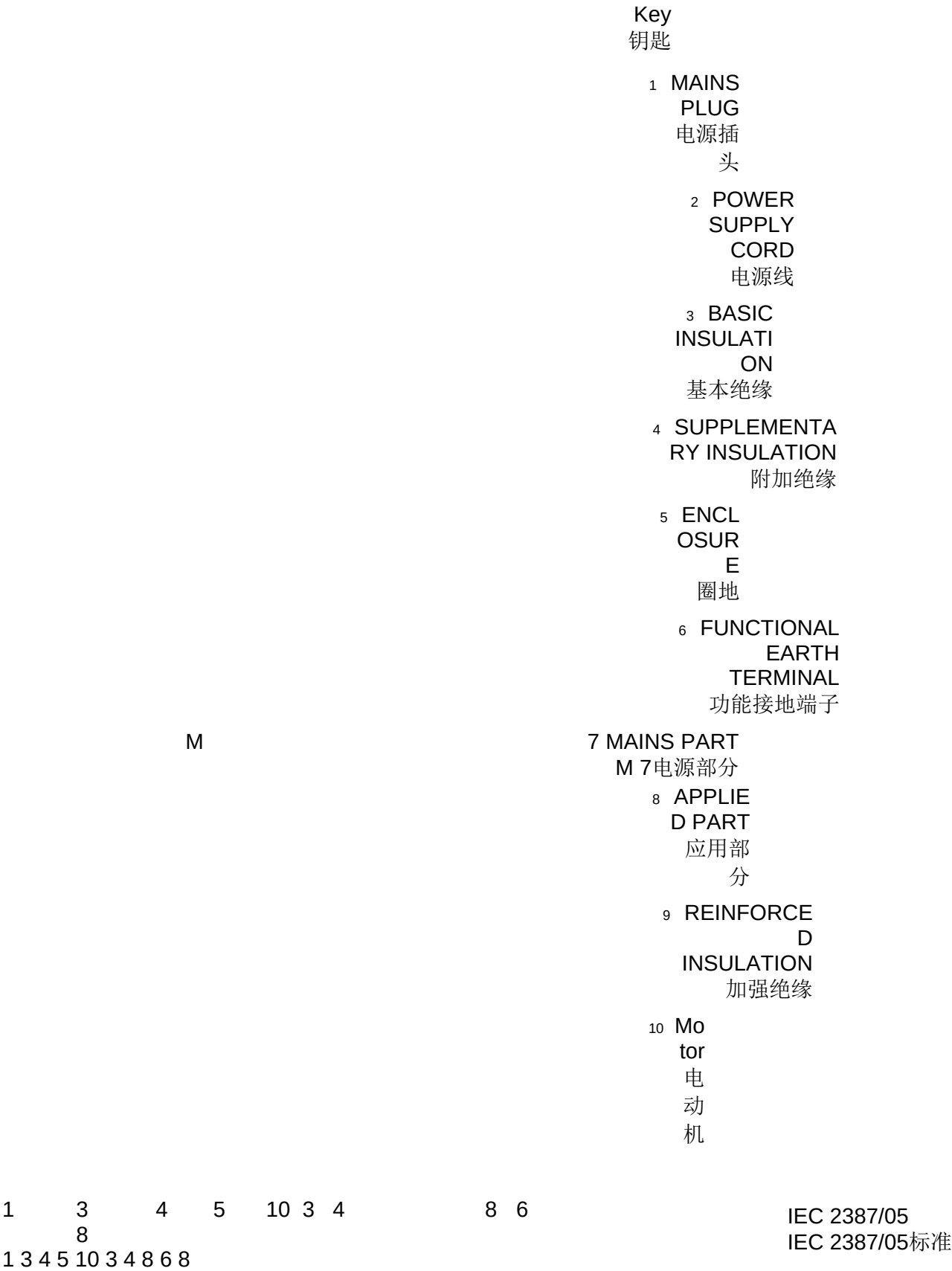


Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT
图4-金属封闭II类医用电气设备示例
(see definitions)

(见定义)

3.10

3.10

* BASIC SAFETY

*基本安全

freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

当医用电气设备在正常和单一故障条件下使用时，不存在直接由物理危害引起的不可接受的风险

3.11

3.11

CATEGORY AP

AP类

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

医用电气设备或医用电气设备部件的额定值，符合有关结构、标记和文件的规定要求，以避免易燃麻醉剂与空气混合物中的火源

3.12

3.12

CATEGORY APG

类别APG

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

医用电气设备或医用电气设备部件的额定值，符合结构、标记和文件的规定要求，以避免在含有氧气或一氧化二氮的易燃麻醉混合物中产生火源

3.13

3.13

CLASS I

第一类

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED

指的是电气设备，在这种设备中，防触电保护不只是依靠基本绝缘，而是包括附加的安全预防措施，即为可触及的金属部件或金属内部部件提供保护接地装置

NOTE See Figure 3.

注：见图3。

3.14

3.14

CLASS II

二级

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions

指的是电气设备，在这些设备中，防触电保护不只是依靠基本绝缘，而是提供了额外的安全预防措施，如双重绝缘或加强绝缘，没有保护接地或依赖于安装条件

NOTE 1 See Figure 4.

注1见图4。

NOTE 2 CLASS II equipment can be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also 8.6.8 and 8.6.9.

注2 II类设备可配备功能性接地端子或功能性接地导体。另见8.6.8和8.6.9。

3.15

3.15

*** CLEARLY LEGIBLE**

*清晰易读

capable of being read by a person with normal vision

能够被视力正常的人阅读

NOTE See also the test in 7.1.2.

注：另见7.1.2中的试验。

3.16

3.16

COLD CONDITION

寒冷条件

condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

当电气设备断电足够长时间以达到环境温度时所获得的状态

3.17

3.17

*** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS**

具有高完整性特征的部件

component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this standard during the EXPECTED SERVICE LIFE of the ME EQUIPMENT in NORMAL USE and reasonably foreseeable misuse

一个或多个特性确保其功能在医用电气设备正常使用和合理可预见的误用的预期使用寿命内无故障

3.18

3.18

*** CONTINUOUS OPERATION**

连续运行

operation in NORMAL USE for an unlimited period of time without the specified limits of temperature being exceeded

在不超过规定温度限制的情况下无限制地正常使用

3.19

3.19

CREEPAGE DISTANCE

爬电距离

shortest distance along the surface of the insulating material between two conductive parts [IEV 151-15-50, modified]

两个导电部件之间沿绝缘材料表面的最短距离[IEV 151-15-50，修改]

3.20

3.20

*** DEFIBRILLATION-PROOF APPLIED PART**

除颤应用部分

APPLIED PART that is protected against the effects of a discharge of a cardiac defibrillator to the PATIENT

防止心脏除颤器对患者放电影响的应用部件

3.21

3.21

*** DETACHABLE POWER SUPPLY CORD**

可拆卸电源线

flexible cord intended to be connected to electrical equipment by means of a suitable

拟通过合适的

APPLIANCE COUPLER for mains supply purposes

电源用电器耦合器

NOTE See Figure 1, Figure 2 and Figure 3.

注：见图1、图2和图3。

3.22

3.22

*** DIRECT CARDIAC APPLICATION**

心脏直接应用

use of APPLIED PART that can come in direct contact with the PATIENT'S heart

使用可直接接触患者心脏的应用部分

3.23

3.23

*** DOUBLE INSULATION**

双重绝缘

insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION

绝缘包括基本绝缘和辅助绝缘

[IEV 195-06-08]

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

注：双重绝缘提供两种保护方法。

3.24

3.24

*** DUTY CYCLE**

占空比

maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT

医用电气设备安全运行所需的最长激活（打开）时间，随后是最小停用（关闭）时间

3.25

3.25

EARTH LEAKAGE CURRENT

接地漏电电流

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR or a functional earthed connection according to 8.6.9
根据第8.6.9节，从电源部分流过或穿过绝缘层进入保护接地导体或功能性接地连接的电流

3.26

3.26

* ENCLOSURE

圈地

exterior surface of electrical equipment or parts thereof
电气设备或其部件的外表面

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

注：为了按照本标准进行试验，与由低导电性材料或绝缘材料制成的外表面部件接触的规定尺寸的金属箔被视为外壳的一部分（见图2、图3和图4）。

3.27

3.27

* ESSENTIAL PERFORMANCE

基本性能

performance necessary to achieve freedom from unacceptable RISK performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK
为避免不可接受风险所必需的性能临床功能的性能，与基本安全性相关的性能除外，其中损失或退化超过制造商规定的限度会导致不可接受的风险

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

注：基本性能最容易通过考虑其缺失或退化是否会导致不可接受的风险来理解。

3.28

3.28

EXPECTED SERVICE LIFE

预期使用寿命

maximum period of useful life as defined by the MANUFACTURER time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)
制造商规定的制造商时间段规定的最长使用寿命，在此期间，医用电气设备或医用电气系统有望保持安全使用（即保持基本安全和基本性能）

NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

注：在预期使用寿命内，可能需要进行维护。

3.29

3.29

F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)

F型隔离（浮动）应用部件（以下简称F型应用部件）

APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth

将患者连接与医用电气设备的其他部件隔离的应用部件，如果将来自外部电源的意外电压连接到患者，则不会有高于允许的患者泄漏电流的电流流过的应用部件，从而应用于病人连接和接地之间

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

注：F型应用部件为BF型应用部件或CF型应用部件。

3.30

3.30

FIXED

固定的

term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

术语的意思是固定或以其他方式固定在一个特定的位置，无论是永久性的还是只能通过工具分离的

EXAMPLE 1 Permanently affixed by welding, etc.

示例1通过焊接等方式永久固定。

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

例2通过紧固件（螺钉、螺母等）固定，不使用工具就无法拆卸/打开。

NOTE See the taxonomy in the rationale for definition 3.63.

注：参见定义3.63的基本原理中的分类法。

3.31

3.31

FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

与空气混合的易燃麻醉剂

mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

易燃麻醉蒸汽与空气的混合物，其浓度在规定的条件下可以着火

3.32

3.32

FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

含氧或一氧化二氮的易燃麻醉剂混合物

mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition can occur under specified conditions

易燃麻醉蒸汽与氧气或一氧化二氮的混合物，其浓度在规定的条件下可发生着火

3.33

3.33

*** FUNCTIONAL CONNECTION**

功能连接

connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

电气或其他连接，包括用于传输信号、数据、电力或物质的连接

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is

not considered to result in a FUNCTIONAL CONNECTION.

注：与固定电源插座连接，无论是单个还是多个，都不被视为功能性连接。

3.34

3.34

FUNCTIONAL EARTH CONDUCTOR

功能接地导体

conductor to be connected to a FUNCTIONAL EARTH

TERMINAL NOTE See Figure 2.

连接到功能接地端子的导体注见图2。

3.35

3.35

*** FUNCTIONAL EARTH TERMINAL**

功能接地端子

terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes

直接连接到电路或屏蔽部件的端子，用于功能性接地

NOTE See Figure 2, Figure 3 and Figure 4.

注：见图2、图3和图4。

3.36

3.36

GUARD

守卫

part of equipment specifically used to provide protection by means of a physical barrier

专门用于通过物理屏障提供保护的设备的一部分

NOTE Depending on its construction, a GUARD can be called a casing, cover, screen, door, enclosing guard, etc. A GUARD can act:

注：根据其结构，防护装置可被称为外壳、盖子、屏幕、门、封闭防护装置等。防护装置可起到以下作用：

- alone; it is then only effective when it is in place;
只有在适当的时候，它才是有效的；
- in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.
与带或不带防护装置锁定的联锁装置一起使用；在这种情况下，无论防护装置的位置如何，都能确保保护。

3.37

3.37

HAND-HELD

手持式

term referring to electrical equipment intended to be supported by the hand during NORMAL USE
term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

指在正常使用期间用手支撑的电气设备术语，指的是一旦安装并投入使用，就打算用手支撑的设备

NOTE 1 Equipment can refer to ACCESSORIES or

equipment parts. NOTE 2 See the taxonomy in the

rationale for definition 3.63.

注1：设备可指附件或设备部件。注2见定义依据3.63

中的分类法。

3.38

3.38

* HARM

危害

physical injury or damage to the health of people or animals, or damage to property or the environment

对人或动物健康造成的身体伤害或损害，或对财产或环境的损害

[ISO 14971:20002007, definition 2.2, modified]

[ISO 14971:20002007, 定义2.2, 修改]

3.39

3.39

HAZARD

危害

potential source of HARM

潜在危害源

[ISO 14971:20002007, definition 2.3]

【ISO 14971:20002007, 定义2.3】

3.40

3.40

* HAZARDOUS SITUATION

危险情况

circumstance in which people, property, or the environment are exposed to one or more

人、财产或环境暴露于一个或多个环境中的环境

HAZARD(S)

危险

[ISO/IEC Guide 51:1999, definition 3.6 ISO 14971:2007, definition 2.4]

[ISO/IEC指南51:1999, 定义3.6 ISO 14971:2007, 定义2.4]

3.41

3.41

HIGH VOLTAGE

高压

voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value

交流电压超过1000 V或直流电压超过1500 V或峰值超过1500 V

3.42

3.42

HYDRAULIC TEST PRESSURE

水压试验压力

pressure applied to test a vessel or part of it

用于测试容器或其一部分的压力

NOTE See 9.7.5.

注：见9.7.5。

3.43

3.43

INSULATION CO-ORDINATION

绝缘配合

mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

考虑预期微环境和其他影响应力的电气设备绝缘特性的相互关系

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

注：这包括绝缘类型、爬电距离、空气间隙、绝缘距离、涂层、封装、环境因素等。

3.44

3.44

* INTENDED USE

预期用途

INTENDED PURPOSE

预期用途

use of for which a product, PROCESS or service in accordance with is intended according to the specifications, instructions and information provided by the MANUFACTURER

根据制造商提供的规范、说明和信息，产品、工艺或服务的用途

[ISO 14971:20002007, definition 2.5]

【ISO 14971:20002007，定义2.5】

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

注：不应将预期用途与正常用途混淆。虽然两者都包含了制造商预期的使用概念，但预期用途侧重于医疗目的，而正常使用不仅包括医疗目的，还包括维护、服务、运输等。

3.45

3.45

INTERNAL ELECTRICAL POWER SOURCE

内部电源

electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

操作设备的电源，是设备的一部分，从其他形式的能量中产生电流

EXAMPLE Chemical, mechanical, solar, or nuclear

例如化学、机械、太阳能或核能

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

注：内部电源可以位于设备主体内部，连接到外部，也可以包含在单独的外壳中。

3.46

3.46

INTERNALLY POWERED

内部供电

term referring to electrical equipment that is able to operate from an INTERNAL ELECTRICAL POWER SOURCE

指能从内部电源供电的电气设备

3.47

3.47

LEAKAGE CURRENT

漏电流

current that is not functional

不起作用的电流

NOTE The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.

注：定义了以下泄漏电流：接地泄漏电流、接触电流和患者泄漏电流。

3.48

3.48

MAINS CONNECTOR

电源连接器

part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS

电器耦合器的一部分，与拟连接到电源干线的软线连接在一起

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment (see Figure 1 and Figure 2).

注：电源连接器拟插入电气设备的电器插座（见图1和图2）。

3.49

3.49

* MAINS PART

电源部分

electrical circuit part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

电路构成电路的电气设备的一部分，用于连接电源

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one

注1：电源部分包括所有未与电源干线分开至少一个的导电部件

MEANS OF PROTECTION.

保护手段。

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the

注2：在本定义中，保护接地导体不被视为

MAINS PART (see Figure 2 and Figure 3).

电源部分（见图2和图3）。

3.50

3.50

* MAINS PLUG

电源插头

part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

与电气设备的电源线集成在一起或拟连接在电源插座上的部件

NOTE 1 See Figure 1.

注1见图1。

NOTE 2 See also IEC 60083 and IEC 60309-1 [8].

注2另见IEC 60083和IEC 60309-1[8]。

3.51

3.51

MAINS SUPPLY TRANSFORMER

电源变压器

static piece of equipment with two or more windings which, by electro-magnetic induction, transforms an alternating voltage and current from a SUPPLY MAINS into a voltage and current usually of different values at the same frequency

带有两个或多个绕组的静态设备，通过电磁感应，将电源中的交流电压和电流转换成通常在同一频率下具有不同值的电压和电流

3.52

3.52

MAINS TERMINAL DEVICE

电源终端设备

TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made
与供电干线进行电气连接的终端装置

NOTE See Figure 2.

注：见图2。

3.53

3.53

MAINS TRANSIENT VOLTAGE

电源瞬态电压

highest peak voltage expected at the power input to the electrical equipment, arising from external transients on the SUPPLY MAINS

电源干线上的外部瞬态引起的电气设备电源输入处预期的最高峰值电压

3.54

3.54

MAINS VOLTAGE

电源电压

voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

多相系统的两条导线之间的供电干线电压，或单相系统的线路导线和中性导线之间的电压

3.55

3.55

MANUFACTURER

制造商

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

负责医用电气设备的设计、制造、包装或贴标签，装配医用电气系统，或改装医用电气设备或医用电气系统的自然人或法人，无论这些操作是由该人执行还是由第三方代表该人执行

NOTE 1 ISO 13485 [30] defines “labelling” as written, printed or graphic matter

注1 ISO 13485[30]将“标签”定义为书面、印刷或图形

- affixed to a medical device or any of its containers or wrappers, or
贴在医疗器械或其任何容器或包装上，或
- accompanying a medical device,
随身携带医疗器械，

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

与医疗器械的标识、技术说明和使用有关，但不包括装运单据。在本标准中，该材料被描述为标记和随附文件。

NOTE 2 “Adapting” includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

注2“适应”包括对医用电气设备或已使用的医用电气系统进行实质性修改。

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

注3：在某些司法管辖区，当涉及所述活动时，责任组织可被视为制造商。

NOTE 4 Adapted from ISO 14971:2000 2007, definition 2.6 2.8.

注4改编自ISO 14971:2000 2007，定义2.6 2.8。

3.56

3.56

* MAXIMUM MAINS VOLTAGE

最大电源电压

voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts

与电源电压有关并连接到某些医用电气设备部件的试验用电压

NOTE The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

注：最大电源电压值根据8.5.3确定。

3.57

3.57

* MAXIMUM PERMISSIBLE WORKING PRESSURE

最大允许工作压力

maximum pressure permitted on a component according to a declaration of the manufacturer of such component

根据部件制造商的声明，部件上允许的最大压力

3.58

3.58

* MEANS OF OPERATOR

PROTECTION MOOP

操作员保护方式MOOP

MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the
降低触电风险的保护装置

PATIENT

病人

3.59

3.59

* MEANS OF PATIENT

PROTECTION MOPP

病人保护方法

MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT

降低触电风险的保护措施

3.60

3.60

* MEANS OF

PROTECTION MOP

保护手段拖把

means for reducing the RISK due to electric shock in accordance with the requirements of this

根据本规范的要求降低触电风险的方法

standard

标准

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and

注：保护方法包括绝缘、空气间隙、爬电距离、阻抗和

PROTECTIVE EARTH CONNECTIONS.

保护接地连接。

3.61

3.61

MECHANICAL HAZARD

机械危险

HAZARD connected with or produced by physical force

与体力有关或由体力引起的危险

3.62

3.62

MECHANICAL PROTECTIVE DEVICE

机械保护装置

device that eliminates or reduces mechanical RISK to an acceptable level and which

operates in the case of SINGLE FAULT CONDITION

消除或降低机械风险至可接受水平的装置，在单一故障条件下运行

3.63

3.63

* MEDICAL ELECTRICAL

EQUIPMENT ME EQUIPMENT

医用电气设备

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or
具有应用部件或向患者或从患者传输能量的电气设备

detecting such energy transfer to or from the PATIENT and which is:

检测到这种能量转移到或从病人身上转移，并且：

a) provided with not more than one connection to a particular SUPPLY MAINS; and
设有不多于一个与特定供电干线的连接；及

b) intended by its MANUFACTURER to be used:
制造商打算使用：

1) in the diagnosis, treatment, or monitoring of a PATIENT; or
在对病人的诊断、治疗或监护中；或

2) for compensation or alleviation of disease, injury or disability
补偿或减轻疾病、伤害或残疾

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the
MANUFACTURER that are necessary to enable the NORMAL USE of the ME
EQUIPMENT.

注1医用电气设备包括制造商规定的能够正常使用医用电气设备所需的附件。

NOTE 2 Not all electrical equipment used in medical practice falls within this definition
(e.g. some in vitro diagnostic equipment).

注2：并非医疗实践中使用的所有电气设备都属于此定义范围（例如一些体外诊断设备）。

NOTE 3 The implantable parts of active implantable medical devices can fall within this
definition, but they are excluded from the scope of this standard by appropriate wording in
Clause 1.

注3有源植入式医疗器械的可植入部分可属于本定义范围，但第1条中的适当措辞将其排除在
本标准的范围之外。

NOTE 4 This standard uses the term “electrical equipment” to mean ME EQUIPMENT or
other electrical equipment. NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

注4本标准使用术语“电气设备”指医用电气设备或其他电气设备。注5另见4.10.1、8.2.1和
16.3。

3.64

3.64

* MEDICAL ELECTRICAL

SYSTEM ME SYSTEM

医用电气系统ME系统

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which
制造商规定的设备组合，至少有一个

is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a
MULTIPLE SOCKET-OUTLET

医用电气设备是否通过功能连接或使用多个插座进行互连

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

注：本标准中提到的设备应包括医用电气设备。

3.65

3.65

MOBILE

移动

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

指的是可运输的设备，一旦安装并投入使用，就打算在由其自身的轮子或同等的工具支撑的情况下从一个位置移动到另一个位置

NOTE See the taxonomy in the rationale for definition 3.63.

注：参见定义3.63的基本原理中的分类法。

3.66

3.66

*** MODEL OR TYPE REFERENCE**

型号或型号参考

combination of figures, letters or both used to identify a particular model of equipment or
用于识别特定设备的字母或组合

ACCESSORY

附件

3.67

3.67

*** MULTIPLE SOCKET-**

OUTLET MSO

多插座MSO

one or more socket-outlets intended to be connected to, or integral with, flexible cables, or
一个或多个用于连接软电缆或与软电缆集成的插座，或

cords or ME EQUIPMENT for providing SUPPLY MAINS or equivalent voltage

提供电源线或等效电压的电线或医用电气设备

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

注：多个插座可以是单独的项目，也可以是设备的组成部分。

3.68

3.68

*** NETWORK/DATA COUPLING**

网络/数据耦合

any means to transmit or receive information to or from other equipment in accordance with the
MANUFACTURER'S specifications

根据制造商规范向其他设备发送或接收信息的任何方式

3.69

3.69

NOMINAL (value)

标称（值）

value quoted for reference purposes that is subject to agreed tolerances

为参考目的而引用的值，以商定的公差为准

EXAMPLE NOMINAL MAINS VOLTAGE or NOMINAL diameter of a screw

示例标称电源电压或螺钉的标称直径

3.70

3.70

NORMAL

CONDITION

正常状态

condition in which all means provided for protection against HAZARDS are intact

所有防护措施完好无损的状态

3.71

3.71

NORMAL

USE

正常使用

operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

操作，包括由任何操作员进行的常规检查和调整，并根据使用说明进行备用

NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

注：正常使用不应与预期用途混淆。虽然两者都包含了制造商预期的使用概念，但预期用途侧重于医疗目的，而正常使用不仅包括医疗目的，还包括维护、服务、运输等。

3.72

3.72

OBJECTIVE EVIDENCE

客观证据

information which can be proven true, based on facts obtained through observation, measurement, test or other means data supporting the existence or verity of something

根据通过观察、测量、测试或其他手段获得的支持某物存在或真实性的数据而被证明是真实的信息

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

注：客观证据可以通过观察、测量、测试或其他方式获得。

[ISO 14971:2000 2007, definition 2.8 2.10]

【ISO 14971:2000 2007，定义2.8 2.10】

3.73

3.73

*** OPERATOR**

操作员

person handling equipment

人员搬运设备

NOTE See also 3.101.

注：另见3.101。

3.74

3.74

OVER-CURRENT RELEASE

过电流脱扣器

protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

当电路中的电流超过预定值时，使电路断开的保护装置

[IEV 441-16-33, modified]

[IEV 441-16-33，修改]

3.75

3.75

*** OXYGEN RICH ENVIRONMENT**

富氧环境

environment in which the concentration of oxygen is:

氧气浓度为:

- a) greater than 25 % for ambient pressures up to 110 kPa; or
环境压力高达110 kPa时大于25%; 或
- b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa
氧的分压大于环境气压的27,5千帕

3.76

3.76

PATIENT

病人

living being (person or animal) undergoing a medical, surgical or dental procedure

正在接受医学、外科或牙科手术的活着的人（人或动物）

NOTE A PATIENT can be an OPERATOR.

注意患者可以是操作员。

3.77

3.77

*** PATIENT AUXILIARY CURRENT**

病人辅助电流

current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other
正常使用时，任何患者连接和所有其他连接之间的电流

PATIENT CONNECTIONS and not intended to produce a physiological effect

与病人的关系，而不是为了产生生理效应

3.78

3.78

*** PATIENT CONNECTION**

病人联系

individual point on the APPLIED PART through which current can flow between the
PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT
CONDITION

在正常情况下或单一故障条件下，电流可在患者和医用电气设备之间流动的应用部件上的单个点

3.79

3.79

*** PATIENT ENVIRONMENT**

患者环境

any volume in which intentional or unintentional contact can occur between a PATIENT and
parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons
touching parts of the ME EQUIPMENT or ME SYSTEM

患者与医用电气设备或医用电气系统部件之间，或患者与其他人接触医用电气设备或医用电气系统部件之间可能发生有意或无意接触的任何容积

3.80

3.80

PATIENT LEAKAGE CURRENT

病人漏电流

current:

当前:

- flowing from the PATIENT CONNECTIONS via the PATIENT to earth; or
从病人的连接处经由病人流到地面; 或
- originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth
源于意外出现的来自患者外部电源的电压, 并通过F-TYPE应用部件的患者连接流至地面

3.81

3.81

* PEAK WORKING VOLTAGE

峰值工作电压

highest peak or d.c. value of a WORKING VOLTAGE, including repetitive peak impulses generated in the electrical equipment, but not including external transients

工作电压的最高峰值或直流值, 包括电气设备中产生的重复峰值脉冲, 但不包括外部瞬态

[IEC 60950-1:2001 2005, definition 1.2.9.7 1.2.9.8, modified]

[IEC 60950-1:2001 2005, 定义1.2.9.7 1.2.9.8, 修改]

3.82

3.82

PEMS DEVELOPMENT LIFE-CYCLE

PEMS开发生命周期

necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete

从项目概念阶段开始到PEMS验证完成后的一段时间内发生的必要活动

NOTE See also 3.90.

注: 另见3.90。

3.83

3.83

PEMS VALIDATION

PEMS验证

PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE

在开发过程中或开发过程结束时, 评估PEMS或PEMS组件的过程, 以确定其是否满足其预期用途的要求

NOTE See also 3.90.

注: 另见3.90。

3.84

3.84

PERMANENTLY INSTALLED

永久性安装

term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

该术语的意思是通过一个只能通过工具分离的永久性连接与供电干线进行电气连接

3.85

3.85

PORTABLE

便携式

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons
指可运输设备，一旦安装并投入使用，在由一人或多人携带的情况下，打算从一个地点移到另一个地点

NOTE 1 Equipment can refer to ACCESSORIES or
equipment parts. NOTE 2 See the taxonomy in the
rationale for definition 3.63.

注1：设备可指附件或设备部件。注2见定义依据3.63
中的分类法。

3.86

3.86

POTENTIAL EQUALIZATION CONDUCTOR

电位均衡导体

conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

保护接地导体或中性导体以外的导体，在电气设备和电气装置的电位均衡母线之间提供直接连接

NOTE See Figure 2.

注：见图2。

3.87

3.87

POWER SUPPLY CORD

电源线

flexible cord, FIXED to or assembled with electrical equipment for connection to

SUPPLY MAINS NOTE See Figure 1 to Figure 4 (inclusive).

软线，固定在或装配在电气设备上，用于连接电源。注：见图1至图4（包括）。

3.88

3.88

PROCEDURE

程序

specified way to perform carry out an activity or a PROCESS

执行一项活动或过程的特定方式

[ISO 14971:2000 2007, definition 2.9 2.12]

【ISO 14971:2000 2007，定义2.9 2.12】

3.89

3.89

PROCESS

过程

set of inter-related or interacting resources and activities which transforms inputs into outputs [ISO

14971:2000 2007, definition 2.10 2.13]

将输入转换为输出的一组相互关联或相互作用的资源和活动[ISO 14971:2000 2007，定义2.10 2.13]

3.90

3.90

PROGRAMMABLE ELECTRICAL MEDICAL

SYSTEM PEMS

可编程电子医疗系统

ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC

医用电气设备或包含一个或多个可编程电子设备的医用电气系统

SUBSYSTEMS (PESS)

子系统（PES）

3.91

3.91

PROGRAMMABLE ELECTRONIC

SUBSYSTEM PESS

可编程电子子系统PESS

system based on one or more central processing units, including their software and interfaces

基于一个或多个中央处理单元的系统，包括它们的软件和接口

3.92

3.92

PROPERLY INSTALLED

正确安装

installed in accordance with the ACCOMPANYING DOCUMENTS

按照随附文件安装

3.93

3.93

PROTECTIVE EARTH CONDUCTOR

保护接地导体

conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

保护接地端子 and 外部保护接地系统之间连接的导线

NOTE See Figure 2.

注：见图2。

3.94

3.94

PROTECTIVE EARTH CONNECTION

保护接地连接

connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying with the requirements of this standard

连接到保护性接地端子上，以达到保护目的，并符合本标准的要求

3.95

3.95

PROTECTIVE EARTH TERMINAL

保护接地端子

terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

为安全起见，端子连接至I类设备的导电部件。该端子旨在通过保护接地导线连接到外部保护接地系统

NOTE See Figure 2.

注：见图2。

3.96

3.96

PROTECTIVELY EARTHED

保护接地

connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this standard

通过符合本标准要求的方式连接至保护接地端子，以达到保护目的

3.97

3.97

RATED (value)

额定（值）

term referring to a value assigned by the MANUFACTURER for a specified operating condition

指制造商在规定的操作条件下指定的值的术语

3.98

3.98

RECORD

记录

document which furnishes OBJECTIVE EVIDENCE of activities performed or results achieved

document stating results achieved or providing evidence of activities performed

提供所执行活动或已实现结果的客观证据的文件，说明已取得的结果或提供所执行活动的证据

[ISO 14971:2000 2007, definition 2.11 2.14]

【ISO 14971:2000 2007，定义2.11 2.14】

3.99

3.99

*** REINFORCED INSULATION**

加强绝缘

single insulation system that provides two MEANS OF PROTECTION

提供两种保护方式的单一绝缘系统

3.100

3.100

RESIDUAL RISK

剩余风险

RISK remaining after protective RISK CONTROL measures have been taken

[ISO 14971:2000 2007, definition 2.12 2.15]

采取保护性风险控制措施后的剩余风险[ISO 14971:2000 2007，定义2.12 2.15]

3.101

3.101

RESPONSIBLE ORGANIZATION

责任单位

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

负责医用电气设备或医用电气系统使用和维护的实体

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

注1：责任实体可以是医院、个体临床医生或外行人员。在家用应用程序中，患者、操作员和责任组织可以是同一个人。

NOTE 2 Education and training is included in “use.”

注2教育和培训包含在“使用”中

3.102

3.102

RISK

风险

combination of the probability of occurrence of HARM and the SEVERITY of that HARM

损害发生的概率和危害的严重程度的组合

[ISO 14971:2000 2007, definition 2.13 2.16]

【ISO 14971:2000 2007，定义2.13 2.16】

3.103

3.103

RISK ANALYSIS

风险分析

systematic use of available information to identify HAZARDS and to estimate the RISK

系统地使用可用信息来识别危险并估计风险

[ISO 14971:2000 2007, definition 2.14 2.17]

【ISO 14971:2000 2007，定义2.14 2.17】

3.104

3.104

RISK ASSESSMENT

风险评估

overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

包括风险分析和风险评估的整个过程

[ISO 14971:2000 2007, definition 2.15 2.18]

【ISO 14971:2000 2007，定义2.15 2.18】

3.105

3.105

RISK CONTROL

风险控制

PROCESS through which decisions are reached and protective measures are implemented for reducing RISKS to, or maintaining RISKS within, specified levels
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

为将风险降低到规定水平或将风险保持在规定水平内而作出决策和实施措施的过程，通过该过程，风险降低或保持在规定水平内

[ISO	14971:2000	2007,	definition	2.16	2.19]
定义[ISO 14972:2007]					

3.106

3.106

RISK EVALUATION

风险评估

judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK
在风险分析的基础上，根据社会的当前价值判断在给定的环境下是否达到了可接受的风险。将估计的风险与给定的风险标准进行比较，以确定风险的可接受性

[ISO	14971:2000	2007,	definition	2.17	2.21]
【ISO 14971:2000 2007，定义2.17 2.21】					

3.107

3.107

RISK MANAGEMENT

风险管理

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK
系统地应用管理政策、程序和实践来分析、评估和控制风险

[ISO 14971:2000 2007, definition 2.18 2.22]
【ISO 14971:2000 2007，定义2.18 2.22】

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

注：在本标准中，风险管理不包括生产和生产后信息的规划或监控；但这是为符合ISO 14971（见4.2.2）而要求的。

3.108

3.108

RISK MANAGEMENT FILE

风险管理文件

set of RECORDS and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

由风险管理过程产生的一组记录和其他文件，不一定是连续的

[ISO 14971:2000 2007, definition 2.19 2.23]

【ISO 14971:2000 2007，定义2.19 2.23】

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

注：所有安全相关信息，包括制造商的计算、试验结果等，均视为风险管理文件的一部分。
另见4.2。

3.109

3.109

SAFE WORKING LOAD

安全工作负荷

maximum external mechanical load (mass) on equipment or an equipment part that is permitted in NORMAL USE

设备或设备部件正常使用时允许的最大外部机械载荷（质量）

3.110

3.110

*** SECONDARY CIRCUIT**

二次回路

circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE
通过至少一种保护手段与电源部分分离的电路，其电源来自变压器、转换器或等效隔离装置或内部电源

NOTE See also 8.9.1.12.

注：另见8.9.1.12。

3.111

3.111

SELF-RESETTING THERMAL CUT-OUT

自复位热断路器

THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled

在电气设备的相关部分冷却后自动恢复电流的热断路器

3.112

3.112

*** SEPARATION DEVICE**

分离装置

component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM

具有输入部件和输出部件的部件或部件布置，出于安全原因，防止在医用电气系统部件之间传输不需要的电压或电流

3.113

3.113

SERVICE PERSONNEL

服务人员

individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment

负责安装、装配、维护或维修医用电气设备、医用电气系统或设备的个人或实体

3.114

3.114

SEVERITY

严重程度

measure of the possible consequences of a HAZARD

危害可能后果的度量

[ISO 14971:2000 2007, definition 2.21 2.25]

【ISO 14971:2000 2007，定义2.21 2.25】

3.115

3.115

* SIGNAL INPUT/OUTPUT

PART SIP/SOP

信号输入/输出部分SIP/SOP

part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

医用电气设备的一部分，非应用部件，用于向其他电气设备发送或接收信号，例如，用于显示、记录或数据处理

NOTE See Figure 2.

注：见图2。

3.116

3.116

SINGLE FAULT CONDITION

单一故障条件

condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

医用电气设备的状况，其中降低风险的单一方法存在缺陷或存在单一异常情况

NOTE See 4.7 and 13.2.

注：见4.7和13.2。

3.117

3.117

SINGLE FAULT SAFE

单一故障保险

characteristic of ME EQUIPMENT or its parts whereby it remains free of unacceptable RISK

医用电气设备或其部件的特性，使其不存在不可接受的风险

during its EXPECTED SERVICE LIFE under SINGLE FAULT

CONDITIONS NOTE See 4.7.

在单一故障条件下的预期使用寿命内注：见4.7。

3.118

3.118

STATIONARY

固定的

term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another

指一旦安装并投入使用后，不打算从一个地方移到另一个地方的设备

NOTE See the taxonomy in the rationale for definition 3.63.

注：参见定义3.63的基本原理中的分类法。

3.119

3.119

SUPPLEMENTARY INSULATION

附加绝缘

independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION

除了基本绝缘外，还应用了独立绝缘，以便在基本绝缘发生故障时提供防触电保护

[IEV 826-12-15, modified]

[IEV 826-12-15, 修改]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

注：附加绝缘提供了一种保护方法。

3.120

3.120

*** SUPPLY MAINS**

供电干线

source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

不构成医用电气设备或医用电气系统一部分的电源

NOTE This also includes battery systems and converter systems in ambulances and the like.

注：这还包括救护车中的电池系统和转换器系统等。

3.121

3.121

TENSILE SAFETY FACTOR

拉伸安全系数

ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD

抗拉强度与总荷载对应的应力之比

3.122

3.122

TENSILE STRENGTH

抗拉强度

maximum tensile stress a test piece will withstand before rupturing

断裂前试件承受的最大拉应力

3.123

3.123

TERMINAL DEVICE

终端设备

part of electrical equipment by which electrical connection is made

电气设备的一部分，通过它进行电气连接

NOTE A TERMINAL DEVICE can contain several individual contacts.

注：一个终端设备可以包含几个单独的触点。

3.124

3.124

THERMAL CUT-OUT

热断路器

device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified SERVICE PERSONNEL

在异常情况下，通过自动断开电路或降低电流来限制电气设备或其一部分温度的装置，其结构应确保其设定值只有合格的维修人员才能更改

3.125

3.125

THERMAL STABILITY

热稳定性

condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

物体温度在1小时内上升不超过2°C的状态

3.126

3.126

THERMOSTAT

恒温器

temperature sensing control that is intended to keep a temperature within a specific range or above/below a preset value

用于将温度保持在特定范围内或高于/低于预设值的温度感应控制

3.127

3.127

TOOL

工具

extra-corporeal object that can be used to secure or release fasteners or to make adjustments

可以用来固定或释放紧固件或进行调整的额外的物质物体

NOTE Coins and keys are considered TOOLS within the context of this standard.

注：硬币和钥匙在本标准范围内被视为工具。

3.128

3.128

TOTAL LOAD

总负荷

maximum total loading of a part including the maximum SAFE WORKING LOAD, where applicable, and the static and dynamic forces occurring in NORMAL USE

零件的最大总载荷，包括最大安全工作载荷（如适用），以及正常使用中产生的静动力

NOTE 1 Examples of dynamic forces include forces caused by acceleration or deceleration of masses.

注1：动力示例包括由质量加速度或减速度引起的力。

NOTE 2 Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility is to be considered.

注2：当一个荷载被分配到几个平行的支撑部件上，并且这些部件上的分布没有明确地确定，则应考虑最不利的可能性。

3.129

3.129

TOUCH CURRENT

接触电流

LEAKAGE CURRENT flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE
从外壳或其部件流出的泄漏电流，不包括病人连接，正常使用时任何操作人员或病人都能接触到，通过保护接地导体以外的外部路径流到接地或外壳的另一部分

NOTE The meaning of this term is the same as that of “enclosure leakage current” in the first and second editions of this standard. The term has been changed to align with IEC 60950-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

注：该术语的含义与本标准第一版和第二版中“外壳泄漏电流”的含义相同。该术语已更改，以符合IEC 60950-1，并反映出该测量值现在也适用于通常保护接地的部件。

3.130

3.130

TRANSPORTABLE

可运输的

term referring to equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

指的是一旦安装并投入使用后，无论是否与电源相连，并且没有明显范围限制的设备

EXAMPLE MOBILE equipment, and PORTABLE equipment. and

BODY-WORN equipment NOTE See the taxonomy in the rationale

for definition 3.63.

例如移动设备和便携式设备。和人体穿戴设备注释见3.63定义的基本

原理中的分类法。

3.131

3.131

TRAPPING ZONE

陷波区

accessible location on or within the ME EQUIPMENT, ME SYSTEM or in the equipment environment where a human body or a part of the human body is exposed to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD
医用电气设备、医用电气系统上或内部或设备环境中的可接近位置，人体或人体的一部分暴露在诱捕、压碎、剪切、冲击、切割、缠绕、吸入、刺伤或磨损危险中

3.132

3.132

* TYPE B APPLIED PART

B型应用部件

APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT
符合本标准规定要求的应用部件，以提供电击保护，特别是关于允许的患者泄漏电流和患者辅助电流

NOTE 1 A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (DB:2002-10) (see Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (DB:2002-10) (see Table D.1, symbol 25). See also 3.20.

注1：B类应用部件标记有符号IEC 60417-5840（DB:2002-10）（见表D.1，符号19），或者，如果适用，标有符号IEC 60417-5841（DB:2002-10）（见表D.1，符号25）。另见3.20。

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

注2：B型应用部件不适用于直接心脏应用。

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

注3：关于不属于应用部件定义范围，但由于应用风险管理过程而需要被视为应用部件的部件的处理，另见4.6。

3.133

3.133

*** TYPE BF APPLIED PART**

BF型应用部件

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

符合本标准规定要求的F型应用部件提供比B型应用部件更高的电击防护等级

NOTE 1 A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (DB:2002-10) (see Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (DB:2002-10) (see Table D.1, symbol 26). See also 3.20.

注1：BF型应用部件标有符号IEC 60417-5333（DB:2002-10）（见表D.1，符号20）或（如适用）标有符号60417-5334（DB:2002-10）（见表D.1，符号26）。另见3.20。

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

注2：BF型应用部件不适用于直接心脏应用。

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

注3：关于不属于应用部件定义范围，但由于应用风险管理过程而需要被视为应用部件的部件的处理，另见4.6。

3.134

3.134

*** TYPE CF APPLIED PART**

CF型应用部件

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

符合本标准规定要求的F型应用部件提供比BF型应用部件更高的电击防护等级

NOTE 1 A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (DB:2002-10) (see Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (DB:2002-10) (see Table D.1, symbol 27). See also 3.20.

注1：CF型应用部件标有符号IEC 60417-5335（DB:2002-10）（见表D.1，符号21）或（如适用）标有符号60417-5336（DB:2002-10）（见表D.1，符号27）。另见3.20。

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

注2: 关于不属于应用部件定义范围, 但由于应用风险管理过程而需要被视为应用部件的部件的处理, 另见4.6。

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

注3: 关于需要为CF型应用部件的应用部件, 见直接心脏应用(3.22)定义的基本原理。

3.135

3.135

TYPE TEST

型式试验

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

对具有代表性的设备样品进行试验，以确定设计和制造的设备是否符合本标准的要求

3.136

3.136

USABILITY

可用性

characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of

操作员界面的特征，建立有效性、效率、易用性

OPERATOR learning and OPERATOR learnability and satisfaction

操作员学习和操作员可学习性和满意度

[IEC 60601-1-6:2004, definition 2.211 IEC 62366:2007, definition 3.17, modified]

[IEC 60601-1-6:2004, 定义2.211 IEC 62366:2007, 定义3.17, 修改]

3.137

3.137

USABILITY ENGINEERING

可用性工程

application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve adequate

USABILITY

在设计工具、机器、设备、设备、系统、任务、工作和环境时，应用有关人类行为、能力、限制和其他特征的知识，以获得足够的可用性

[IEC 60601-1-6:2004, definition 2.212 IEC 62366:2007, definition 3.18]
定义[IEC 626-2007, 定义]

3.138

3.138

VERIFICATION

验证

confirmation by examination and, through the provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled

通过检查和提供客观证据确认已满足规定的要求

NOTE In design and development, VERIFICATION concerns the PROCESS of examining the result of a given activity to determine conformity with the stated requirements for that activity.

注：在设计和开发中，验证涉及对给定活动的结果进行检查，以确定是否符合该活动的规定要求。

NOTE 1 The term “verified” is used to designate the

corresponding status. NOTE 2 Confirmation can comprise

activities such as:

注1：术语“已验证”用于表示相应的状态。注2确认可包括以下活动：

- performing alternative calculations;
进行替代计算；
- comparing a new design specification with a similar proven design specification;
将新的设计规范与经验证的类似设计规范进行比较；

- undertaking tests and demonstrations;
进行测试和演示;
- reviewing documents prior to issue.
文件发布前进行审查。

[ISO 14971:2000 2007, definition 2.22 2.28]
【ISO 14971:2000 2007, 定义2.22 2.28】

3.139

3.139

* WORKING VOLTAGE

工作电压

highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of NORMAL USE
当电气设备在正常使用条件下运行时，所考虑的绝缘或部件所承受的最高电压

[IEC 60950-1:20012005, definition 1.2.9.6]
[IEC 60950-1:20012005, 定义1.2.9.6]

3.140

3.140

AIR KERMA

空气比释动能

K

K

quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

dE_{tr}除以dm的商，其中dE_{tr}是空气质量dm中未带电粒子释放的所有带电粒子的初始动能之和，因此

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg⁻¹

单位: J kg⁻¹

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

空气比释动能单位的特殊名称为灰色（Gy）（ICRU 60）[IEC 60601-1-

3-2008, 定义3.4]

3.141

3.141

ALARM CONDITION

报警条件

state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required
当警报系统确定存在需要操作员意识或响应的潜在或实际危险情况时，警报系统的状态

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive

ALARM CONDITION. NOTE 2 An ALARM CONDITION can be

missed, i.e. a false negative ALARM CONDITION. [IEC 60601-1-

8:2006 / Amendment 1 (2012), definition 3.1]

注1：报警条件可能无效，即假阳性报警条件。注2：可忽略报警条件，

即假阴性报警条件。[IEC 60601-1-8:2006/修改件1（2012），定义

3.1]

3.142

3.142

ALARM SIGNAL

报警信号

type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an
报警系统生成的信号类型，用于指示

ALARM CONDITION

报警条件

[IEC 60601-1-8:2006, definition 3.9]

【IEC 60601-1-8-2006，定义3.9】

3.143

3.143

ALARM SYSTEM

报警系统

parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as
appropriate, generate ALARM SIGNALS

医用电气设备或医用电气系统的一部分，用于检测报警条件并在适当情况下产生报警信号

[IEC 60601-1-8:2006, definition 3.11]

[IEC 60601-1-8-2006，定义3.11]

3.144

3.144

BODY-WORN

身体磨损

term referring to TRANSPORTABLE equipment whose INTENDED USE includes
operation while being worn by a PATIENT or attached to a PATIENT'S clothing

指可移动设备的术语，其预期用途包括病人穿着或附在病人衣服上时的操作

NOTE 1 TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

注1：可移动设备既可穿戴式，也可手持。

[IEC 60601-1-11:2010, definition 3.1]

【IEC 60601-1-11-2010，定义3.1】

NOTE 2 See the taxonomy in the rationale for definition 3.63.

注2见定义依据3.63中的分类法。

3.145

3.145

IT-NETWORK

IT网络

INFORMATION TECHNOLOGY NETWORK

信息技术网络

a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes
由通信节点和传输链路组成的一个或多个系统，在两个或多个指定的通信节点之间提供物理连接或无线传输

[IEC 80001-1:2010, definition 2.12]

[IEC 80001-1:2010, 定义2.12]

3.146

3.146

PRIMARY OPERATING FUNCTION

主要操作功能

function that involves OPERATOR interaction that is frequently used or related to the safety of the ME EQUIPMENT

经常使用或与医用电气设备安全相关的操作员交互功能

[IEC 62366:2007, definition 3.14, modified]

[IEC 62366:2007, 定义3.14, 修改]

3.147

3.147

USABILITY ENGINEERING FILE

可用性工程文件

set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

可用性工程过程产生的一组记录和其他文件

[IEC 62366:2007, definition 3.19]

[IEC 62366:2007, 定义3.19]

4 General requirements

一般要求

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

*医用电气设备或医用电气系统的应用条件

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

除非另有规定，本标准的要求应适用于正常使用和合理可预见的误用。

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term

当本标准适用于用于补偿或减轻疾病、伤害或残疾的医用电气设备或医用电气系统时，使用该术语的定义和要求

PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

患者应被视为向医用电气设备或医用电气系统的预期对象提出申请。

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

*医用电气设备或医用电气系统的风险管理流程

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.

应执行符合ISO 14971的风险管理流程。

In applying ISO 14971:

在应用ISO 14971时：

- The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.
术语“医疗器械”应具有与医用电气设备或医用电气系统相同的含义。
- The term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.
ISO 14971中提及的术语“故障条件”应包括但不限于本标准中确定的单一故障条件。
- The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.
制造商应制定确定可接受风险和剩余风险可接受性的政策。
- Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.
如果本标准或其任何抵押品或特定标准规定了应对特定风险的可验证要求，且这些要求得到遵守，则除非有客观证据相反，否则这些要求所述的剩余风险应被推定为可接受。

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with ME EQUIPMENT or ME SYSTEMS, and is intended to serve as a tool during the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS should identify not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

注1：本标准规定了通常适用于医用电气设备或医用电气系统相关风险的要求，旨在作为风险管理过程中的工具。风险管理过程不仅应识别本标准所述的危害，还应识别所有危害及其相关风险和风险控制措施。

NOTE 2 Conditions or faults that can give rise to HAZARDS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDS are and the tests that need to be done to show that the identified HAZARDS do not arise in the specified circumstances.

注2：本标准条款中确定了可能导致危险的条件或故障。在这些情况下，通常需要执行风险管理流程，以确定实际危害是什么，以及需要进行的测试，以证明已识别的危险不会在特定情况下出现。

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures.

注3：制造商可能无法遵循本标准中为医用电气设备或医用电气系统的每个组成部分确定的所有流程，例如专有组件、非医疗来源的子系统和遗留设备。在这种情况下，制造商应特别考虑是否需要额外的风险控制措施。

NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in

accordance with the MANUFACTURER'S policy for determining acceptable RISK.

注4：当本标准要求涉及不可接受风险时，制造商应根据制造商确定可接受风险的政策来确定该风险的可接受性或不可接受性。

NOTE 5 Not all the RISKS associated with ME EQUIPMENT and ME SYSTEMS are subject to specific requirements of this standard (see 1.1).

注5：并非所有与医用电气设备和医用电气系统相关的风险均受本标准具体要求的约束（见1.1）。

Compliance is checked by inspection of the RISK MANAGEMENT FILE. The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has: 通过检查风险管理文件来检查合规性。如果制造商具备以下条件，则视为满足本条和本标准中有关风险管理文件检查的所有要求：

- established a RISK MANAGEMENT PROCESS;
建立风险管理流程；
- established acceptable levels of RISK; and
确定可接受的风险水平；以及
- demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).
–证明剩余风险是可接受的（根据确定可接受风险的政策）。

4.2.1 Introduction to RISK MANAGEMENT

风险管理概论

Subclause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:

第4.2款规定了遵守本标准所需的风险管理过程。本风险管理流程旨在达到以下目的：

- a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.
确定本标准第5条至第17条中规定的规范性要求，以及适用的附属文件和特殊标准的要求，是否解决了与特定医用电气设备或医用电气系统相关的所有危险。
- b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.
确定本标准中规定的某些特定试验应用于特定医用电气设备或医用电气系统的方式。
- c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate the RESIDUAL RISKS.
确定本标准未提供具体验收标准的特定危险或危险情况是否会导致特定医用电气设备或医用电气系统的任何风险，如果是，确定可接受的风险水平并评估残余风险。

- d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing
通过比较来评估替代风险控制策略的可接受性
RESIDUAL RISK with that achieved by applying the full requirements of this standard.
通过应用本标准的全部要求实现的剩余风险。

Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS. 尽管本标准中规定的风险管理过程需要符合ISO 14971的相关要求，但其范围不及ISO 14971，也不包括符合ISO 14971要求的所有要素。例如，符合本标准所需的风险管理过程不包括ISO 14971中要求的生产和生产后监控。此外，可通过检查本标准要求的记录和其他文件以及评估本标准中引用的过程来完成对本标准风险管理要求合规性的验证，无需对风险管理过程进行审计。

4.2.2 General requirement for RISK MANAGEMENT

风险管理的一般要求

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except:
应执行符合ISO 14971的风险管理流程。为符合本标准，ISO 14971:2007风险管理过程的所有要素均应适用，但以下情况除外：

- the planning for and execution of production and post-production monitoring (subclause 3.1, fourth dash, subclause 3.4, item f), and Clause 9 of ISO 14971:2007), and
生产和生产后监控的计划和执行（第3.1款第四个破折号，第3.4款，第f项）和ISO 14971:2007第9条），以及
- periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (subclause 3.2, fourth dash, of ISO 14971:2007).
风险管理过程适用性的定期评审（ISO 14971:2007第4部分第3.2款）。

When applying any of the requirements of ISO 14971:

当应用ISO 14971的任何要求时：

- the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and
术语“医疗器械”应具有与医用电气设备或医用电气系统相同的含义；以及
- the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.
ISO 14971中提及的术语“故障条件”应包括但不限于本标准中确定的单一故障条件。

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with the ME EQUIPMENT or ME SYSTEMS. Those requirements are intended to facilitate the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS is aimed at identifying not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.
注1：本标准规定了通常适用于医用电气设备或医用电气系统相关风险的要求。这些要求旨在促进风险管理过程。风险管理过程的目的不仅在于识别本标准所述的危害，还包括所有危害及其相关风险和风险控制措施。

NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.

注2：本标准条款中确定了可能导致危险情况的条件或故障。在这些情况下，通常需要执行风险管理流程，以确定实际的危险情况是什么，以及需要进行的测试，以证明所识别的危险情况不是在特定情况下发生的。

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER would need to take special account of the need for additional RISK CONTROL measures.

注3：制造商可能无法遵循本标准中为医用电气设备或医用电气系统的每个组成部分确定的所有流程，例如专有组件、非医疗来源的子系统和遗留设备。在这种情况下，制造商需要特别考虑是否需要额外的风险控制措施。

NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.

注4：当本标准要求涉及不可接受风险时，制造商应根据制造商确定可接受风险的政策来确定该风险的可接受性或不可接受性。

NOTE 5 Not all the RISKS associated with the ME EQUIPMENT or ME SYSTEM are subject to specific requirements of this standard (see 1.1).

注5：并非所有与医用电气设备或医用电气系统相关的风险均受本标准具体要求的约束（见1.1）。

Compliance is checked by:
合规性检查人：

- inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability;
检查制造商确定风险可接受标准的政策；
- inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration;
检查特定医用电气设备或医用电气系统的风险管理计划正在考虑中；以及
- confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.
确认制造商已准备好一份风险管理文件，其中包含风险管理记录和本标准要求的其他文件，用于考虑中的特定医用电气设备或医用电气系统。

NOTE 6 It is helpful to keep an index containing references or pointers to the RISK MANAGEMENT RECORDS and other documentation required by this standard.

注6：保存一个索引，其中包含本标准要求的风险管理记录和其他文件的参考或指针。

4.2.3 Evaluating RISK
风险评估

4.2.3.1 HAZARDS identified in the IEC 60601-series
IEC 60601系列中确定的危害

The requirements of this standard shall be applied in the following way when evaluating RISK:
在评估风险时，本标准的要求应按以下方式应用：

- a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.
如果本标准或其附属标准或特定标准规定了处理特殊危险或危险情况的要求，以及具体的验收标准，则假定符合这些要求将确定剩余风险已降低到可接受水平，除非有客观证据证明相反。

EXAMPLE 1 Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

例1第8.5.1.2款，病人保护方法（MOPP）

EXAMPLE 2 Subclause 9.4.2.1, Instability in transport position

例2子条款9.4.2.1，运输位置不稳定性

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

通过满足本标准及其附属标准和特殊标准的相关要求来检查合规性。

- b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.
如果本标准或其附属标准或特定标准规定了处理特殊危险或危险情况的要求，但未提供具体的验收标准，制造商应提供风险管理计划中规定的验收标准。这些验收标准应确保剩余风险根据风险管理计划中记录的风险可接受性标准可接受。

EXAMPLE 3 Subclause 9.8.3.3, Dynamic forces due to

loading from persons **EXAMPLE 4 Subclause 11.6.3,**

Spillage on ME EQUIPMENT and ME SYSTEMS

例3子条款9.8.3.3，人员荷载引起的动力示例4子条款11.6.3，

医用电气设备和医用电气系统溢出

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

通过确认风险管理文件中的记录证明，在应用本标准的具体要求后，满足制造商确定的验收标准，来检查合规性。仅需审查风险管理文件的相关部分，例如制造商的计算或试验结果，或风险可接受性的确定。

- c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:
如果本标准或其附属标准或特定标准确定了必须进行调査的特定危险或危险情况，而不提供具体的技术要求：

- the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, and
制造商应确定是否存在此类危险或危险情况

存在于特定医用电气设备或医用电气系统，以及

- where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2.

如果特定医用电气设备或医用电气系统存在此类危险或危险情况，制造商应按照4.2.2中规定的风险管理流程评估和（如有必要）控制这些风险。

EXAMPLE 5 Subclause 10.2, Alpha, beta, gamma, neutron and other particle radiation
中子、中子辐射和其他中子辐射

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

合规性通过确认风险管理文件中的记录证明剩余风险是可接受的，使用风险管理计划中记录的风险可接受性标准，即不存在不可接受的风险。仅需审查风险管理文件的相关部分，例如制造商的计算或试验结果，或风险可接受性的确定。

NOTE When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARDS no HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

注：当医用电气设备或医用电气系统的设计方式使某种类型的危险不存在危险情况时，无需对该危险进行进一步的风险评估。这可以通过测试或检查来验证。

4.2.3.2 HAZARDS not identified in the IEC 60601 series **IEC 60601系列中未识别的危险**

For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2. 对于特定医用电气设备或医用电气系统识别出的危险或危险情况，但本标准或其附属标准或特定标准中未具体说明，制造商应按照4.2.2的规定，在风险管理过程中解决这些危险。

EXAMPLE ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard.

例如医用电气设备或医用电气系统存在特殊风险，但没有特定标准。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

4.3 * ESSENTIAL PERFORMANCE

*基本性能

The MANUFACTURER shall identify which functions of the ME EQUIPMENT and ME SYSTEMS are ESSENTIAL PERFORMANCE. Where this standard specifies that ESSENTIAL PERFORMANCE is to be maintained following a particular test, these functions shall be used and compliance shall be checked by inspection, and if necessary, by functional test.

制造商应确定医用电气设备和医用电气系统的哪些功能是基本性能。如果本标准规定在特定试验后保持基本性能，则应使用这些功能，并通过检查和必要时通过功能试验检查符合性。

NOTE Where requirements of this standard refer to ESSENTIAL PERFORMANCE, that ESSENTIAL PERFORMANCE is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for RISK acceptability.

注：当本标准的要求涉及基本性能时，基本性能由制造商根据制造商的风险可接受性政策确定。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

在风险分析期间，制造商应确定医用电气设备或医用电气系统临床功能的性能，但与基本安全相关的性能除外，这些性能是实现其预期用途所必需的，或可能影响医用电气设备或医用电气系统的安全性的。

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

然后，制造商应规定在正常条件和单一故障条件下，完全功能和所识别性能的全部损失之间的性能限制。

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

然后，制造商应评估超出制造商规定限值的已识别性能损失或退化的风险。如果由此产生的风险不可接受，则确定的性能构成医用电气设备或医用电气系统的基本性能。

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.
制造商应实施风险控制措施，将已识别性能的损失或退化风险降低至可接受水平。

NOTE 1 The performance of the RISK CONTROL measure might well become an aspect of the ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM. For example, the generation of the ALARM SIGNAL to indicate the interruption of the SUPPLY MAINS could be "essential" if an interruption of the SUPPLY MAINS could result in an unacceptable RISK if it went unattended.

注1：风险控制措施的性能很可能成为医用电气设备或医用电气系统基本性能的一个方面。例如，如果电源中断可能导致无法接受的风险（如果无人照管），则发出指示电源中断的警报信号可能是“必要的”。

The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.

制造商应规定用于验证风险控制措施有效性的方法。这应包括为确定是否需要验证而进行的任何评估。

NOTE 2 Following the principles of RISK MANAGEMENT, the MANUFACTURER is required to verify the effectiveness of each RISK CONTROL measure. This can involve demonstrating that the RISK CONTROL measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.
注2: 遵循风险管理的原则, 要求制造商验证各项风险控制措施的有效性。这可能涉及证明风险控制措施将在导致所识别性能损失或退化的情况下运行。

EXAMPLE 1 If ESSENTIAL PERFORMANCE is lost because of an interruption of the SUPPLY MAINS, an ALARM SYSTEM intended to notify the OPERATOR that the SUPPLY MAINS has been interrupted would need to have a backup power source so that the generation of the ALARM SIGNAL would not depend on the SUPPLY MAINS.
例1如果由于供电干线中断而丧失了基本性能, 则用于通知操作员供电干线已中断的报警系统需要备用电源, 以便报警信号的生成不依赖于供电干线。

EXAMPLE 2 If the failure of a component results in the loss of ESSENTIAL PERFORMANCE, the design of the ME EQUIPMENT or ME SYSTEM would need to be such that the component failure does not compromise the effectiveness of any RISK CONTROL measures put in place to mitigate the RISK from the loss of the ESSENTIAL PERFORMANCE.

示例2如果部件故障导致基本性能损失, 则医用电气设备或医用电气系统的设计应确保部件故障不会为减轻基本性能损失而采取的任何风险控制措施的有效性。

NOTE 3 Each collateral standard or particular standard in the IEC 60601 or the IEC/ISO 80601 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.3.

注3: IEC 60601或IEC/ISO 80601系列中的每个并列标准或特定标准可列出潜在的基本性能, 以指导制造商根据4.3确定特定的基本性能。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

Where this standard requires that ESSENTIAL PERFORMANCE is to be maintained following a particular test, compliance is checked by inspection and, if necessary, by functional test(s) that demonstrate the MANUFACTURER'S specified limits are maintained or the ME EQUIPMENT or ME SYSTEM transitions to a safe state as defined by the MANUFACTURER.

如果本标准要求在特定试验后保持基本性能, 则通过检查和(如有必要)功能试验检查合规性, 以证明维持了制造商规定的限值, 或医用电气设备或医用电气系统过渡到制造商规定的安全状态。

4.4 * EXPECTED SERVICE LIFE

*预期使用寿命

The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM

制造商应说明医用电气设备或医用电气系统的预期使用寿命

in the RISK MANAGEMENT FILE.

在风险管理文件中。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS

*医用电气设备或医用电气系统的同等安全性

* Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or

*医用电气设备或

ME SYSTEMS

ME系统

Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard. 如果本标准规定了应对特定风险的要求，解决这些风险的替代方法是可接受的，前提是制造商可以证明，采用替代方法产生的残余风险等于或小于应用本标准要求所产生的残余风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

如果本标准规定了特定的风险控制措施或测试方法，则可接受替代风险控制措施或测试方法，前提是制造商可以通过科学数据、临床意见或比较研究证明，应用替代风险控制措施或测试方法所产生的残余风险测量或试验方法仍然是可接受的，并可与应用本标准要求产生的残余风险相比较。

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

本文中的比较研究，是指将替代性风险控制措施或测试方法与本标准规定的风险控制措施或测试方法的效果进行比较的研究。

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

注：如果提供了额外的补偿措施，替代风险控制措施可允许超过本标准或其抵押品或特定标准中规定的限额。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

*与患者接触的医用电气设备或医用电气系统部件

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard shall apply, except that 7.2.10 does not apply to such parts.

风险管理过程应包括评估可与患者接触但不在应用部件定义范围内的部件是否符合应用部件的要求。如果风险管理过程确定这些部件符合应用部件的要求，则应适用本标准的所有相关要求和试验，但7.2.10不适用于此类部件。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply. 风险管理过程应包括评估可与患者接触但不在应用部件定义范围内的部件是否需要符合应用部件的要求。对于相关零件，应采用B型应用零件的要求，除非评估确定需要应用BF型应用零件或CF型应用零件的要求。

If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts. 如果风险管理过程确定该等部分受适用部分的要求约束，则应适用本标准、相关抵押品和特殊标准的所有相关要求和测试，但7.2.10不适用于该等部分。

Compliance is checked by inspection of the RISK MANAGEMENT FILE. 通过检查风险管理文件来检查合规性。

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

*医用电气设备的单一故障状态

ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2. 医用电气设备的设计和制造应使其保持单一故障安全，或通过应用4.2确定的风险仍然可接受。

NOTE 1 The NORMAL CONDITIONS identified in 8.1 a) are taken into consideration during evaluation of compliance with any requirement of this standard that they might affect.

注1：在评估是否符合本标准的任何要求时，应考虑8.1 a) 中确定的正常条件。

ME EQUIPMENT is considered SINGLE FAULT SAFE if:

医用电气设备被认为是单一故障安全的，如果：

- a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES

它采用单一的方法来降低失效概率可忽略不计的风险（例如，加强绝缘、无机械保护装置的悬挂质量

employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or
采用8倍拉伸安全系数，具有高完整性特征的部件），或

b) a SINGLE FAULT CONDITION occurs, but:

出现单一故障，但：

- the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES); or
初始故障将在医用电气设备的预期使用寿命期间以及第二种降低风险的方法失效之前检测到（例如，带有机电保护装置的悬挂质量）；或
- the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible.
第二种降低风险的方法在医用电气设备的预期使用寿命内失效的可能性可以忽略不计。

Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

当一个单一故障条件导致另一个单一故障条件时，这两个故障被视为一个单一故障条件。

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.
在单一故障条件下进行的任何试验中，一次只能施加一个故障。

NOTE 2 Faults are generally divided into 3 probability categories:

注2：故障一般分为3个概率类别：

- a) so remote that they can be ignored. The RISKS arising from these faults are considered acceptable;
如此遥远以至于它们可以被忽略。这些故障引起的风险被认为是可接受的；
- b) probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971 that meet the SINGLE FAULT CONDITION criteria;
很可能需要考虑它们，但不太可能一次只考虑一个（单一故障）。这类故障包括本标准中所有被确定为单一故障条件的故障，以及在应用ISO 14971时确定的满足单一故障条件标准的任何其他故障；
- c) so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.
很有可能，如此不可预测或无法检测到，它们被认为是一种正常情况，需要单独和集体地加以考虑。

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.
风险分析的结果应用于确定应测试哪些故障。应通过物理或理论模拟任何一个组件一次可能导致危险情况的故障，包括13.1中所述的故障。评估部件是否进行故障模拟时，应考虑与医用电气设备预期使用寿命期间部件故障相关的风险。该评估应通过应用风险管理原则来完成。评估应考虑可靠性、拉伸安全系数和部件额定值等问题。此外，在模拟单一故障条件期间，应模拟极有可能或无法检测到的部件故障。

NOTE 3 See also Note 2 in 4.2.

注3另见4.2中的注2。

This requirement and relevant tests shall not be applied to failures of DOUBLE or

REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

本要求和相关试验不适用于双重或加强绝缘或具有高完整性特征的部件的故障。

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK. 合规性是通过应用与13.2中确定的单一故障条件相关的具体要求和测试，以及通过风险分析结果评估确定的故障测试来确定的。如果引入13.2中描述的任何单一故障条件（一次一个）不会直接导致13.1中所述的危险情况，或导致不可接受风险的任何其他结果，则确认合规性。

4.8 * Components of ME EQUIPMENT

*医用电气设备部件

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5): 除非本标准或风险管理过程中有特殊例外，否则所有可能导致危险情况的部件（包括接线）应按照其规定的额定值使用。应根据医用电气设备的使用条件对用作保护装置的部件的可靠性进行评估。它们应符合以下要求之一（另见4.5）：

- a) the applicable safety requirements of a relevant IEC or ISO standard;
相关IEC或ISO标准的适用安全要求；

NOTE 1 For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.
注1：对于部件，无需进行相同或等效的试验，以检查是否符合部件标准。

- b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.
如果本标准或IEC标准没有相关要求，则应采用该标准。

NOTE 2 If there are neither requirements in this standard nor in an IEC or ISO standard, any other applicable source (e.g. standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.
注2：如果本标准或IEC或ISO标准中均无要求，则可使用任何其他适用来源（例如其他类型装置的标准、国家标准）证明符合风险管理流程。

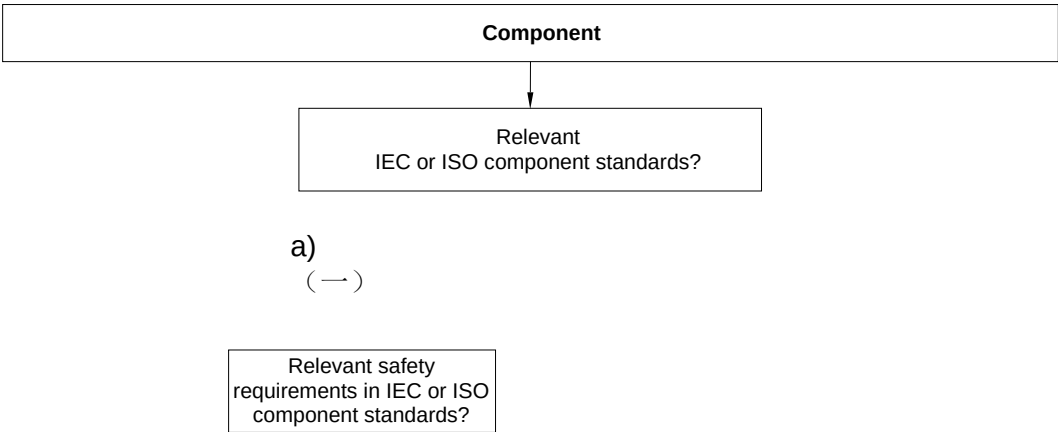
See Figure 5 for a schematic flow chart for a) and b).
a) 和b) 的示意流程图见图5。

Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME SYSTEM components that provide isolation from non-ME EQUIPMENT are evaluated to Clause 16.
通过检查和必要时通过试验检查合规性。本标准对电动机（见13.2.8和13.2.13.3）和变压器（见15.5.3）的试验被认为是全面的，并且根据表22对电动机或变压器绝缘系统的评估代表了本标准要求的所有试验。根据第16条对提供与非医用电气设备隔离的医用电气系统部件进行评估。

4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT
*医用电气设备中高完整性部件的使用

A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK. COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.
当特定部件的故障可能产生不可接受的风险时，应使用具有高完整性特征的部件。应根据医用电气设备预期使用寿命内的使用条件和合理可预见的误用情况，选择和评估具有高完整性特征的部件。

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.
通过检查风险管理文件和具有高完整性特征的部件的选择标准来检查合规性。





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Figure 5 – Schematic flow chart for component qualification

图5——组件鉴定流程示意图

(see 4.8)

(见4.8)

4.10 * Power supply

*电源

4.10.1 Source of power for ME EQUIPMENT

医用电气设备电源

ME EQUIPMENT shall be suitable for connection to a SUPPLY MAINS, be specified for connection to a separate power supply or be powered by an INTERNAL ELECTRICAL POWER SOURCE. Alternatively, a combination of these sources may be used. 医用电气设备应适合连接到电源干线，指定用于连接到单独的电源或由内部电源供电。或者，可以使用这些源的组合。

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.
通过检查随附文件检查合规性。

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

医用电气设备和医用电气系统的电源

For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:

对于拟连接至电源的医用电气设备，不得超过以下额定电压：

- 250 V for HAND-HELD ME EQUIPMENT;
手持式医用电气设备为250V;
- 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS
医用电气设备和医用电气系统用250 V直流或单相交流或500 V多相交流
with a RATED input □ 4 kVA;
额定输入□4kVA; 或
- 500 V for all other ME EQUIPMENT and ME SYSTEMS.
所有其他医用电气设备和医用电气系统均为500伏。

SUPPLY MAINS in this standard shall be assumed to have the following characteristics:

本标准中的供电干线应假定具有以下特征：

- overvoltage category II for mains transients unless a higher category is specified by the MANUFACTURER;
电源瞬变的II类过电压，除非制造商；
- no voltage in excess of 110 % or lower than 90 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (see 7.9.3.1);
系统任何导体之间或这些导体与地面之间的电压不得超过标称电压的110%或低于90%（见7.9.3.1）；

NOTE 1 IEC 60601-1-2 contains requirements and tests for voltage dips, short interruptions and voltage variations on the SUPPLY MAINS. See also 1.3.
注1 IEC 60601-1-2包含电源电压骤降、短时中断和电压变化的要求和试验。另见1.3。

- voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;
在多相供电的情况下，电压实际上是正弦的，并形成几乎对称的供电系统；
- a frequency of □ 1 kHz;
1 kHz的频率；
- a frequency deviation of □ 1 Hz from the NOMINAL frequency up to 100 Hz and □ 1 % from the NOMINAL frequency from 100 Hz to 1 kHz;
从标称频率到100赫兹的频率偏差为1赫兹，从100赫兹到1千赫的标称频率偏差为1%；
- the protective measures as described in IEC 60364-4-41;
IEC 60364-4-41中所述的保护措施；

NOTE 2 If ME EQUIPMENT or an ME SYSTEM is intended to be operated from a SUPPLY MAINS with characteristics different from the SUPPLY MAINS described in this subclause, additional safety measures could be necessary.

注2：如果医用电气设备或医用电气系统拟从具有不同于本款所述电源特性的电源干线上运行，则可能需要采取额外的安全措施。

- a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

峰值间纹波不超过平均值10%的直流电压（用动圈表或等效方法测量）。

Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

当峰间纹波超过平均值的10%时，必须施加峰值电压。

4.11 Power input

4.11电源输入

The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10 % (see 7.2.7).

医用电气设备或医用电气系统在使用说明书中规定的额定电压和操作设置下的稳态测量输入不得超过标记额定值的10%（见7.2.7）。

Compliance is checked by inspection and by the following tests.

通过检查和下列试验检查是否符合要求。

- The ME EQUIPMENT or ME SYSTEM is operated as specified in the instructions for use until the input has reached a stable value. Input is measured and compared with markings and the contents of the technical description. 医用电气设备或医用电气系统按照使用说明书的规定进行操作，直到输入达到稳定值。测量输入并与标记和技术说明的内容进行比较。
 - ME EQUIPMENT or an ME SYSTEM marked with one or more RATED voltage ranges is tested at both upper and lower limits of the range, unless each marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is performed at a voltage equal to the mean value of that range. 标记有一个或多个额定电压范围的医用电气设备或医用电气系统在该范围的上限和下限进行测试，除非额定输入的每个标记与相关电压范围的平均值相关，在这种情况下，测试是在等于该范围平均值的电压下进行的。
 - The steady state current is measured with a true r.m.s. reading instrument.
- 稳态电流用真实的r.m.s.读数仪测量。

Power input, if expressed in volt-amperes, is either measured with a volt-ampere meter or determined as the product of the steady state current (measured as described above) and the supply voltage.

如果功率输入以伏安表示, 则可以用伏安表测量, 或者确定为稳态电流 (如上所述测量) 和电源电压的乘积。

NOTE 1 Technical details of a true r.m.s. meter can be found in IEC 62354

注1: IEC 62354中提供了真实有效功率计的技术细节

A supplier certification may be used in place of the above measurement as the basis for steady state current or power input specification.

可使用供应商认证代替上述测量作为稳态电流或功率输入规范的基础。

NOTE 2 Supplier information can be used to supplement the above measurement as a power input specification.

注2: 供应商信息可用于补充上述测量作为电源输入规范。

5 * General requirements for testing ME EQUIPMENT

*医用电气设备测试的一般要求

5.1 * TYPE TESTS

*型式试验

The tests described in this standard are TYPE TESTS. The tests to be performed are determined taking into consideration the requirements of Clause 4, in particular 4.2.

本标准所述试验为型式试验。要进行的试验应考虑到第4条的要求, 特别是4.2的要求。

A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

如果分析表明被测条件已通过其他试验或方法得到充分评估, 则无需进行试验。

The results of the RISK ANALYSIS are used to determine which combination(s) of simultaneous faults are to be tested.

风险分析的结果用于确定要测试的同时故障的组合。

The combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION shall be documented in the RISK MANAGEMENT FILE (see also 4.7). When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations. 可能导致危险情况的同时独立故障的组合应记录在风险管理文件中 (另见4.7)。当有必要进行试验以证明在这些同时发生的独立故障下基本安全和基本性能得以保持时, 相关试验可能仅限于最坏情况。

NOTE 1 The test results might necessitate a revision of the RISK ANALYSIS.

注1: 试验结果可能需要修改风险分析。

NOTE 2 When considering use of tests described in this standard as routine tests, see Annex K of IEC/TR 62354 (production line tests) or see IEC 62353 (recurrent tests).

注2: 当考虑将本标准中描述的试验作为常规试验使用时, 见IEC/TR 62354 (生产线试验) 附录K或IEC 62353 (重复试验)。

5.2 * Number of samples

*样品数量

TYPE TESTS are performed on a representative sample of the item being tested.

型式试验是在试验项目的代表性样品上进行的。

NOTE Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

注：如果结果的有效性不受显著影响，则可同时使用多个样本。

5.3 Ambient temperature, humidity, atmospheric pressure **环境温度、湿度、大气压**

- a) After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1).
待测试的医用电气设备设置为正常使用后（根据5.7），在技术说明中所示的环境条件范围内进行测试（见7.9.3.1）。
- b) ME EQUIPMENT is shielded from other influences (for example, draughts), that might affect the validity of the tests.
医用电气设备不受其他可能影响测试有效性的影响（例如，气流）。
- c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.
如果无法保持环境温度，应相应地修改试验条件并相应地调整结果。

5.4 Other conditions **其他条件**

- a) a) Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favourable working conditions as specified in the instructions for use that are identified during RISK ANALYSIS. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions shall be documented for every test where they apply.
a) 除非本标准另有规定，医用电气设备应在风险分析期间确定的使用说明中规定的最不利工作条件下进行测试。工作条件见随附文件。在适用的每个试验中，应记录最不利的工作条件。
- b) ME EQUIPMENT having operating values that can be adjusted or controlled by anyone other than SERVICE PERSONNEL shall be adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.
医用电气设备的工作值可由维修人员以外的任何人进行调整或控制，作为试验的一部分，应将其调整至对相关试验最不利的数值，但应符合使用说明。

- c) If the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description.

如果试验结果受到冷却液入口压力和流量或化学成分的影响, 则应在技术说明中规定的这些特性限值内进行试验。

- d) Where cooling water is required, potable water is used.

如果需要冷却水, 则使用饮用水。

5.5 Supply voltages, type of current, nature of supply, frequency

电源电压、电流类型、电源性质、频率

- a) Where test results are influenced by deviations of the supply voltage the characteristics of the SUPPLY MAINS from its their RATED values, the effect of such deviations is taken into account.

如果试验结果受到电源电压、电源特性与其额定值的偏差的影响, 则应考虑此类偏差的影响。

The supply voltage values used during tests is testing are according to 4.10.2 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.

试验期间使用的电源电压值应符合4.10.2或医用电气设备上标记的电压值(见7.2.6), 以最不利者为准。

NOTE 1 For the RATED value(s) given on the ME EQUIPMENT, deviations of the SUPPLY MAINS as provided in

注1: 对于医用电气设备的额定值, 供电干线的偏差如

4.10.2 are only to be tested if the deviations have a negative impact on BASIC SAFETY or ESSENTIAL PERFORMANCE.

4.10.2只有当偏差对基本安全或基本性能有负面影响时才进行试验。

- b) ME EQUIPMENT having a MAINS PART intended for connection to a.c. SUPPLY MAINS is only tested with a.c. at RATED frequency (if marked) ± 1 Hz up to and including 100 Hz and

医用电气设备的电源部分用于连接交流电源, 仅在额定频率(如有标记) ± 1 Hz至100 Hz(包括100 Hz)下进行交流试验

± 1 % above 100 Hz. ME EQUIPMENT marked with a RATED frequency range is tested at the least favourable frequency within that range.

100赫兹以上 ± 1 %。标有额定频率范围的医用电气设备在该范围内以最不利的频率进行测试。

- c) ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., or for both external power and an INTERNAL ELECTRICAL POWER SOURCE, is tested in conditions (described in 5.4) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.

医用电气设备设计用于一个以上额定电压, 或同时用于交流和直流, 或同时用于外部电源和内部电源, 在与最不利电压和电源性质相关的条件下(如5.4所述)进行测试, 例如相数(单相电源除外)和电流类型。为了确定哪种电源配置最不利, 可能需要进行多次测试。

- d) ME EQUIPMENT having a MAINS PART intended for connection to d.c. SUPPLY MAINS is only tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is taken into consideration, according to the instructions for use. See also 8.2.2.

医用电气设备的电源部分用于连接直流电源。仅使用直流电对医用电气设备进行测试。根据使用说明, 在进行测试时, 应考虑极性对医用电气设备操作的可能影响。另见8.2.2。

e) ME EQUIPMENT for which alternative ACCESSORIES or components specified in the ACCOMPANYING DOCUMENTS (see 7.9.2.14 and 7.9.3.2) are available is tested with those ACCESSORIES or components that give the least favourable conditions. 对于随附文件（见7.9.2.14和7.9.3.2）中规定的备用附件或组件可用的医用电气设备，应使用提供最不利条件的附件或部件进行测试。

f) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is connected to such a power supply. See also 7.2.5 and 8.2.1.

如果使用说明书规定医用电气设备将从独立电源接收电源，则应将其连接到该电源。另见7.2.5和8.2.1。

NOTE 2 What was referred to in the first and second editions of this standard as a “specified power supply” is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.

注2：本标准第一版和第二版中所指的“指定电源”现在被视为同一医用电气设备的另一部分或医用电气系统中的另一设备。

5.6 Repairs and modifications

修理和改装

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

如果在试验过程中发生故障或未来可能发生故障后需要进行修理或修改，试验实验室和医用电气设备供应商可同意，或者在提交一个新样品时，再次对其进行影响结果的所有试验，或者，最好是在进行所有必要的修理或修改之后，仅重复相关的试验。

5.7 * Humidity preconditioning treatment

*湿度预处理

Prior to the tests of 8.7.4 and 8.8.3, all ME EQUIPMENT or its parts shall be subjected to a humidity preconditioning treatment.

在对设备进行第7.8.8节和第8.8节的所有部件进行预处理之前，应对其进行预处理。

ME EQUIPMENT or its parts shall be set up complete (or where necessary partially). Covers used during transport and storage are detached.

医用电气设备或其部件应设置完整（或在必要时部分设置）。在运输和储存过程中使用的盖子是分开的。

This treatment is applied only to those ME EQUIPMENT parts which are influenced by the climatic conditions that are simulated by the test.

该处理仅适用于受试验模拟气候条件影响的医用电气设备部件。

Parts that can be detached without the use of a TOOL are detached but are treated simultaneously with the major part.

无需使用工具即可拆卸的零件被拆下，但与主要零件同时处理。

ACCESS COVERS that can be opened or detached without the use of a TOOL are opened and detached.

无需使用工具即可打开或拆卸的检修盖被打开和拆下。

The humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of $93\% \pm 3\%$ where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by $\pm 6\%$. The temperature of the air in the cabinet, at all places where ME EQUIPMENT or its parts can be located, is shall be maintained within $2\text{ }^{\circ}\text{C}$ of any convenient value T in the range of $+20\text{ }^{\circ}\text{C}$ to $+32.30\text{ }^{\circ}\text{C}$. Before being placed in the humidity cabinet, ME EQUIPMENT or its parts shall be brought to a temperature between T and $T + 4\text{ }^{\circ}\text{C}$, and kept at this temperature for at least 4 h before the humidity treatment starts. 湿度预处理是在湿度箱中进行的，湿度箱中含有相对湿度为 $93\%\pm 3\%$ 的空气，其中医用电气设备或其部件所在位置。试验箱其他位置的湿度条件可能变化 $\pm 6\%$ 。在医用电气设备或其部件所在的所有地方，机柜内的空气温度应保持在 $+20^{\circ}\text{C}\sim +32.30^{\circ}\text{C}$ 范围内的任何方便值 T 的 2°C 。在将医用电气设备或其部件放入湿度柜之前，应将医用电气设备或其部件的温度保持在 T 和 $T+4$ 之间 4°C ，并在湿度处理开始前保持该温度至少4小时。

KEEP ME EQUIPMENT and its parts, where the ENCLOSURE is classified as IPX0, is kept in the humidity cabinet for 48 h.

将医用电气设备及其部件存放在湿度柜内48小时，外壳为IPX0。

Keep ME EQUIPMENT and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

将医用电气设备及其部件（外壳设计用于提供更高的液体进入保护）放在湿度柜中168小时。

Where the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT can be exposed to high humidity for extended periods (such as ME EQUIPMENT intended for outdoor use), the period is extended appropriately.

如果风险管理过程表明医用电气设备可长时间暴露在高湿度环境中（如拟用于室外使用的医用电气设备），则应适当延长该期限。

After the treatment, the ME EQUIPMENT is reassembled, if necessary.

如有必要，在治疗后重新组装设备。

5.8 Sequence of tests

试验顺序

Unless stated otherwise, the tests in this standard are sequenced in such a way that the results of any test do not influence the results of a subsequent test.

除非另有说明，本标准中的试验顺序应确保任何试验的结果不会影响后续试验的结果。

NOTE It is recommended that all tests be performed in the sequence given in Annex B.

5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS
*应用部件和可触及部件的确定

APPLIED PARTS are identified by inspection and by reference to the ACCOMPANYING DOCUMENTS
应用部件通过检查和参考随附文件进行标识

See 另见4.6。	also	4.6.

5.9.2 ACCESSIBLE PARTS

可触及部件

5.9.2.1 * Test finger

*试验指

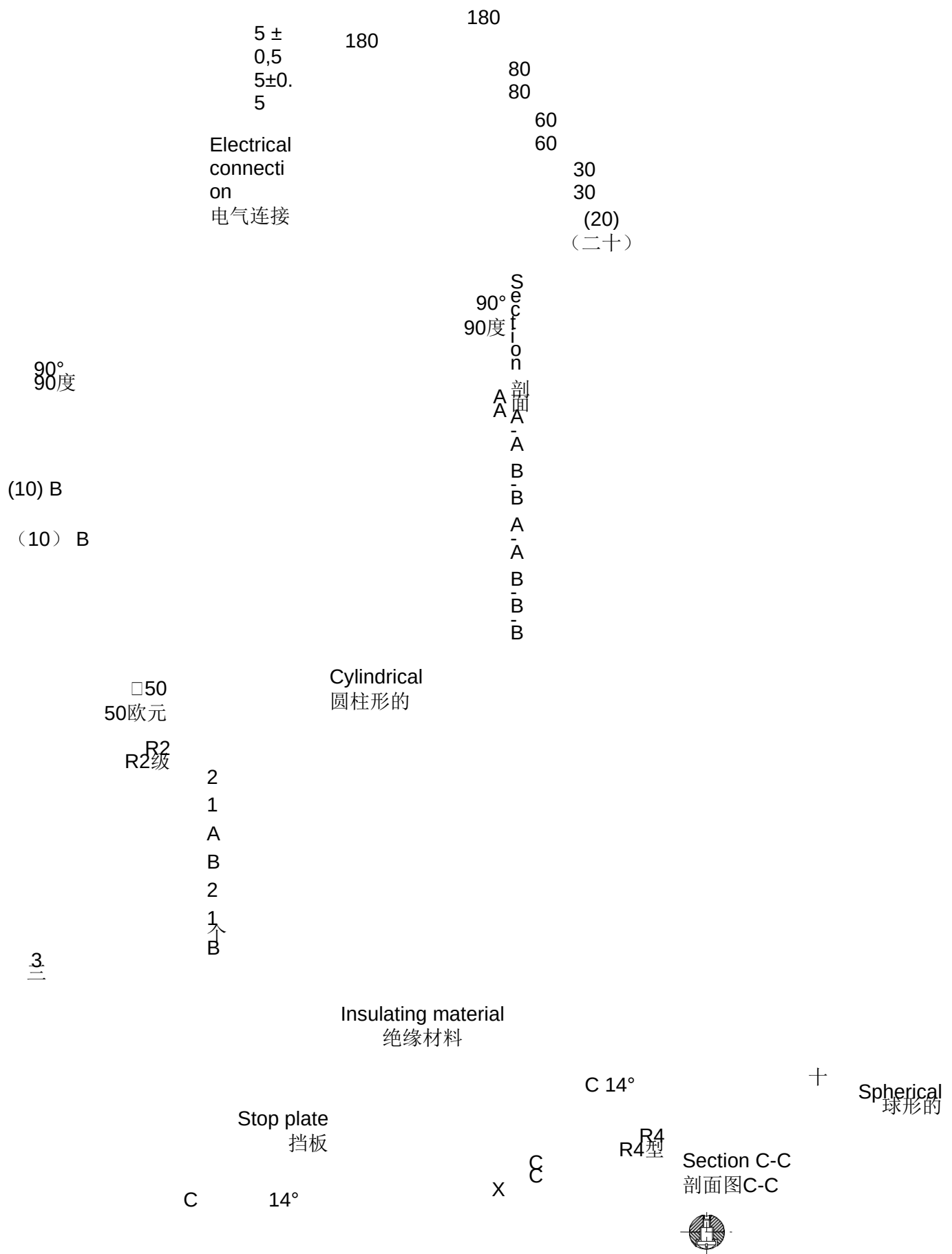
Parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and where necessary by test. In case of doubt, accessibility is determined by a test with the standard test finger shown in Figure 6, applied in a bent or straight position: 医用电气设备中被视为可接近部件的部件通过检查和必要时通过试验进行识别。如有疑问，可用图6所示的标准试验指，以弯曲或笔直的位置进行试验，以确定可接近性：

- for all positions of ME EQUIPMENT when operated as in NORMAL USE,
对于医用电气设备在正常使用时的所有位置，
- even after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuseholders, without the use of a TOOL or according to the instructions for use.
即使在未使用工具或按照使用说明打开检修盖并拆下零件（包括灯、保险丝和保险丝座）后。

The standard test finger is applied without appreciable force in every possible position, except that ME EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 45 kg is not tilted. ME EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, is tested in its final mounting position.

标准试验指在每个可能的位置都没有施加明显的力，但拟用于地板上且在任何操作条件下质量超过45 kg的医用电气设备不得倾斜。根据技术说明，拟安装在机柜中的医用电气设备在其最终安装位置进行测试。

Openings preventing the entry of the standard test finger of Figure 6 are mechanically tested by means of a straight unjointed test finger of the same dimensions, which is applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 6 is repeated, the finger being pushed through the opening if necessary. 如果用手指的标准开口进行机械试验，则用手指的标准尺寸6进行重复试验，如有必要，手指被推过开口。



Chamfer
all

Edges
倒角所有边

View on back side
背面视图

Part 3 Part 2 Part 1
第3部分 第2部分 第1部分

IEC 2389/05
IEC/2389标准

Linear dimensions in millimetres
线性尺寸（毫米）

Tolerances on dimensions without specific tolerances:
无特定公差的尺寸公差：

– 14° and 37° angles: ± 15'
–14度和37度角：±15′

– on radii: ± 0,1 mm
半径：±0,1 mm

– on linear dimensions:
线性尺寸：

≤ 15 mm:	0 mm
≤ 15毫米:	0毫米
	0,1
	0,1

> 15 mm ≤ 25 mm: ± 0,1 mm
>15毫米≤25毫米：±0.1毫米

> 25 mm: ± 0,3 mm
>25毫米：±0.3毫米

Material of finger: heat-treated steel, for example.
手指材料：例如热处理钢。

Both joints of this finger can be bent through an angle of 90° ± 10°, but in one and the same direction only.
这个手指的两个关节都可以弯曲90°-10°，但只能朝向一个方向弯曲。

NOTE 1 Using the pin and groove solution is only one of the possible approaches in order to limit the bending angle to 90°. For this reason, dimensions and tolerances of these details are not given in the drawing. The actual design must insure a 90° bending angle with a 0° to + 10° tolerance.

角度为90°。因此，图纸中未给出这些细节的尺寸和公差。实际设计必须确保90°的弯曲角度，公差为0°到+10°的公差。

NOTE 2 Dimensions in parentheses are for information only.
注2：括号内的尺寸仅供参考。

NOTE 3 The test finger is taken from IEC 60950-1, Figure 2A. That test finger is based on IEC 61032), Figure 2, test probe B. In some cases, the tolerances are different.

注3：试验指取自IEC 60950-1图2A。该试验指基于IEC 61032），图2，试验探针B。在某些情况下，公差不同。

Figure 6 – Standard test finger

图6-标准测试指

(see 5.9.2.1)

（见5.9.2.1）

¹⁸⁾ IEC 61032:1997, Protection of persons and equipment by enclosures - Probes for verification
IEC 61032:1997，外壳对人和设备的保护.检验用探头

5.9.2.2 Test hook 试验钩

ME EQUIPMENT openings are mechanically tested by means of the test hook (see Figure 7), if the hook can be inserted.
 医用电气设备开口通过试验钩（见图7）进行机械试验，前提是吊钩可以插入。

The test hook is inserted in all openings in question and is subsequently pulled with a force of 20 N for 10 s and in a direction substantially perpendicular to the surface in which the relevant opening is present. Any additional parts that have become accessible are identified by using the standard test finger of Figure 7 6 and by inspection.
 将测试钩插入所有有问题的开口中，然后用20 N的力拉动10 s，并以基本垂直于相关开口所在表面的方向拉动。使用图7-6中的标准试验指和通过检查来识别任何可接近的附加零件。

Dimensions in millimetres
 尺寸单位为毫米

1
 1

$1 \pm 0,1$
 $1 \pm 0,1$

$90^\circ \pm 15^\circ$
 $90^\circ \pm 15^\circ$

$5 \pm 0,1$
 $5 \pm 0,1$

2
I
E
C

1403/1
2标准

Material:
steel
材质：钢

Figure 7 – Test hook
图7-测试钩
(see 5.9.2.2)
(见5.9.2.2)

5.9.2.3 Actuating mechanisms 执行机构

Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS. Conductive parts of actuating mechanisms are not considered ACCESSIBLE PARTS if removal of handles, knobs, etc. requires the use of a TOOL and inspection of the RISK MANAGEMENT FILE demonstrates that the relevant part is unlikely to become detached unintentionally during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. See also 15.4.6.1.
在拆除手柄、旋钮、杠杆等之后可以接近的电气控制装置的执行机构的导电部件被视为可触及部件。如果拆除手柄、旋钮等需要使用工具，且风险管理文件的检查表明，在医用电气设备的预期使用寿命内，相关部件不太可能意外脱落，则执行机构的导电部件不被视为可触及部件。另见15.4.6.1。

Compliance is checked by tests according to 5.9.2.1 and 15.4.6.1.
根据5.9.2.1和15.4.6.1通过试验检查符合性。

6 * Classification of ME EQUIPMENT and ME SYSTEMS

*医用电气设备和医用电气系统的分类

6.1 General 总则

For purposes of this standard, ME EQUIPMENT, or parts thereof, including APPLIED PARTS, shall be classified as follows.

在本标准中，医用电气设备或其部件（包括应用部件）应分类如下。

6.2 * Protection against electric shock *防触电保护

ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.6). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.
由外部电源供电的医用电气设备应分为一类医用电气设备或二类医用电气设备（见7.2.6）。其他医用电气设备应归类为内部供电的医用电气设备。

INTERNALLY POWERED ME EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT while not so connected.
内部供电的医用电气设备与供电干线连接时，应符合一类医用电气设备或二类医用电气设备的要求，以及未连接时内部供电医用电气设备的要求。

APPLIED PARTS shall be classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3). APPLIED PARTS may be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5).
应用部件分为B类应用部件、BF类应用部件或CF类应用部件（见7.2.10和8.3）。应用部件可归类为防除颤应用部件（见8.5.5）。

6.3 * Protection against harmful ingress of water or particulate matter *防止有害水或颗粒物进入

ENCLOSURES shall be classified according to the degree of protection against harmful ingress of water and particulate matter as detailed in IEC 60529 (see 7.2.9 and 11.6.5).
外壳应根据IEC 60529（见7.2.9和11.6.5）中详述的防止水和颗粒物进入的防护等级进行分类。

NOTE 1 This classification is IPN1N2, where:

注1：该分类为IPN1N2，其中：

- N1 is an integer indicating degree of protection against particulate matter or the letter “X”.
N1是表示颗粒物防护等级的整数或字母“X”。

– N2 is an integer indicating the degree of protection against ingress of water or the letter “X”. NOTE 2 See also Table D.3.

N2是一个整数，表示防止进水的程度或字母“X”。注2另见表D.3。

6.4 Method(s) of sterilization

灭菌方法

ME EQUIPMENT or its parts intended to be sterilized shall be classified according to the method(s) of sterilization as indicated in the instructions for use (see 7.9.2.12 and 11.6.7).

拟灭菌的医用电气设备或其部件应按照使用说明书中规定的灭菌方法进行分类（见7.9.2.12和11.6.7）。

EXAMPLE 1 By ethylene oxide gas

例1环氧乙烷气体

EXAMPLE 2 By irradiation such

as gamma ray EXAMPLE 3 By

moist heat such as by autoclave

实施例2通过辐照（例如伽马射线）实施

例3通过湿热（例如高压灭菌器）进行照

射

EXAMPLE 4 By other methods validated and described by the MANUFACTURER

例4由制造商验证和描述的其他方法

6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT

适用于富氧环境

ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT shall be classified for such use (see 11.2.2).

拟在富氧环境中使用的医用电气设备和医用电气系统应进行分类（见11.2.2）。

6.6 * Mode of operation

***操作方式**

ME EQUIPMENT shall be classified for either CONTINUOUS OPERATION or non-CONTINUOUS OPERATION (see 7.2.11).

医用电气设备应分类为连续运行或非连续运行（见7.2.11）。

7 ME EQUIPMENT identification, marking and documents 医用电气设备标识、标记和文件

NOTE Annex C contains a guide to assist the reader in locating the marking and labelling requirements for
注：附录C包含一个指南，帮助读者确定
ME EQUIPMENT and ME SYSTEMS contained in other clauses of this standard.
本标准其他条款中包含的医用电气设备和医用电气系统。

7.1 General 总则

7.1.1 * USABILITY of the identification, marking and documents *标识、标记和文件的可用性

The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY associated with the design of the ME EQUIPMENT'S identification, marking and documents. See IEC 60601-1-6 and also see 1.3 and 12.2.
制造商应在可用性工程过程中解决与医用电气设备标识、标记和文件设计相关的低可用性风险。
见IEC 60601-1-6和1.3和12.2。

Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.
通过检查可用性工程过程的结果来检查合规性。

See 12.2.
见12.2。

7.1.2 * Legibility of markings *标记的易读性

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions:

7.2、7.3、7.4、7.5和7.6要求的标记应在以下条件下清晰可辨：

- for warning statements, instructive statements, safety signs and drawings on the outside of ME EQUIPMENT: from the intended position of the person performing the related function;
医用电气设备外部的警告声明、指导性声明、安全标志和图纸：从执行相关功能的人员的预期位置；
- for FIXED ME EQUIPMENT: when the ME EQUIPMENT is mounted in its position of NORMAL USE;
对于固定医用电气设备：医用电气设备安装在其正常使用位置时；
- for TRANSPORTABLE ME EQUIPMENT and for STATIONARY ME EQUIPMENT that is not FIXED
可移动医用电气设备和非固定医用电气设备
ME EQUIPMENT: in NORMAL USE or after dislodging the ME EQUIPMENT from a wall against which it has been positioned, or after turning the ME EQUIPMENT from its position of NORMAL USE and, in the case of dismountable rack units, after their removal from the rack;
医用电气设备：在正常使用中，或将医用电气设备从墙壁上移开后，或将医用电气设备从其正常使用位置旋转后，如果是可拆卸的机架单元，则在将其从机架上拆下后；
- for markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts: when viewed from the intended position of the person performing the related function.
医用电气设备或医用电气设备部件内部的标记：从执行相关功能的人员的预期位置观察。

Compliance for clear legibility is checked by the following test:
通过以下测试检查是否符合清晰易读性：

The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR; or. If the intended position of the OPERATOR is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a

distance of 1 m. The ambient illuminance illumination is the least favourable level in the range of 100 lx to 1 500 lx. 医用电气设备或其部件的位置应确保视点操作员的预期位置；或。如果未规定操作员的预期位置，且位置不明显，则视点位于与垂直于标记平面中心的轴成30°角的圆锥体底部内的任何一点，且距离为1 m。环境照度照度是该范围内最不利的水平100勒克斯到1500勒克斯。

The observer has a visual acuity, corrected if necessary, of:
观察者具有以下视力，必要时进行矫正：

- 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and
–在对数最小分辨率角（log-MAR）刻度上为0或6/6（20/20）；以及
- is able to read N6 of the Jaeger test card;
能够读取N6的Jaeger测试卡；

in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the
viewpoint.

在正常的室内照明条件下（约500 lx）。观察者从视角正确地读出标记。

7.1.3 * Durability of markings *标记的耐久性

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be removable only with a TOOL or by appreciable force and shall be sufficiently durable to remain CLEARLY LEGIBLE during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. In considering the durability of the markings, the effect of NORMAL USE shall be taken into account. 7.2、7.3、7.4、7.5和7.6中要求的标记只能用工具或通过相当大的力才能移除，并且应足够耐用，以便在医用电气设备的预期使用寿命期间保持清晰易读。在考虑标志的耐久性时，应考虑正常使用的影响。

Compliance is checked by inspection and the following tests:
通过检查和以下试验检查合规性：

a) After all the tests of this standard have been performed (see the recommended sequence of tests in Annex B):

完成本标准的所有试验后（见附录B中推荐的试验顺序）：

- markings are tested to the requirements of 7.1.2; and
根据7.1.2的要求对标记进行测试；以及
- adhesive labels are not to have worked loose or become curled at the edges.
胶粘标签不得松脱或在边缘卷曲。

b) For markings required by 7.2, 7.4, 7.5 and 7.6, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol. 对于7.2、7.4、7.5和7.6要求的标记，应进行额外的耐久性试验。用手在没有过度压力的情况下摩擦标记，首先用浸有蒸馏水的抹布擦拭15 s，然后用浸有96%甲基化酒精的抹布擦拭15 s，然后用浸有异丙醇的抹布擦拭15 s。

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)
医用电气设备或医用电气设备零件外部的标记（另见表C.1）

7.2.1 Minimum requirements for marking on ME EQUIPMENT
医用电气设备标记的最低要求
and on interchangeable parts
以及可互换的零件

If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.20 (inclusive), then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10 and 7.2.13 (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking of the ME EQUIPMENT is practicable, these markings may be affixed to the individual packaging. 如果医用电气设备、医用电气设备零件或附件的尺寸，或其外壳的性质，不允许粘贴7.2.2至7.2.20（包括7.2.2）、7.2.5、7.2.6（不适用于永久安装的医用电气设备）中规定的所有标记，7.2.10和7.2.13（如适用）应予以粘贴，其余标记应完整记录在随附文件中。如果医用电气设备的标记不可行，可将这些标记贴在单独的包装上。

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol ISO 7000-1051 (DB:2004-01) (see Table D.1, symbol 28). 任何一次性使用的材料、部件、附件或医用电气设备或其包装应标有“仅供一次性使用”、“请勿重复使用”或带有ISO 7000-1051（DB:2004-01）的标志（见表D.1，符号28）。

NOTE See also 7.9.2.12.
注：另见7.9.2.12。

7.2.2 * Identification
*鉴定

ME EQUIPMENT and its detachable components shall be marked with the name or trademark of the MANUFACTURER, and with a MODEL OR TYPE REFERENCE unless misidentification does not present an unacceptable RISK. 医用电气设备及其可拆卸部件应标有制造商的名称或商标，以及型号或型号参考，除非错误识别不会造成不可接受的风险。

ME EQUIPMENT	shall	be	marked	with:
医用电气设备应标有：				
– the name or trademark	and	contact information	of the	MANUFACTURER;
制造商的名称或商标及联系方式；				
– a MODEL	OR	TYPE		REFERENCE;
模型或类型参考；				
– a serial number	or	lot	or	batch identifier; and
序列号或批次或批次标识符；以及				
– the date of manufacture	or	use	by	date, if applicable.
生产或使用日期（如适用）。				

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

注：制造商符号、序列号、批次、制造年份和使用日期见ISO 15223-1。

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID. 序列号、批次或批次标识符和生产日期可以用可读代码或通过自动识别技术（如条形码或RFID）提供。

Detachable components of the ME EQUIPMENT shall be marked with: 医用电气设备的可拆卸部件应标有：

– the name or trademark of the MANUFACTURER; and 制造商的名称或商标；以及

– a MODEL OR TYPE REFERENCE; 模型或类型参考；

unless misidentification does not result in an unacceptable RISK. 除非错误识别不会导致不可接受的风险。

Software that forms part of a PEMS shall be identified with a unique identifier, such as revision level or date of release/issue. The identification shall be available to designated persons, e.g. SERVICE PERSONNEL. The identification does not need to need not be on the outside of the ME EQUIPMENT.

构成PEMS一部分的软件应使用唯一标识符进行标识，例如修订级别或发布/发布日期。标识应提供给指定人员，例如服务人员。标识不必在医用电气设备的外部。

7.2.3 * Consult ACCOMPANYING DOCUMENTS *查阅随附文件

When appropriate, symbol ISO 7000-1641 (DB:2004-01) (see Table D.1, symbol 11) may be used to advise the OPERATOR to consult the ACCOMPANYING DOCUMENTS. When consulting the ACCOMPANYING DOCUMENTS is a mandatory action, safety sign ISO 7010-M002 (see Table D.2, safety sign 10) shall be used instead of symbol ISO 7000-1641. 适当时，可使用ISO 7000-1641（DB:2004-01）（见表D.1，符号11）建议操作员查阅随附文件。当查阅随附文件时，应使用安全标志ISO 7010-M002（见表D.2，安全标志10）代替ISO 7000-1641。

7.2.4 * ACCESSORIES *配件

ACCESSORIES shall be marked with the name or trade-mark of their MANUFACTURER or supplier, and with a MODEL OR TYPE REFERENCE. Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging. 附件应标有制造商或供应商的名称或商标，以及型号或型号参考。如果附件没有标记，这些标记可以贴在单独的包装上。

ACCESSORIES shall be marked with:
附件应标记：
- the name or trade-mark and contact information of their MANUFACTURER
制造商的名称或商标和联系方式
- a MODEL OR TYPE REFERENCE;
模型或类型参考；
- a serial number or lot or batch identifier; and
序列号或批次或批次标识符；以及
- the date of manufacture or use by date, if applicable.
生产或使用日期（如适用）。

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

注：制造商符号、序列号、批次、制造年份和使用日期见ISO 15223-1。

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID. 序列号、批次或批次标识符和生产日期可以用可读代码或通过自动识别技术（如条形码或RFID）提供。

Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.
如果附件没有标记，这些标记可以贴在单独的包装上。

7.2.5 ME EQUIPMENT intended to receive power from other equipment 从其他设备接收电力的医用电气设备

If ME EQUIPMENT is intended to receive its power from other equipment including ME EQUIPMENT in an ME SYSTEM and connection to another source could result in an unacceptable RISK, the MODEL OR TYPE REFERENCE of the specified other equipment shall be marked adjacent to the relevant connection point. See also 7.9.2.3, 8.2.1 and 16.3. 如果医用电气设备打算从其他设备（包括医用电气系统中的医用电气设备）接收电源，并且连接到另一个电源可能会导致不可接受的风险，则应在相关连接点附近标记指定其他设备的型号或类型参考。另见7.9.2.3、8.2.1和16.3。

If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided: 如果医用电气设备拟从医用电气系统中的其他电气设备接收电源，并且符合本标准要求的情况取决于该其他设备，则应提供以下设备之一：

- the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point;
其他电气设备制造商的名称或商标，以及相关连接点附近指定其他设备的型号或型号参考；
- placing safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or
在相关连接点附近放置安全标志ISO 7010-M002（见表D.2，安全标志10），并在使用说明中列出所需细节；或

- using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.
使用市面上不常见的特殊连接器样式，并在使用说明中列出所需的详细信息。

See also 7.9.2.3, 8.2.1 and 16.3.
另见7.9.2.3、8.2.1和16.3。

7.2.6 Connection to the SUPPLY MAINS 与供电干线的连接

ME EQUIPMENT shall be marked with the following information:
医用电气设备应标有以下信息：

- the RATED supply voltage(s) or RATED voltage range(s) to which it may be connected. A RATED supply voltage range shall have a hyphen (-) between the minimum and maximum voltages. Where multiple RATED supply voltages or multiple RATED supply voltage ranges are given, they shall be separated by a solidus (/);
可连接的额定电源电压或额定电压范围。额定电源电压范围应在最小和最大电压之间有一个连字符（-）。如果给出了多个额定电源电压或多个额定电源电压范围，则应使用实心线（/）将其分开；

EXAMPLE 1 RATED supply voltage range: 100-240 V. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL voltage between 100 V and 240 V.

示例1额定电源电压范围：100-240 V。这意味着医用电气设备设计为连接到标称电压在100 V和240 V之间的电源干线。

EXAMPLE 2 Multiple RATED supply voltage: 120/220/240 V. This means that the ME EQUIPMENT is designed to be switched to allow connection to a SUPPLY MAINS having a NOMINAL voltage of 120 V or 220 V or 240 V.

示例2多个额定电源电压：120/220/240 V。这意味着医用电气设备被设计成允许连接到标称电压为120 V或220 V或240 V的电源干线。

NOTE 1 Marking of RATED supply voltage is taken from IEC 61293).
注1：额定电源电压的标记取自IEC 61293）。

¹⁹⁾ IEC 61293:1994, Marking of electrical equipment with ratings related to electrical supply - Safety requirements
IEC 61293:1994，具有与电源相关额定值的电气设备的标记-安全要求

- nature of supply, for example, number of phases (except for single-phase supply) and type of current. Symbols IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033 (all DB:2002-10)

供电性质，例如相数（单相供电除外）和电流类型。符号IEC 60417-5032、5032-1、5032-2、5031和5033（所有DB:2002-10）

may be used for this purpose (see Table D.1, symbols 1, 2, 3, 4 and 5);

可用于此目的（见表D.1，符号1、2、3、4和5）；

NOTE 2 For alternating current, the RATED frequency in hertz is sufficient to identify the type of current.

注2：对于交流电流，以赫兹为单位的额定频率足以识别电流类型。

- the RATED supply frequency or RATED frequency range in hertz;
额定电源频率或额定频率范围（赫兹）；

EXAMPLE 3 RATED supply frequency range: 50-60 Hz. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL frequency between 50 Hz and 60Hz.

例3额定电源频率范围：50-60 Hz。这意味着医用电气设备被设计成与标称频率在50赫兹到60赫兹之间的电源干线相连。

- For CLASS II ME EQUIPMENT, symbol IEC 60417-5172 (DB:2003-02) (see Table D.1, symbol 9).

对于II类医用电气设备，符号IEC 60417-5172（DB:2003-02）（见表D.1，符号9）。

Except for PERMANENTLY INSTALLED ME EQUIPMENT, these markings shall appear on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point. For PERMANENTLY INSTALLED ME EQUIPMENT, the NOMINAL supply voltage or voltage range to which it can be connected may be marked on the inside or the outside of the ME EQUIPMENT, preferably adjacent to the supply connection terminals SUPPLY MAINS connection.

除永久安装的医用电气设备外，这些标记应出现在包含电源连接的部件外部，最好靠近连接点。对于永久性安装的医用电气设备，可在医用电气设备的内部或外部标记其可连接的标称电源电压或电压范围，最好靠近电源连接端子电源连接。

7.2.7 Electrical input power from the SUPPLY MAINS

电源输入电源

The RATED input shall be given in amperes or volt-amperes or where the power factor exceeds 0,9, in watts.

额定输入应以安培或伏安为单位，或功率因数超过0.9时，以瓦特为单位。

The RATED input from the SUPPLY MAINS shall be marked on the ME EQUIPMENT. The RATED input shall be given in:

输入应包括：

- amperes or volt-amperes, or
安培或伏安，或
- if the power factor exceeds 0,9, in amperes, volt-amperes or watts.
如果功率因数超过0.9，则为瓦特。

In the case of ME EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges, if the range(s) is/are greater than $\pm 10\%$ of the mean value of the given range. 对于一个或多个额定电压范围的医用电气设备，如果范围大于给定范围平均值的 $\pm 10\%$ ，则应始终为该范围的上限和下限提供额定输入。

In the case of range limits which do not differ by more than 10 % from the mean value, marking of the input at the mean value of the range is sufficient.

如果量程限值与平均值相差不超过10%，则在量程平均值处标记输入值就足够了。

If the rating of ME EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and the most relevant momentary volt- ampere ratings, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS. 如果医用电气设备的额定值包括长期和瞬时电流或伏安额定值，则标记应包括长期和最相关的瞬时伏安额定值，每种额定值应在随附文件中明确标识和说明。

The marked input of ME EQUIPMENT provided with means for the connection of supply conductors of other electrical equipment shall include the RATED (and marked) output of such means. 医用电气设备的标记输入应包括此类装置的额定（和标记）输出。

7.2.8

Output
输出连接器

connectors

7.2.8.1

Mains
电源输出

power

output

For MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT, see 16.9.2.1 b). 对于与医用电气设备集成的多个插座，见16.9.2.1 b）。

7.2.8.2

Other
其他电源

power

sources

With the exception of MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment, equipment parts or ACCESSORIES, output connectors of ME EQUIPMENT intended to deliver power shall be marked with the following information: 除专用于指定设备、设备部件或附件的多个插座或连接器外，用于供电的医用电气设备的输出连接器应标有以下信息：

- RATED output voltage;
- RATED current or power (when applicable);
- output frequency (when applicable).

7.2.9	IP IP分类	classification

ME EQUIPMENT or its parts shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the classification in 6.3 (see Table D.3, Code 2).
医用电气设备或其部件应根据6.3中的分类，使用字母IP和IEC 60529中所述名称标记符号（见表D.3，代码2）。

ME EQUIPMENT classified IPX0 or IP0X need not be marked as such.
分类为IPX0或IP0X的医用电气设备无需标记。

7.2.10	* *应用部件	APPLIED PARTS

This requirement does not apply to parts that have been identified according to 4.6.
本要求不适用于根据4.6进行标识的零件。

The degree of protection against electric shock as classified in 6.2 for all APPLIED PARTS shall be marked with the relevant symbol, i.e., TYPE B APPLIED PARTS with symbol IEC 60417-5840, TYPE BF APPLIED PARTS with symbol IEC 60417-5333 or TYPE CF APPLIED PARTS with symbol IEC 60417-5335 (all DB:2002-10) (see Table D.1, symbols 19, 20 and 21).
6.2中分类的所有应用部件的电击防护等级应标记有相关符号，即带有符号IEC 60417-5840的B型应用部件、带有IEC 60417-5333符号的BF型应用部件或带有符号IEC 60417-5335的CF型应用部件（所有DB:2002-10）（见表D.1，符号19，20和21）。

For DEFIBRILLATION-PROOF APPLIED PARTS, symbols IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336 shall be used as applicable (all DB:2002-10) (see Table D.1, symbols 25, 26 and 27).
对于除颤应用部件，符号IEC 60417-5841、IEC 60417-5334，或IEC 60417-5336应作为适用（所有DB:2002-10）（见表D.1，符号25、26和27）。

The relevant symbol shall be marked adjacent to or on the connector for the APPLIED PART, unless either:
相关符号应标记在应用部件的连接器附近或其上，除非：

- there is no such connector, in which case the marking shall be on the APPLIED PART; or
如果接头上没有标记，则不应在接头上进行标记
- the connector is used for more than one APPLIED PART and the different APPLIED PARTS have different classifications, in which case each APPLIED PART shall be marked with the relevant symbol.
连接器用于多个应用部件，不同的应用部件有不同的分类，在这种情况下，每个应用部件都应标记相应的符号。

For clear differentiation with symbol IEC 60417-5333, symbol IEC 60417-5840 shall not be applied in such a way as to give the impression of being inscribed within a square (see Table D.1, symbols 19 and 20).
为明确区分符号IEC 60417-5333，符号IEC 60417-5840的使用方式不得给人以刻在正方形内的印象（见表D.1，符号19和20）。

If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, safety sign ISO 7010-W001, shall be placed near the relevant outlet (see Table D.2, safety sign 2). The instructions for use shall explain that protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.
如果心脏除颤器放电影响的防护部分在患者电缆中，则应在相关插座附近放置安全标志ISO 7010-W001（见表D.2，安全标志2）。使用说明应说明医用电气设备免受心脏除颤器放电影响的保护取决于使用适当的电缆。

7.2.11	Mode 操作方式	operation

If no marking is provided, ME EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION. For ME EQUIPMENT intended for non-CONTINUOUS OPERATION, the DUTY CYCLE shall be indicated using an appropriate marking giving the maximum activation (on) time and the minimum deactivation (off) time.
如果没有标记，则认为医用电气设备适合连续运行。对于非连续运行的医用电气设备，应使用适当的标记来指示工作循环，给出最大激活（打开）时间和最小停用（关闭）时间。

7.2.12 *
***保险丝**

Fuses

Where the fuse-holder is an ACCESSIBLE PART, the type and full rating of the fuse (voltage, current, operating speed and breaking capacity) shall be marked adjacent to the fuse-holder.
如果保险丝座是可触及部件，则应在保险丝座附近标记保险丝的类型和额定值（电压、电流、工作速度和断开容量）。

7.2.13 Physiological effects (safety signs and warning statements)
生理效应（安全标志和警告声明）

ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and can cause HARM to the PATIENT or OPERATOR shall bear a suitable safety sign (see 7.5). The safety sign shall appear in a prominent location so that it will be CLEARLY LEGIBLE in NORMAL USE after the ME EQUIPMENT has been PROPERLY INSTALLED.
医用电气设备产生的生理效应对操作人员不明显，可能对患者或操作人员造成伤害的，应带有适当的安全标志（见7.5）。安全标志应出现在显眼的地方，以便在医用电气设备正确安装后，其在正常使用中清晰易读。

The instructions for use shall describe the nature of the HAZARD and the precautions for avoiding it or minimising the associated RISK.
使用说明应说明危害的性质以及避免危害或将相关风险降至最低的预防措施。

7.2.14 HIGH VOLTAGE TERMINAL DEVICES **高压终端设备**

HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT that are accessible without the use of a TOOL shall be marked with symbol IEC 60417-5036 (DB:2002-10) (see Table D.1, symbol 24). 医用电气设备外部无需使用工具即可接近的高压终端设备应标有IEC 60417-5036 (DB:2002-10) (见表D.1, 符号24)。

NOTE CREEPAGE DISTANCES and AIR CLEARANCES between the high voltage contacts and the standard test finger are subject to the requirements in 8.9.

注: 高压触点和标准试验指之间的爬电距离和空气间隙应符合8.9的要求。

7.2.15 Cooling conditions **冷却条件**

Requirements for cooling provisions for ME EQUIPMENT (for example, supply of water or air) shall be marked.

应标记医用电气设备的冷却要求(例如, 供水或供气)。

7.2.16 Mechanical stability **机械稳定性**

For requirements on ME EQUIPMENT with a limited stability, see 9.4.

有关稳定性有限的医用电气设备的要求, 见9.4。

7.2.17 Protective packaging **保护性包装**

If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780).

如果在运输或储存过程中必须采取特殊处理措施, 则包装应作相应标记(见ISO 780)。

The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223-1).

运输和储存的允许环境条件应标记在包装外部(见7.9.3.1和ISO 15223-1)。

Where premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK, the packaging shall be marked with a suitable safety sign (see 7.5).

若医用电气设备或其部件过早开箱可能导致不可接受的风险, 则包装应标有适当的安全标志(见7.5)。

EXAMPLE 1 Humidity sensitive ME EQUIPMENT.

例1湿敏医用电气设备。

EXAMPLE 2 ME EQUIPMENT containing hazardous substances and materials.

示例2含有危险物质和材料的医用电气设备。

The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1).

无菌医用电气设备或附件的包装应标记为无菌, 并说明灭菌方法(见ISO 15223-1)。

7.2.18 External pressure source **外部压力源**

The RATED maximum supply pressure from an external source shall be marked on the external source's rated maximum supply pressure shall be marked on the

ME EQUIPMENT adjacent to each input connector.

每个输入连接器附近的医用电气设备。

Adjacent to each input connector, the ME EQUIPMENT shall be marked with:

在每个输入连接器附近, 医用电气设备应标有:

- the RATED maximum supply pressure from an external source, and
来自外部源的额定最大供应压力，以及
- the RATED flow rate if required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.
额定流量（如果保持基本安全或基本性能）。

7.2.19 FUNCTIONAL EARTH TERMINALS

功能接地端子

A FUNCTIONAL EARTH TERMINAL shall be marked with symbol IEC 60417-5017 (DB:2002-10 2006-08) (see Table D.1, symbol 7).

功能接地端子应标有符号IEC 60417-5017（DB:2002-10 2006-08）（见表D.1，符号7）。

7.2.20 Removable protective means

可拆卸保护装置

If ME EQUIPMENT has alternative applications that require the removal of a protective means to use a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided. 如果医用电气设备有其他用途，需要拆除保护装置以使用特定功能，则应标记保护装置，以表明不再需要相关功能时更换的必要性。无需联锁时提供。

Compliance with the requirements of 7.2 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.
通过检查和应用7.1.2和7.1.3中的试验和标准来检查是否符合7.2的要求。

7.2.21 * Mass of MOBILE ME EQUIPMENT

***移动式医用电气设备质量**

MOBILE ME EQUIPMENT shall be marked with its mass including its SAFE WORKING LOAD in kilograms. The marking shall be done in a way that it is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.

移动式医用电气设备应标明其质量，包括其安全工作负荷（千克）。标记的方式应确保当装载安全工作负载时，其适用于整个移动式医用电气设备，并与与最大箱子、架子或抽屉装载要求相关的任何标记分开，且与之不同。

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)
医用电气设备或医用电气设备零件内部的标记（另见表C.2）

7.3.1 Heating elements or lampholders
加热元件或灯座

The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be marked near the heater or in the heater itself.

设计用于加热灯的加热元件或灯座的最大功率负载应标记在加热器附近或加热器内部。

For heating elements or lampholders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.
对于设计用于加热灯的加热元件或灯座，只有维修人员使用工具才能进行更换，参考随附文件中所述信息的识别标记就足够了。

7.3.2 * HIGH VOLTAGE parts
***高压部件**

The presence of HIGH VOLTAGE parts shall be marked with symbol IEC 60417-5036 (DB:2002-高压部件的存在应标记为IEC 60417-5036（DB:2002-10）(see Table D.1, symbol 24) or with safety sign 3 (see Table D.2, safety sign 3). See also 7.5.10）（见表D.1，符号24）或带有安全标志3（见表D.2，安全标志3）。另见7.5。

7.3.3 Batteries
电池

The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2).
应标记电池类型和插入方式（如适用）（见15.4.3.2）。

For batteries intended to be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.
对于仅由维修人员使用工具更换的电池，参考随附文件中所述信息的识别标记就足够了。

Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.
如果使用了锂电池或燃料电池，并且不正确的更换会导致不可接受的风险，则会发出警告，说明由未经充分培训的人员进行更换可能会导致危险（例如温度过高，除了参考随附文件中所述信息的识别标记外，还应提供火灾或爆炸）。

7.3.4 * Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES
***保险丝、热断路器 and 过电流脱扣器**

Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL shall be identified either by type and full rating specification

adjacent to the component (voltage, current, operating speed, size, breaking capacity), or by a reference to information in the ACCOMPANYING DOCUMENTS.
只有使用工具才能接近的保险丝、可更换热断路器和过电流脱扣器应通过部件附近的类型和全额定规格（电压、电流、工作速度、尺寸、断开容量）或参考随附文件中的信息进行标识。

The nomenclature of IEC 60127-1 may be used.
可使用IEC 60127-1的术语。

7.3.5

*

PROTECTIVE

EARTH

TERMINALS

*保护接地端子

PROTECTIVE EARTH TERMINALS shall be marked with symbol IEC 60417-5019 (DB:2002-10 2006-08) (see Table D.1, symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC 60320-1.
保护接地端子应标有符号IEC 60417-5019（DB:2002-10 2006-08）（见表D.1，符号6），除非保护接地端子位于IEC 60320-1规定的电器插座中。

Markings that are on or adjacent to PROTECTIVE EARTH TERMINALS shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.
保护接地端子上或附近的标记不得贴在连接时必须拆下的零件上。连接完成后，它们应保持可见。

7.3.6

FUNCTIONAL

EARTH

TERMINALS

功能接地端子

FUNCTIONAL EARTH TERMINALS shall be marked with symbol IEC 60417-5017 (DB:2002-10 2006-08) (see Table D.1, symbol 7).
功能接地端子应标有符号IEC 60417-5017（DB:2002-10 2006-08）（见表D.1，符号7）。

7.3.7 Supply terminals
电源端子

Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no HAZARDOUS SITUATION unacceptable RISK an result if connections are interchanged.

电源导线的端子应在端子附近进行标记，除非可以证明如果互换连接，不会出现不可接受的危险情况。

If ME EQUIPMENT is so small that the terminal markings cannot be affixed, they shall be included in the ACCOMPANYING DOCUMENTS.

如果医用电气设备太小，以致终端标记无法粘贴，则应将其包含在随附文件中。

Terminals that are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT shall be marked with the appropriate code from IEC 60445 (see Table D.3, Code 1).
专用于连接永久性医用电气设备中性电源导线的端子应标有IEC 60445中的相应代码（见表D.3，代码1）。

If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445.

如果有必要标记三相电源，则应符合IEC 60445。

Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

电气连接点上或附近的标记不得贴在必须拆除以进行连接的部件上。连接完成后，它们应保持可见。

7.3.8 Temperature of supply terminals
电源端子温度

If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for PERMANENTLY INSTALLED ME EQUIPMENT (including such conductors themselves), attains a temperature of more than 75 □C during NORMAL USE and NORMAL CONDITION at the maximum ambient operating temperature as indicated in the technical description (see 7.9.3.1), the ME EQUIPMENT shall be marked with the following or an equivalent statement:
如果用于连接永久性安装医用电气设备电源导线（包括此类导线本身）的接线盒或接线盒内的任何一点，在正常使用和正常条件下，在技术规范中规定的最高环境工作温度下，温度超过75℃说明（见7.9.3.1），医用电气设备应标有以下内容或同等声明：

“For supply connections, use wiring materials suitable for at least X □C.”

“对于电源连接，使用至少适用于X□C的接线材料。”

where “X” is greater than the maximum temperature measured in the terminal box or wiring compartment in NORMAL USE and NORMAL CONDITION. This statement shall be located at or near the point where the supply connections are to be made. This statement shall not be affixed to parts that have to be removed to make the connection. It shall be CLEARLY LEGIBLE after the connections have been made.

其中“X”大于正常使用和正常条件下在接线盒或接线盒中测得的最高温度。该声明应位于电源连接点或附近。本声明不得附在必须拆除以进行连接的部件上。连接完成后，其应清晰可辨。

Compliance with the requirements of 7.3 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

通过检查和应用7.1.2和7.1.3中的试验和标准来检查是否符合7.3的要求。

7.4 Marking of controls and instruments (see also Table C.3)
控制装置和仪表的标记（另见表C.3）

7.4.1 * Power switches
*电源开关

Switches used to control power to ME EQUIPMENT or its parts, including mains switches, shall have their “on” and “off” positions:

用于控制医用电气设备或其部件电源的开关（包括电源开关）应具有“开”和“关”位置：

– marked with symbols IEC 60417-5007 (DB:2002-10) and IEC 60417-5008 (DB:2002-10)
– 标记符号IEC 60417-5007 (DB:2002-10) 和IEC 60417-5008 (DB:2002-10)
(see Table D.1, symbols 12 and 13); or
(见表D.1, 符号12和13); 或

– indicated by an adjacent indicator light; or
由相邻指示灯指示; 或

– indicated by other unambiguous means.
以其他明确的方式表示。

If a push button with bistable positions is used:
如果使用双稳态按钮:

– it shall be marked with symbol IEC 60417-5010 (DB:2002-10) (see Table D.1, symbol 14);
and
应标记符号IEC 60417-5010 (DB:2002-10) (见表D.1, 符号14); 以及

– the status shall be indicated by an adjacent indicator light; or
状态应通过相邻的指示灯指示; 或

– the status shall be indicated by other unambiguous

means. If a push button with momentary on position is used:

状态应以其他明确的方式表示。如果使用瞬时开启位置的按钮:

– it shall be marked with symbol 60417-5011 (DB:2002-10) (see Table D.1, symbol 15); or
应标记符号60417-5011 (DB:2002-10) (见表D.1, 符号15); 或

– the status shall be indicated by an adjacent indicator light; or
状态应通过相邻的指示灯指示; 或

- the status shall be indicated by other unambiguous means.
状态应以其他明确的方式表示。

7.4.2 * Control devices *控制装置

Different positions of control devices and different positions of switches on ME EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by use of symbols IEC 60417- 5264 (DB:2002-10) and IEC 60417-5265 (DB:2002-10) (see Table D.1, symbols 16 and 17).
控制装置的不同位置和医用电气设备上开关的不同位置应以数字、字母或其他视觉方式表示，例如使用符号IEC 60417-5264（DB:2002-10）和IEC 60417-5265（DB:2002-10）（见表D.1，符号16和17）。

If in NORMAL USE, the change of setting of a control could result in an unacceptable RISK to the
如果在正常使用中，改变控制装置的设置可能会对
PATIENT, such controls shall be provided with either:
患者，此类控制装置应配备：

- an associated indicating device, e.g. instruments or scale, or
相关的指示装置，如仪器或刻度，或
- an indication of the direction in which the magnitude of the function changes. See also
15.4.6.2.
函数大小变化方向的指示。另见15.4.6.2。

A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).
可使用符号IEC 60417-5009（2002-10）表示使医用电气设备进入“备用”状态的控制装置或开关（见表D.1，符号29）。

7.4.3 Units of measure measurement 计量单位

Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to ISO 31 80000-1 except the base quantities listed in Table 1 may be expressed in the indicated units, which are outside the SI units system.
医用电气设备上参数的数字显示应根据ISO 31 80000-1以国际单位制表示，但表1中列出的基本数量可以用所示单位表示，这些单位不在国际单位制内。

For application of SI units, their multiples and certain other units, ISO 1000 80000-1 applies.
对于国际单位制及其倍数和某些其他单位的应用，ISO 1000 80000-1适用。

Compliance with the requirements of 7.4 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

通过检查和应用7.1.2和7.1.3中的试验和标准来检查是否符合7.4的要求。

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT
表1中的设备可以使用国际单位制

Base quantity 基准量	Unit 单位	
	Name 姓名	Symbol 符号
Plane angle	revolution 革命	r r
	gon 冈州	gon or grade gon或等级

平面角	degree 度	° °
	minute of angle 角分	' '
	second of angle 角秒	" "
Time 时间	minute 分钟	min 最小
	hour 小时	h h
	day 白天	d d
Energy 能量	electron volt 电子伏特	eV 电动汽车
Volume 音量	litre 升	l a 洛杉矶
Pressure of respiratory 呼吸压 gases, blood, and other body fluids 气体、血液 和其他体液	millimetres of mercury 毫米汞柱	mmHg 毫米汞柱
	centimetres of water 厘米的水	cmH2O 立方厘米水
Pressure of gases 气体压力	bar 酒吧	bar 酒吧
	millibar 毫巴	mbar 工商管理硕士
a For consistency, in international standards only the symbol “l” is used for litre, although the symbol “L” is also given in ISO 31 80000-1. a为保持一致性，在国际标准中，升仅使用符号“l”，尽管ISO 31 80000-1中也给出了符号“l”。		

7.5 Safety signs 安全标志

For the purpose of this clause, markings used to convey a warning, prohibition or mandatory action that mitigates a RISK that is not obvious to the OPERATOR shall be a safety sign selected from ISO 7010. If a safety sign with an established meaning is appropriately used, the use of the general warning sign ISO 7010:2003-W 001 (see Table D.2, safety sign 2) is not required. 在本条款中，用于传达警告、禁止或强制措施的标志，以减轻操作员不明显的风险，应为ISO 7010中选择的标志。如果正确使用具有既定含义的安全标志，则不需要使用一般警告标志ISO 7010:2003-W 001（见表D.2，安全标志2）。

NOTE 1 In this context, warning is used to mean, “There is certain danger”; prohibition is used to mean, “You must not...”; and mandatory action is used to mean, “You must...”.

注1：在这种情况下，“警告”是指“存在一定的危险”；禁止是指“你不能.....”，强制行动是指“你必须.....”。

Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods.

如果安全标志无法显示特定的期望含义，可通过以下方法之一获得该含义。

- a) Constructing a safety sign according to ISO 3864-1:2002, Clause 7 (for the corresponding templates, see Table D.2, safety signs 1, 4 and 8).
按照ISO 3864-1:2002第7条的要求制作安全标志（相应模板见表D.2，安全标志1、4和8）。
- b) Using the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g. “Causes burns”, “Risk of explosion”, etc.). 使用一般警告标志ISO 7010:2003-W001（见表D.2，安全标志2）与补充符号或文本一起放置。与一般警告标志相关的文本应为肯定性声明（即安全通知），描述预见的主要风险（如“导致烧伤”、“爆炸风险”等）。
- c) Using the general prohibition sign ISO 7010:2003-P001 (see Table D.2, safety sign 4) placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e. a safety notice) describing what is prohibited (e.g. “Do not open”, “Do not drop”, etc.). 使用一般禁止标志ISO 7010:2003-P001（见表D.2，安全标志4）与补充符号或文本一起放置。与一般禁止标志相关的文本应是一份声明（即安全通知），说明禁止的内容（如“请勿打开”、“请勿跌落”等）。
- d) Using the general mandatory action sign ISO 7010:2003-M001 (see Table D.2, safety sign 9) placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e. a safety notice) describing required action (e.g. “Wear protective gloves”, “Scrub before entering”, etc.). 9) 与补充符号或文字放在一起的。与一般强制性行动标志相关的文字应为说明所需行动的命令（即安全通知）（如“戴防护手套”、“进入前擦洗”等）。

If there is insufficient space to place the affirmative statement together with the safety sign on the ME EQUIPMENT, it may be placed in the instructions for use.

如果没有足够的空间将肯定声明和安全标志一起放置在医用电气设备上，可将其放在使用说明中。

NOTE 2 The colours for safety signs are specified in ISO 3864-1 and it is important to use the specified colour.

注2安全标志的颜色在ISO 3864-1中有规定，使用规定的颜色很重要。

NOTE 3 A safety notice should include the appropriate precautions or include instructions on how to reduce the

注3安全通知应包括适当的预防措施或说明如何减少
RISK (e.g. “Do not use for . . .”, “Keep away from . . .”, etc.).
风险（例如“请勿用于。”，“远离。”，等等）。

Safety signs, including any supplementary symbol or text, shall be explained in the
instructions for use (see 7.9.2).
安全标志，包括任何补充符号或文字，应在使用说明中加以说明（见7.9.2）。

When supplementary text is placed together with safety signs, the supplementary text shall be in a
language that is acceptable to the intended OPERATOR.
当补充文本与安全标志放在一起时，补充文本应采用预期操作员可接受的语言。

NOTE 4 In some countries, more than one language is required.
注4：在一些国家，需要一种以上的语文。

Compliance is checked by inspection.
通过检查检查合规性。

7.6 Symbols
符号

7.6.1 Explanation of symbols
符号说明

The meanings of the symbols used for marking shall be explained in the instructions for use.
用于标记的符号的含义应在使用说明书中说明。

7.6.2 Symbols from Annex D
附录D中的符号

Symbols required by this standard shall conform to the requirements in the referenced IEC or ISO
publication. Annex D provides the symbol graphic and description for these symbols as a quick
reference.
本标准要求的符号应符合参考IEC或ISO出版物的要求。附录D提供了这些符号的符号图形和说明，作为
快速参考。

7.6.3 Symbols for controls and performance **控制和性能符号**

Symbols used for controls and performance shall conform to the requirements of the IEC or ISO publication where the symbol is defined, when applicable. See also 7.2.13.

用于控制和性能的符号应符合定义符号的IEC或ISO出版物的要求（如适用）。另见7.2.13。

NOTE IEC 60878 provides a survey of titles, descriptions and graphical representations of symbols for electrical equipment used in medical practice.

注：IEC 60878提供了医疗实践中所用电气设备符号的标题、说明和图形表示法。

Compliance with the requirements of 7.6 is checked by inspection.

通过检查检查是否符合7.6的要求。

7.7 Colours of the insulation of conductors **导体绝缘颜色**

7.7.1 PROTECTIVE EARTH CONDUCTOR **保护接地导体**

A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

保护接地导体的整个长度应通过绿色和黄色绝缘进行标识。

7.7.2 PROTECTIVE EARTH CONNECTIONS **保护接地连接**

Any insulation on conductors inside ME EQUIPMENT that form PROTECTIVE EARTH CONNECTIONS shall be identified by the colours green and yellow at least at the termination of the conductors.

医用电气设备内形成保护接地连接的导线上的任何绝缘应至少在导线端部用绿色和黄色标识。

EXAMPLE Conductors of a multi-conductor cord that are connected in parallel, where the maximum allowed resistance of the PROTECTIVE EARTH CONNECTIONS would be exceeded if only the green and yellow coloured conductor were used. 并联连接的多导体电线的示例导体，如果只使用绿色和黄色导体，则会超过保护接地连接的最大允许电阻。

7.7.3 Green and yellow insulation **绿色和黄色绝缘**

Identification by green and yellow insulation shall only be used for:

绿色和黄色绝缘的标识只能用于：

- PROTECTIVE EARTH CONDUCTORS (see 8.6.2);
保护接地导体（见8.6.2）；
- conductors as specified in 7.7.2;
7.7.2中规定的导体；

NOTE In other safety standards such as IEC 60950-1, internal connections between conductive parts and the main protective earth are called protective bonding conductors.

注：在其他安全标准（如IEC 60950-1）中，导电部件与主保护接地之间的内部连接称为保护性连接导体。

- POTENTIAL EQUALIZATION CONDUCTORS (see 8.6.7);
电位均衡导体（见8.6.7）；
- FUNCTIONAL EARTH CONDUCTORS (see 8.6.9).
功能接地导体（见8.6.9）。

7.7.4 Neutral conductor **中性导线**

Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC 60227-1 or in IEC 60245-1.
拟连接至供电系统中性导线的电源线中的导线应为IEC 60227-1或IEC 60245-1中规定的“浅蓝色”。

7.7.5 POWER SUPPLY CORD conductors **电源线导体**

Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC 60227-1 or with IEC 60245-1.
电源线中导线的颜色应符合IEC 60227-1或IEC 60245-1。

Compliance with the requirements of 7.7 is checked by inspection.
通过检查检查是否符合7.7的要求。

7.8 * Indicator lights and controls ***指示灯和控制装置**

7.8.1 Colours of indicator lights **指示灯颜色**

The colours of indicator lights and their meanings shall comply with Table 2.
指示灯的颜色及其含义应符合表2的规定。

NOTE IEC 60601-1-8 contains specific requirement for the colour, flashing frequency and DUTY CYCLE of alarm indicator lights.

注：IEC 60601-1-8包含报警指示灯颜色、闪烁频率和占空比的具体要求。

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.
点阵和其他字母数字显示器不被视为指示灯。

Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT
表2-医用电气设备指示灯颜色及其意义

Colour 颜色	Meani ng 意义
Red 红色	Warning – immediate response by the OPERATOR is required 警告-要求操作员立即响应
Yellow 黄色的	Caution – prompt response by the OPERATOR is required 注意-需要操作员迅速响应
Green 绿色	Ready for use 随时可用
Any other colour 还有其他颜色吗	Meaning other than that of red, yellow or green 不是指红色、黄色或绿色

7.8.2 Colours of controls 控件的颜色

The colour red shall be used only for a control by which a function is interrupted in case of emergency.
红色仅用于紧急情况下功能中断的控制。

Compliance with the requirements of 7.8 is checked by inspection. See also 15.4.4.
通过检查检查是否符合7.8的要求。另见15.4.4。

7.9 ACCOMPANYING DOCUMENTS 随附文件

7.9.1 * General (see also Table C.4) *概述（另见表C.4）

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.
医用电气设备应附有至少包含使用说明和技术说明的文件。随附文件应视为医用电气设备的一部分。

NOTE The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its EXPECTED SERVICE LIFE.
注：随附文件旨在促进医用电气设备在使用过程中的安全使用预期使用寿命。

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:
随附文件应通过包括以下内容（如适用）来识别医用电气设备：

- name or trade-name of the MANUFACTURER and an address contact information to which the RESPONSIBLE ORGANIZATION can refer;
制造商的名称或商品名以及负责组织可以参考的地址联系信息；
- MODEL OR TYPE REFERENCE (see 7.2.2).
型号或型号参考（见7.2.2）。

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format on CD- ROM. If the ACCOMPANYING DOCUMENTS are provided electronically, the RISK

MANAGEMENT PROCESS USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT, e.g. to cover emergency operation (see 12.2). 可以电子方式提供随附文件，例如CD-ROM上的电子文件格式。如果随附文件是以电子方式提供的，则风险管理过程可用性工程过程应考虑哪些信息还需要作为硬拷贝或医用电气设备上的标记提供，例如紧急操作（见12.2）。

EXAMPLE Information to cover emergency operation

涵盖紧急操作的示例信息

NOTE ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

注：并非所有司法管辖区都接受以电子方式提供的随附文件。

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used. 随附文件应详细说明预期操作员或责任组织所需的任何特殊技能、培训和知识，以及对医用电气设备可使用位置或环境的任何限制。

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

随附文件的书写水平应与拟提交文件的人员的教育、培训和任何特殊需求相一致。

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

通过检查随附文件以及IEC 60601-1-6中规定的电子文件检查合规性。

7.9.2 Instructions for use (see also Table C.5)

使用说明（另见表C.5）

7.9.2.1 * General

***总则**

The instructions for use shall document:

使用说明书应记录：

- the use of the ME EQUIPMENT as intended by the MANUFACTURER, 按照制造商的计划使用医用电气设备，
- the frequently used functions; and 常用功能；以及
- any known contraindication(s) to the use of the ME EQUIPMENT; and 任何已知的医用电气设备使用禁忌症；以及

- those parts of the ME EQUIPMENT that shall not be serviced or maintained while in use with a PATIENT.
医用电气设备在与患者一起使用时不应进行维修或维护的部件。

Where the PATIENT is an intended OPERATOR, the instructions for use shall indicate:
如果患者是预期的操作员，使用说明应说明：

- the PATIENT is an intended OPERATOR;
患者是有意的操作者；
- a warning against servicing and maintenance while the ME EQUIPMENT is in use;
医用电气设备在使用过程中的维修和维护警告；
- which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and
患者可以安全使用哪些功能，以及在适用的情况下，哪些功能患者无法安全使用；以及
- which maintenance the PATIENT can perform (e.g. changing batteries).
患者可以进行哪些维护（例如更换电池）。

NOTE 1 For ME EQUIPMENT where the INTENDED USE includes the PATIENT partially or fully operating the

注1：医用电气设备的预期用途包括患者部分或全部操作

ME EQUIPMENT, the PATIENT becomes an OPERATOR.
我的设备，病人变成了一个操作员。

NOTE 2 For ME EQUIPMENT where the PATIENT is allowed to perform restricted maintenance, the PATIENT becomes

注2对于允许患者进行限制性维护的ME设备，患者

SERVICE PERSONNEL.
服务人员。

The instructions for use shall indicate:
使用说明书应注明：

- the name or trademark and address of the MANUFACTURER;
制造商的名称、商标和地址；
- the MODEL OR TYPE REFERENCE.
模型或类型引用。

The instructions for use shall include all applicable classifications specified in Clause 6, all markings specified in 7.2, and the explanation of safety signs and symbols (marked on the ME EQUIPMENT).

使用说明应包括第6条中规定的所有适用分类、7.2中规定的所有标记以及安全标志和符号的说明（标记在医用电气设备上）。

NOTE 1 3 The instructions for use are intended for the OPERATOR and the RESPONSIBLE ORGANIZATION and should contain only the information most likely to be useful to the OPERATOR or RESPONSIBLE ORGANIZATION. Additional details can be contained in the technical description. See also 7.9.3.

注1 3：使用说明适用于操作员和责任组织，且应仅包含最有可能对操作员或责任组织有用的信息。技术说明中可包含其他详细信息。另见7.9.3。

NOTE 2 4 Guidance on the preparation of instructions for use is found in IEC 62079 [25]. Guidance on the preparation of educational materials for ME EQUIPMENT is found in IEC/TR 61258 [24].

注2 4：IEC 62079[25]中给出了使用说明的编制指南。有关医用电气设备教育材料准备的指南见IEC/TR 61258[24]。

7.9.2.3 ME EQUIPMENT specified for connection to a separate power supply
指定用于连接到单独电源的医用电气设备

If ME EQUIPMENT is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM. The instructions for use shall state this specification.
如果医用电气设备拟连接至单独的电源，则应将电源指定为医用电气设备的一部分，或将其组合指定为医用电气系统。使用说明书应说明本规范。

7.9.2.4 Electrical power source
电源

For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.
对于带有附加电源但未自动保持在完全可用状态的主电源操作医用电气设备，使用说明应包括警告声明，说明定期检查或更换此类附加电源的必要性。

If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.
如果电池泄漏会导致不可接受的风险，使用说明应包括警告，如果医用电气设备在一段时间内不可能使用，则应移除电池。

If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification.
如果内部电源是可更换的，使用说明书应说明其规格。

If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.
如果失去电源将导致不可接受的风险，使用说明应包含医用电气设备必须连接到适当电源的警告。

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or institutional stand-by generator.
例如内部或外部电池、不间断电源（UPS）或机构备用发电机。

7.9.2.5 ME EQUIPMENT description
医用电气设备说明

The instructions for use shall include:
使用说明书应包括：

- a brief description of the ME EQUIPMENT;
医用电气设备的简要说明；
- how the ME EQUIPMENT functions; and
医用电气设备如何工作；以及
- the significant physical and performance characteristics of the ME EQUIPMENT.
医用电气设备的重要物理和性能特征。

If applicable, this description shall include the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE (see 9.2.2.3).
如适用，该说明应包括操作员、患者的预期位置以及正常使用的医用电气设备附近的其他人员（见9.2.2.3）。

The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an unacceptable RISK (see 11.7).
使用说明应包括有关患者或操作员接触的材料或成分的信息，如果此类接触可能构成不可接受的风险（见11.7）。

The instructions for use shall specify any restrictions on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected.

使用说明应规定对其他设备或网络/数据耦合的任何限制，除了构成医用电气系统一部分的设备，信号输入/输出部分可连接到这些设备或网络/数据耦合。

The instructions for use shall indicate any APPLIED PART.

使用说明应标明任何应用部分。

7.9.2.6 *
***安装**

Installation

If installation of the ME EQUIPMENT or its parts is required, the instructions for use shall contain:
如果需要安装医用电气设备或其部件，使用说明应包括：

- a reference to where the installation instructions are to be found (e.g. the technical description), or
 参考安装说明（如技术说明），或
- contact information for persons designated by the MANUFACTURER as qualified to perform the installation.
 制造商指定有资格执行安装的人员的联系信息。

7.9.2.7 * Isolation from the SUPPLY MAINS
***与电源隔离**

If an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as the isolation means to satisfy 8.11.1 a), the instructions for use shall contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.
如果使用器具耦合器或电源插头或其他可分离插头作为满足8.11.1 a)要求的隔离装置，则使用说明应包含一条说明，说明不得将医用电气设备放置在不易操作断开装置的位置。

7.9.2.8 Start-up PROCEDURE 启动程序

The instructions for use shall contain the necessary information for the OPERATOR to bring the ME EQUIPMENT into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc.
使用说明应包含操作员操作医用电气设备所需的必要信息，包括任何初始控制设置、与患者的连接或定位等。

The instructions for use shall detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used.
使用说明应详细说明可使用医用电气设备、其部件或附件。

EXAMPLE A pre-use checklist.
示例使用前检查表。

7.9.2.9 Operating instructions 操作说明

The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance with its specification. This shall include explanation of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and ACCESSORIES, and replacement of material that is consumed during operation.
使用说明应包含按照其规范操作医用电气设备所需的所有信息。这应包括说明控制装置、显示器和信号的功能、操作顺序、可拆卸部件和附件的连接和断开，以及操作过程中消耗的材料更换。

The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT shall be explained in the instructions for use.
数字、符号、警告说明、缩写和指示灯的含义
医用电气设备应在使用说明书中说明。

7.9.2.10 Messages 信息

The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory.
使用说明应列出生成的所有系统消息、错误消息和故障消息，除非这些消息是自解释的。

NOTE 1 These lists can be identified in groups.
注1：这些列表可以分组标识。

The list shall include an explanation of messages including important causes, and possible action(s) by the OPERATOR, if any, that are necessary to resolve the situation indicated by the message.
清单应包括对信息的解释，包括重要原因和操作员可能采取的措施（如有），这些措施是解决信息所示情况所必需的。

NOTE 2 Requirements and guidelines for messages generated by an alarm system are found in IEC 60601-1-8.

注2：IEC 60601-1-8中规定了报警系统产生信息的要求和指南。

7.9.2.11 Shutdown PROCEDURE 停机程序

The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT.
使用说明应包含操作员安全终止医用电气设备操作的必要信息。

7.9.2.12 Cleaning, disinfection and sterilization 清洁、消毒、灭菌

For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through

contact with the PATIENT or with body fluids or expired gases during NORMAL USE, the instructions for use shall contain:
对于在正常使用过程中可能因接触患者或体液或过期气体而受到污染的医用电气设备零件或附件，使用说明应包括：

- details about cleaning and disinfection or sterilization methods that may be used; and
可能使用的清洁、消毒或灭菌方法的详细信息；以及
- list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.
列出适用的参数，如温度、压力、湿度、时间限制和此类医用电气设备零件或附件可承受的循环次数。

See also 11.6.6 and 11.6.7.
另见11.6.6和11.6.7。

This requirement does not apply to any material, component, ACCESSORY or ME EQUIPMENT that is marked as intended for a single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or ME EQUIPMENT is to be cleaned, disinfected or sterilized before use (see 7.2.1).
本要求不适用于标记为一次性使用的任何材料、部件、附件或医用电气设备，除非制造商规定材料、部件、附件或医用电气设备在使用前应进行清洁、消毒或消毒（见7.2.1）。

7.9.2.13 Maintenance **维护**

The instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.
使用说明应向操作员或责任组织提供足够详细的关于预防性检查、维护和校准的指示，包括此类维护的频率。

The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT.
使用说明书应提供必要的日常维护的安全性能信息，以确保医用电气设备的持续安全使用。

Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance. 此外，使用说明应确定维修人员应进行预防性检查和维护的零件，包括使用的时间，但不一定包括此类维护实际执行的详细信息。

For ME EQUIPMENT containing rechargeable batteries that are intended to be maintained by anyone other than SERVICE PERSONNEL, the instructions for use shall contain instructions to ensure adequate maintenance. 对于包含充电电池的医用电气设备（由维修人员以外的任何人进行维护），使用说明应包含确保充分维护的说明。

7.9.2.14 ACCESSORIES, supplementary equipment, used material
配件、辅助设备、旧材料

The instructions for use shall include a list of ACCESSORIES, detachable parts and materials that the MANUFACTURER has determined are intended for use with the ME EQUIPMENT. 使用说明应包括制造商确定用于医用电气设备的附件、可拆卸部件和材料清单。

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, RATED voltage, maximum or minimum power, protection class, intermittent or continuous service duty). 如果医用电气设备拟从医用电气系统中的其他设备接收电源，则使用说明应充分说明此类其他设备，以确保符合本标准的要求（例如零件号、额定电压、最大或最小功率、保护等级、间歇或连续工作负荷）。

NOTE What was referred to in the first and second editions of this standard as a “specified power supply” is considered either as another part of the same ME EQUIPMENT or as other equipment in an ME SYSTEM. Similarly, a battery charger is considered either as part of the ME EQUIPMENT or as other equipment in an ME SYSTEM. 在第二个版本中，被称为“设备”的第二个版本被称为“设备”。同样，电池充电器被视为医用电气设备的一部分或医用电气系统中的其他设备。

7.9.2.15 Environmental protection
环境保护

The instructions for use shall: 使用说明应：

- identify any RISKS associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE; and 识别与处理废物、残留物等相关的任何风险 医用电气设备和配件在其预期使用寿命结束时；以及
- provide advice on minimizing these RISKS. 提供关于最小化这些风险的建议。

The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE. 使用说明应提供有关在预期使用寿命结束时正确处理废弃产品、残留物等以及医用电气设备和附件的建议。

7.9.2.16 Reference to the technical description
参考技术说明

The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found (e.g. in a service manual). 使用说明应包含7.9.3中规定的信息或7.9.3中规定材料的位置（例如在维修手册中）。

7.9.2.17 ME EQUIPMENT emitting radiation
医用电气设备辐射

For ME EQUIPMENT emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.
对于医用医用辐射设备，使用说明书应说明该辐射的性质、类型、强度和分布。

7.9.2.18 ME EQUIPMENT and ACCESSORIES supplied sterile
医用电气设备和配件供应无菌

The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.
医用电气设备或无菌附件的使用说明应说明其已灭菌并说明灭菌方法。

The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization (see also 7.9.2.12).
使用说明应说明无菌包装损坏时的必要说明，并在适当的情况下，说明适当的再灭菌方法的细节（另见 7.9.2.12）。

7.9.2.19 * Unique version identifier
*唯一版本标识符

The instructions for use shall contain a unique version identifier such as its date of issue.
使用说明书应包含唯一的版本标识，如发布日期。

EXAMPLE Month and year.
例如月份和年份。

Compliance with the requirements of 7.9.2 is checked by inspection of the instructions for use in a language of an intended OPERATOR.
通过检查预期操作员语言的使用说明来检查是否符合7.9.2的要求。

7.9.3 Technical description (see also Table C.6)

技术说明（另见表C.6）

7.9.3.1 * General

*总则

The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the ME EQUIPMENT, and preparing it for use. This shall include:

技术说明应提供安全操作、运输和储存所必需的所有数据，以及安装医用电气设备和准备使用所需的措施或条件。这应包括：

- the permissible environmental conditions of use including conditions for transport and storage. See also 7.2.17;
允许的使用环境条件，包括运输和储存条件。另见7.2.17；
- all characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found;
医用电气设备的所有特性，包括显示值的范围、精度和精度，或在哪里可以找到这些值；
- any special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS;
任何特殊安装要求，如供电干线的最大允许视在阻抗；

NOTE 1 The apparent impedance of the SUPPLY MAINS is the sum of the impedance of the distribution network plus the impedance of the power source.

注1供电干线的视在阻抗为配电网阻抗加上电源阻抗之和。

- if liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid;
如果使用液体冷却，入口压力和流量的允许值范围，以及冷却液的化学成分；
- a description of the means of isolating the ME EQUIPMENT from the SUPPLY MAINS, if such means is not incorporated in the ME EQUIPMENT (see 8.11.1 b));
医用电气设备与供电干线隔离的方法说明，如果医用电气设备中未采用该方法（见8.11.1 b））；
- if applicable, a description of the means for checking the oil level in partially sealed oil-filled ME EQUIPMENT or its parts (see 15.4.9);
如果适用，说明检查部分密封充油医用电气设备或其部件中油位的方法（见15.4.9）；
- a warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT, e.g. a statement to the effect:
警告声明，说明未经授权修改医用电气设备可能造成的危害，例如：
 - “WARNING: No modification of this equipment is allowed.”
“警告：不允许修改此设备。”
 - “WARNING: Do not modify this equipment without authorization of the manufacturer.”
“警告：未经制造商授权，请勿改装此设备。”
 - “WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.”
警告：如果该设备被改装，必须进行适当的检查和测试，以确保设备的持续安全使用
- information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.
与基本性能和任何必要的经常性基本性能和基本安全测试有关的信息，包括方法、方法和建议频率的详细信息。

NOTE 2 This information is directly derived from the ESSENTIAL PERFORMANCE identified by the MANUFACTURER

注2：该信息直接来源于制造商确定的基本性能

in 4.3.
在4.3中。

If the technical description is separable from the instructions for use, it shall contain:
如果技术说明与使用说明书分开，则应包括：

- all applicable classifications specified in Clause 6, any warning and safety notices and the explanation of safety signs (marked on the ME EQUIPMENT);
第6条中规定的所有适用分类、任何警告和安全通知以及安全标志的说明（标记在医用电气设备上）；
- a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and
医用电气设备的简要说明，医用电气设备的功能及其重要的物理和性能特征；以及
- a unique version identifier such as its date of issue.
唯一的版本标识符，如发行日期。

NOTE 2 3 The technical description is intended for the RESPONSIBLE ORGANIZATION and SERVICE PERSONNEL.

注2 3本技术说明仅供负责组织和服务人员使用。

The MANUFACTURER may designate the minimum qualifications for SERVICE PERSONNEL. If present, these requirements shall be documented in the technical description.
制造商可指定维修人员的最低资格。如果有，这些要求应记录在技术说明中。

NOTE 3 4 Some authorities with jurisdiction impose additional requirements for qualification of SERVICE PERSONNEL.

注3 4一些有管辖权的当局对服务人员的资格提出了附加要求。

7.9.3.2 Replacement of fuses, POWER SUPPLY CORDS and other parts 更换保险丝、电源线和其他部件

The technical description shall contain, as applicable, the following:
技术说明应包括以下内容（如适用）：

- the required type and full rating of fuses used in the SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, if the type and rating of these fuses are not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT;
如果从医用电气设备的额定电流和运行模式的信息中看不出这些保险丝的类型和额定值, 则永久性安装医用电气设备外部电源所用保险丝的要求类型和额定值;
- for ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure that the requirements of 8.11.3 will continue to be met;
对于具有不可拆卸电源线的医用电气设备, 说明电源线是否可由维修人员更换, 如果可以, 说明正确连接和锚固, 以确保继续满足8.11.3的要求;
- instructions for correct replacement of interchangeable or detachable parts that the
正确更换可互换或可拆卸部件的说明
MANUFACTURER specifies as replaceable by SERVICE PERSONNEL; and
制造商规定可由维修人员更换; 以及
- where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARD and, if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.
如果更换部件可能导致不可接受的风险, 应提供适当的警告, 以识别危险的性质, 如果制造商指定部件可由维修人员更换, 则应提供安全更换部件所需的所有信息。

7.9.3.3 Circuit diagrams, component part lists, etc. **电路图、部件清单等。**

The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

技术说明应包含制造商应要求提供的电路图、部件清单、说明、校准说明的声明, 或其他有助于维修人员修理制造商指定由维修人员修理的医用电气设备部件的信息。

7.9.3.4 * Mains isolation ***电源隔离**

The technical description shall clearly identify any means used to comply with the requirements of 8.11.1.

技术说明应清楚地说明用于符合8.11.1要求的任何方法。

Compliance with the requirements of 7.9.3 is checked by inspection of the technical description.

通过检查技术说明来检查是否符合7.9.3的要求。

8 * Protection against electrical HAZARDS from ME EQUIPMENT ***医用电气设备的电气危害防护**

8.1 Fundamental rule of protection against electric shock **防触电基本原则**

The limits specified in 8.4 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION or SINGLE FAULT CONDITION. For other HAZARDOUS SITUATIONS in SINGLE FAULT CONDITION, see 13.1.
在正常或单一故障条件下, 可触及部件和应用部件不得超过8.4中规定的限值。对于单一故障条件下的其他危险情况, 见13.1。

a) * NORMAL CONDITION includes all of the following simultaneously:

*正常条件同时包括以下所有条件:

- the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS as specified in 7.9, or, if the ACCOMPANYING DOCUMENTS place no restrictions on such other electrical equipment, the presence of the MAXIMUM MAINS VOLTAGE as specified in 8.5.3;
任何信号输入/输出部分存在根据7.9中规定的随附文件允许连接的其他电气设备的任何电压或电流, 或者, 如果随附文件对此类其他电气设备没有限制, 存在8.5.3中规定的最大电源电压;
- transposition of supply connections, for ME EQUIPMENT intended for connection to a SUPPLY MAINS by means of a MAINS PLUG;
电源连接的转换, 对于打算通过电源插头连接到电源的医用电气设备;
- short circuit of any or all insulation that does not comply with the requirements of 8.8;
任何或所有不符合8.8要求的绝缘短路;
- short circuit of any or all CREEPAGE DISTANCES or AIR CLEARANCES that do not comply with the requirements of 8.9;
不符合8.9要求的任何或所有爬电距离或空气间隙短路;
- open circuit of any or all earth connections that do not comply with the requirements of 8.6, including any functional earth connection.
不符合8.6要求的任何或所有接地连接开路, 包括任何功能性接地连接。

b) * SINGLE FAULT CONDITION includes:

*单一故障条件包括:

- short circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8;
符合8.8中规定的一种保护方式要求的任何一种绝缘短路;

NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8.

注: 这包括符合8.8的双重绝缘的任何组成部分的短路。

- short circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9;
符合8.9中规定的一种保护方式要求的任何一个爬电距离或空气间隙短路；
- short circuit and open circuit of any component other than a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS that is connected in parallel with insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9);
任何部件的短路和开路，除了与绝缘平行连接的具有高完整性特性的部件，具有空气间隙或爬电距离，除非可以证明短路不是部件的故障模式（另见4.8和4.9）；
- open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is
符合8.6要求的任何一个保护接地导体或内部保护接地连接开路：这不适用于永久安装的医用电气设备的保护接地导体，即
considered unlikely to become disconnected;
被认为不太可能断开连接；
- interruption of any one supply conductor, except for the neutral conductor of polyphase
任何一条供电导线中断，多相中性导线除外
ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT;
医用电气设备或永久安装的医用电气设备；
- interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if the RISK ANALYSIS indicates that this condition might cause permitted limits to be exceeded;
如果风险分析表明这种情况可能导致超出允许的限值，则单独外壳内医用电气设备部件之间的任何一根载电导体中断；
- unintended movement of a component; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS (see also 8.10.1);
部件的意外移动；但前提是部件安装不牢固，以确保在医用电气设备的预期使用寿命内不太可能发生此类移动，如风险管理程序所确定（另见8.10.1）；
- accidental detachment of conductors and connectors where breaking free could lead to a
导线和连接器的意外脱离，如果断裂可能导致
HAZARDOUS SITUATION. See also 8.10.2.
危险情况。另见8.10.2。

Determination of which parts are ACCESSIBLE PARTS is performed in accordance
with 5.9. LEAKAGE CURRENTS are measured in accordance with 8.7.

根据第9.5条的规定，零件可接近。根据8.7测量泄漏电流。

8.2	Requirements 电源相关要求	related	to	power	sources
8.2.1	Connection 与独立电源的连接	to	a	separate power	source

If ME EQUIPMENT is specified for connection to a separate power source, other than the SUPPLY MAINS, either the separate power source shall be considered as part of the ME EQUIPMENT and all relevant requirements of this standard shall apply, or the combination shall be considered as an ME SYSTEM. See also 7.2.5, 7.9.2.14, 5.5 f) and Clause 16.
如果医用电气设备被指定连接到一个独立的电源，而不是供电干线，则单独的电源应被视为医用电气设

备的一部分，并且应适用本标准的所有相关要求，或者将该组合视为医用电气系统。另见7.2.5、7.9.2.14、5.5 f) 和第16条。

NOTE What was formerly referred to, in the first and second editions of this standard, as a “specified power supply” is now considered either as another part of the same ME EQUIPMENT or as another electrical equipment in an ME SYSTEM.
注：在本标准第一版和第二版中，以前称为“指定电源”的内容现在被视为同一医用电气设备的另一部分或医用电气系统中的另一电气设备。

Compliance is checked by inspection and by testing as specified in 5.5 f). If a particular separate power supply is specified then the relevant tests are performed with the ME EQUIPMENT connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected.
按照5.5 f) 的规定，通过检查和试验检查合规性。如果指定了特定的独立电源，则在连接到该电源的医用电气设备上进行相关测试。如果指定了通用独立电源，则应检查随附文件中的规范。

8.2.2 Connection to an external d.c. power source **与外部直流电源的连接**

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, no HAZARDOUS SITUATION, other than absence of its intended function, shall develop when a connection with the wrong polarity is made then a connection with the wrong polarity shall not lead to the HAZARDOUS SITUATIONS described in 13.1. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall provide freedom from unacceptable RISK maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.
如果医用电气设备指定由外部直流电源供电，则当连接到错误极性时，除了没有预期功能外，不会出现任何危险情况，那么错误极性的连接不应导致13.1中所述的危险情况。当随后以正确的极性进行连接时，医用电气设备应无不可接受的风险，保持基本安全和基本性能。

Protective devices that can be reset by anyone without the use of a TOOL are acceptable provided that these restore correct operation the ME EQUIPMENT returns to NORMAL CONDITION on reset.

任何人无需使用工具就能复位的保护装置是可以接受的，前提是这些装置能够恢复正常运行，医用电气设备在复位时恢复到正常状态。

NOTE 1 See also 11.8.

注1另见11.8。

NOTE 2 The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM as specified in 8.2.1.

注2：外部直流电源可以是供电干线或其他电气设备。在后一种情况下，组合被视为8.2.1中规定的ME系统。

Compliance is checked by inspection and, if necessary, by functional tests.
通过检查和功能测试（如有必要）检查合规性。

8.3 Classification of APPLIED PARTS 应用部件分类

- a) * An APPLIED PART that is specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be a TYPE CF APPLIED PART.
*随附文件中规定适用于直接心脏应用的应用部件应为CF型应用部件。

NOTE See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the APPLIED PARTS

注：关于应用部件，见直接心脏应用（3.22）定义的基本原理

that need to be TYPE CF APPLIED PARTS. Other restrictions can apply for cardiac applications.
需要是CF型应用部件。其他限制也适用于心脏应用。

Compliance is checked by inspection.
通过检查检查合规性。

- b) * An APPLIED PART that includes a PATIENT CONNECTION that is intended to deliver electrical energy or an electrophysiological signal to or from the PATIENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.
*包括用于向患者传输电能或电生理信号的患者连接的应用部件应为BF型应用部件或CF型应用部件。

Compliance is checked by inspection.
通过检查检查合规性。

- c) An APPLIED PART not covered by a) or b) shall be a TYPE B APPLIED PART, TYPE BF APPLIED PART or TYPE CF APPLIED PART.
a) 或 b) 未涵盖的应用部件应为b类应用部件、BF类应用部件或CF类应用部件。

Compliance is checked by inspection.
通过检查检查合规性。

- d) * For a part that is identified according to 4.6 as needing to be subject to the requirements for an APPLIED PART (except for marking), the requirements for a TYPE B APPLIED PART shall apply unless the RISK MANAGEMENT PROCESS identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.
*对于根据4.6确定需要遵守应用零件要求的零件（标记除外），除非风险管理流程确定需要应用BF型应用零件或CF型应用零件的要求，否则应适用B型应用零件的要求。

8.4 Limitation of voltage, current or energy 电压、电流或能量的限制

- 8.4.1 * PATIENT CONNECTIONS intended to deliver current
*用于传输电流的患者连接

The limits specified in 8.4.2 do not apply to currents that are intended to flow through the body of the PATIENT to produce a physiological effect during NORMAL USE.
8.4.2中规定的限值不适用于在正常使用期间通过患者身体产生生理效应的电流。

8.4.2 ACCESSIBLE PARTS including and APPLIED PARTS 可接近部件包括和应用部件

- a) The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits

for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT specified in Table 3 and Table 4 when measured as specified in 8.7.4. 当表4.8中规定的病人与辅助病人之间的电流连接电流不应超过表4.7中规定的电流。

Compliance is checked by measurement according to 8.7.4.
根据8.7.4通过测量检查合规性。

- b) * The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS other than PATIENT CONNECTIONS shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.
*当按照8.7.4中的规定进行测量时，可触及部件（患者连接除外）之间的泄漏电流不得超过8.7.3 c)中规定的接触电流限值。

Compliance is checked by measurement according to 8.7.4.
根据8.7.4通过测量检查合规性。

- c) * The limits specified in b) above do not apply to the following parts if the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE, and the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:
*如果在正常使用中，直接或通过操作者身体与患者连接的可能性可忽略不计，则上述b)中规定的限值不适用于以下部件：，使用说明书要求操作者不要同时触摸相关部位和病人：
- accessible contacts of connectors;
连接器的可接触触点；
 - contacts of fuseholders that are accessible during replacement of the fuse;
在更换熔断器时可以接触到的保险丝座触点；
 - contacts of lampholders that are accessible after removal of the lamp;
拆卸灯后可接触到的灯座触点；

- parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct any OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER.
无需使用工具即可打开的检修盖内的零件，或需要工具但使用说明指示除维修人员以外的任何操作员打开相关检修盖。

EXAMPLE 1 Illuminated push-

buttons EXAMPLE 2 Indicator

lamps

示例1发光按钮示例2指示灯

EXAMPLE 3 Recorder pens

EXAMPLE 4 Parts of plug-in

modules EXAMPLE 5 Batteries

例3记录笔示例4插件模块部件

例5 电池

For such parts, the voltage to earth or to other ACCESSIBLE PARTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION. The d.c.

对于此类部件，在正常条件下或单一故障条件下，接地或其他可触及部件的电压峰值不得超过**42.4V**交流电压或**60V**直流电压。华盛顿特区。

limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential up to 2 V of 2 V or more.
60 V的限值适用于峰值纹波不超过10%的直流电。如果纹波超过该值,则42.4 V峰值限制适用。在超过60 s的时间内,能量不得超过240 VA,或在电压高达2 V或2 V以上时,可用储存能量不得超过20 J。

NOTE If voltages higher than the limits specified in 8.4.2 c) are present, the LEAKAGE CURRENT limits referred to in 8.4.2 b) apply.

注：如果存在高于8.4.2 c) 中规定限值的电压，则适用8.4.2 b) 中所述的泄漏电流限值。

Compliance is checked by inspection of the RISK MANAGEMENT FILE, by reference to the instructions for use and by measurement.

通过检查风险管理文件、参考使用说明和测量来检查合规性。

- d) * The voltage and energy limits specified in c) above also apply to:

*上述c) 中规定的电压和能量限制也适用于:

- internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 inserted through an opening in an ENCLOSURE;
内部零件，插头、连接器和插座的触点除外，可通过图8所示的测试插针通过外壳中的开口进行接触；以及

– internal parts that can be touched by a metal test rod with a diameter of 4	□0,05 mm and 4
可被直径为4的金属测试棒接触的内部零件	嗯和

a length of 100	—	
长度为100	0,	mm, inserted through any opening in the top of an ENCLOSURE or
	5	mm, 通过外壳顶部的任何开口插入, 或
□ 0,5	0	
	0	

through any opening provided for the adjustment of pre-set controls that may can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL.
通过为调整预设控制提供的任何开口, 责任组织在正常使用时可以使用工具进行调整。

See also 8.9.4 concerning the measurement of CREEPAGE DISTANCES and AIR CLEARANCES

关于爬电距离和空气间隙的测量, 参见8.9.4

through slots or openings in external parts to the standard test finger.

通过外部零件上的槽或开口到标准测试指。

Compliance is checked by inserting the test pin or the test rod through relevant openings. The test pin is inserted in every possible position with minimal force (not more than 1 N).

通过将测试销或测试杆插入相关开口来检查合规性。用最小力(不超过1N)将测试销插入每个可能的位置。

The test rod is inserted in every possible position through openings provided for the adjustment of pre-set controls that can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE, in case of doubt with a force of 10 N. 将测试杆插入每个可能的位置, 通过为调整预设控制而提供的开口, 在正常使用中, 如果有疑问, 可以用10 N的力进行调整。

If the instructions for use specify that a particular TOOL is to be used, the test is repeated with that TOOL.

如果使用说明规定要使用特定工具, 则应使用该工具重复测试。

The test rod is also freely and vertically suspended through any opening in the top of an ENCLOSURE.

测试杆也可以通过顶部的任何开口自由垂直悬挂

圈地。

Dimensions in millimetres
尺寸单位为毫米

Electric al connect ion 电气连 接	20	S t e e l 钢
	4	
	20 4年	
	0	
	0	
Insulati ng materi al 绝缘材 料	-0,1	I E C 2 3 9 1 / 0 5 I E C 2 3 9 1 / 0 5 标 准
	-0,1	

Figure 8 – Test pin
图8-测试销
(see 8.4.2 d))
(见8.4.2 d)

e) Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened, the device(s) used to de- energize the parts shall meet the requirements specified in 8.11.1

for mains isolating switches and shall remain effective in SINGLE FAULT CONDITION. If it is possible to prevent these devices from operating, a TOOL shall be required. 如果无需使用工具即可打开的检修盖可接近电压高于本子条款允许水平的部件，但当检修盖打开时，这些部件会自动断电，用于断开部件电源的装置应满足8.11.1中电源隔离开关的要求，并应在单一故障条件下保持有效。如果有可能阻止这些装置工作，则应使用工具。

Compliance is checked by inspection.
通过检查检查合规性。

8.4.3 * ME EQUIPMENT intended to be connected to a power source by a plug

*医用电气设备通过插头与电源相连

ME EQUIPMENT or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V or, if this value is exceeded, the stored charge does not exceed 45 μ C. 拟通过插头连接至电源的医用电气设备或其部件的设计应确保在断开插头1s后，插头针脚之间以及电源针脚和外壳之间的电压不超过60 V，或者，如果超过该值，则存储的电荷不超过45 μ C。

Compliance is checked by the following test:
通过以下试验检查合规性：

ME EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range. 医用电气设备在额定电压或额定电压范围的上限下运行。

ME EQUIPMENT is disconnected from the power source with any relevant switch in the “On” and “Off” positions. 当任何相关开关处于“开”和“关”位置时，医用电气设备与电源断开。

Either the ME EQUIPMENT is disconnected from the power source by means of the plug, in which case the test is performed as many times as necessary to allow the worst case to be measured, or a triggering circuit is used to ensure that disconnection occurs at the peak of the supply voltage waveform. 通过插头将医用电气设备与电源断开，在这种情况下，应尽可能多次进行试验，以测量最坏情况，或者使用触发电路确保在电源电压波形的峰值处断开。

The voltage between the pins of the plug and between any pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test significantly. 在与仪器断开1s后，测量插头针脚之间以及任何针脚与外壳之间的电压，仪器的内部阻抗不会对测试产生显著影响。

NOTE An example of a measuring arrangement that is considered acceptable is an oscilloscope and probe having an input impedance consisting of a resistance of 100 M Ω $\square$ 5 M Ω in parallel with an input capacitance of 20 pF $\square$ 5 pF. 注：可接受的测量装置示例为输入阻抗为100 M Ω $\square$ 5 M Ω ，输入电容为20 pF $\square$ 5 pF的示波器和探头。

The stored charge can be measured or calculated by any convenient method. 储存电荷可以用任何方便的方法测量或计算。

Where appropriate, a d.c. input voltage equal to the peak of the RATED SUPPLY MAINS voltage may be used. 在适当的情况下，可使用与额定电源电压峰值相等的直流输入电压。

8.4.4 * Internal capacitive circuits
*内部电容电路

Conductive parts of capacitive circuits that become accessible after ME EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a stored charge exceeding 45 □C.
在医用电气设备断电后，电容性电路的导电部分（如正常使用中的检修盖已立即拆除）不得有超过60 V的残余电压，或者，如果超过该值，则其储存的电荷不得超过45°C。

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device that is included and which permits manual discharging is acceptable. The capacitor(s) or the connected circuitry shall then be marked with symbol IEC 60417-5036 (DB:2002-10) (see Table D.1, symbol 24) and the non-automatic discharging device shall be specified in the technical description.
如果无法合理地自动卸料，并且只能借助工具拆下检修盖，则可以使用包含且允许手动卸料的装置。电容器或连接电路应标有IEC 60417-5036（DB:2002-10）（见表D.1，符号24），非自动放电装置应在技术说明中说明。

Compliance is checked by the following test:
通过以下试验检查合规性：

ME EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts is measured and the stored charge calculated.
医用电气设备在额定电压下运行，然后断电。在正常使用中出现的任何检修盖应尽快拆除。紧接着，测量任何可触及电容器或电路部件上的残余电压，并计算储存的电荷。

If a non-automatic discharging device is specified in the technical description, its inclusion and marking are ascertained by inspection.
技术说明书中规定了非自动卸料装置的，其内含物和标识均通过检验确定。

8.5 Separation of parts
零件分离

8.5.1 * MEANS OF PROTECTION (MOP)
*保护手段（MOP）

8.5.1.1 General
总则

ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the limits specified in 8.4.
医用电气设备应具有两种保护方法，以防止应用部件和其他可触及部件不超过8.4中规定的限值。

Each MEANS OF PROTECTION shall be categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking account of 4.6. See also Figure A.12.
每种保护手段应归类为病人保护手段或操作员保护方法，考虑4.6。另请参见图A.12。

Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that can replasticeze at temperatures to be expected during operation (including sterilization), shall not be regarded as a MEANS OF PROTECTION.
上漆、上漆、氧化和类似的保护性饰面，以及在操作（包括灭菌）期间预期温度下能够重新塑化的密封剂覆盖，不得视为保护手段。

NOTE Coatings and other insulation that are intended as a MEANS OF PROTECTION and that comply with IEC 60950-1:20012005 are acceptable may be used as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF

PATIENT PROTECTION. For MEANS OF PATIENT PROTECTION, considerations can arise as a result of the RISK MANAGEMENT PROCESS.
注：作为保护手段且符合IEC 60950-1:20012005的涂层和其他绝缘材料可作为操作员保护的手段使用，但不能自动用作患者保护的手段。作为一种风险管理方法的结果，可能会出现对患者的保护措施。

Components and wiring forming a MEANS OF PROTECTION shall comply with the relevant requirements of 8.10.
构成保护装置的部件和接线应符合8.10的相关要求。

Any insulation, CREEPAGE DISTANCE, AIR CLEARANCES, component or earth connection that does not comply with the requirements of 8.5.1.2 and 8.5.1.3 shall not be considered as a MEANS OF PROTECTION. Failure of any or all such parts shall be regarded as NORMAL CONDITION.
任何不符合8.5.1.2和8.5.1.3要求的绝缘、爬电距离、空气间隙、部件或接地连接不得视为保护手段。任何或所有此类部件的故障应视为正常状态。

Compliance is checked by the test in 8.5.1.3.
通过8.5.1.3中的试验检查符合性。

8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP) ***病人保护方法（MOPP）**

Solid insulation forming a MEANS OF PATIENT PROTECTION shall comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6.
构成病人保护手段的固体绝缘应符合8.8中在表6规定的试验电压下进行的介电强度试验。

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF PATIENT PROTECTION shall comply with the limits specified in Table 12.
构成病人保护手段的爬电距离和空气间隙应符合表12中规定的限值。

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION shall comply with the requirements and tests of 8.6.
构成病人保护手段的保护接地连接应符合8.6的要求和试验。

A Y1 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION provided that it will pass the dielectric strength test for two MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance.

符合IEC 60384-14标准的Y1电容器被视为等同于一种病人保护手段，前提是它将通过两种病人保护方式的介电强度试验。如果两个电容器串联使用，则每个电容器的额定值应为通过对的总工作电压，并且应具有相同的标称电容。

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF PATIENT PROTECTION). 符合IEC 60384-14的Y电容器（仅限于Y1或Y2）被视为等同于一种保护患者的方法。当两个电容器串联使用时，它们的类型应相同（Y1或Y2都是），并且具有相同的标称电容。电容器应满足所用保护类型的介电强度（即一种或两种患者保护方式）。

Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION. 当穿过形成病人保护装置的屏障的工作电压小于42.4V交流峰值或60V直流电时，一个Y1电容器可用于两种病人保护装置。

Compliance is checked by the test in 8.5.1.3. 通过8.5.1.3中的试验检查符合性。

8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP) 操作员保护方法（MOOP）

Solid insulation forming a MEANS OF OPERATOR PROTECTION shall:
构成操作员保护手段的固体绝缘应：

- comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6; or
在表6规定的试验电压下，符合8.8规定的介电强度试验；或
- comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.
符合IEC 60950-1的绝缘配合要求。

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF OPERATOR PROTECTION shall:
构成操作员保护手段的爬电距离和空气间隙应：

- comply with the limits specified in Table 13 to Table 16 (inclusive); or
符合表13至表16（含）中规定的限值；或
- comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.
符合IEC 60950-1的绝缘配合要求。

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either:
构成操作员保护手段的保护接地连接应：

- comply with the requirements of 8.6; or
符合8.6的要求；或
- comply with the requirements and tests of IEC 60950-1 for protective earthing.
符合IEC 60950-1保护接地的要求和试验。

A Y2 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF

OPERATOR PROTECTION provided that it will pass the dielectric strength test for one MEANS OF OPERATOR PROTECTION. A Y1 capacitor complying with IEC 60384-14 is considered equivalent to two MEANS OF OPERATOR PROTECTION provided that it will pass the dielectric strength test for two MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance. 符合IEC 60384-14的Y2电容器被视为等同于一种操作员保护装置，前提是它将通过一种操作员保护装置的介电强度试验。符合IEC 60384-14标准的Y1电容器被视为等同于两种操作员保护方式，前提是它将通过两种操作员保护方式的介电强度试验。如果两个电容器串联使用，则每个电容器的额定值应为通过对的总工作电压，并且应具有相同的标称电容。

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF OPERATOR PROTECTION). A Y1 capacitor can be used for two MEANS OF OPERATOR PROTECTION. 符合IEC 60384-14的Y电容器（仅限于Y1或Y2）被视为等同于一种操作员保护方法。当两个电容器串联使用时，它们的类型应相同（Y1或Y2都是），并且具有相同的标称电容。电容器应满足所用保护类型的介电强度（即一种或两种操作员保护方式）。Y1电容器可用于两种操作员保护方式。

Compliance with 8.5.1.1 to 8.5.1.3 (inclusive) is checked by examination of the physical and electrical configuration of the ME EQUIPMENT to identify points at which insulation, CREEPAGE DISTANCES, AIR CLEARANCES, impedances of components or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS or APPLIED PARTS from exceeding the limits specified in 8.4. 通过检查医用电气设备的物理和电气配置，检查是否符合8.5.1.1至8.5.1.3（包括8.5.1.3）的要求，以确定绝缘、爬电距离、空气间隙、部件阻抗或保护接地连接的阻抗，以防止可触及部件或应用部件超过规定限值在8.4中。

NOTE Such points typically include insulation between parts different from earth potential and ACCESSIBLE PARTS or APPLIED PARTS but can also include, for example, insulation between a floating circuit and earth or other circuits. A survey of insulation paths is found in Annex J. 注：此类点通常包括不同于接地电位的部件之间的绝缘以及可触及的部件或应用部件，但也可以包括浮动电路和接地或其他电路之间的绝缘。绝缘路径调查见附录J。

For each such point, it is determined whether:
对于每个这样的点，确定是否：

- solid insulation complies with the dielectric strength test according to 8.8 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;
固体绝缘符合第8.8节规定的介电强度试验，或者，对于操作人员的保护，符合IEC 60950-1关于绝缘配合的要求；
- CREEPAGE DISTANCES and AIR CLEARANCES are as specified in 8.9 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;
爬电距离和空气间隙如第8.9节所述，或作为操作员保护的一种方式，符合IEC 60950-1绝缘配合的要求；
- components that are connected in parallel with an insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE comply with 4.8 and 8.10.1;
与绝缘平行连接的部件，具有空气间隙或爬电距离符合4.8和8.10.1的要求；
- PROTECTIVE EARTH CONNECTIONS comply with the requirements of 8.6 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for protective earthing;
保护接地连接应符合8.6的要求，或对于操作员保护的方式，应符合IEC 60950-1的保护接地要求；

and hence whether a failure at that point is to be regarded as a NORMAL CONDITION or as a SINGLE FAULT CONDITION.
因此，在这一点上的故障是被视为正常状态还是单一故障状态。

Each MEANS OF PROTECTION is categorized in relation to the ME EQUIPMENT part(s) which it protects from exceeding permitted limits. It is a MEANS OF PATIENT PROTECTION if it protects APPLIED PARTS or parts that are identified according to 4.6 as needing to be subject to the same requirements as APPLIED PARTS. Otherwise it is a MEANS OF OPERATOR PROTECTION.
根据医用电气设备部件，对每种保护方式进行分类，以防止超出允许限值。如果它保护应用部件或根据4.6确定需要与应用部件遵循相同要求的部件，则这是一种保护患者的方法。否则，这是一种保护操作员的方法。

The WORKING VOLTAGE is determined by inspection, calculation or measurement, according to 8.5.4.
根据8.5.4，通过检查、计算或测量确定工作电压。

The voltage, current or energy that can appear between any ACCESSIBLE PART or APPLIED PART and any other ACCESSIBLE PART, APPLIED PART or earth in NORMAL CONDITION and in SINGLE FAULT CONDITION is determined by inspection or calculation or, where necessary, by measurement in the relevant conditions.
在正常条件下和单一故障条件下，任何可触及部分或应用部分与任何其他可触及部分、应用部分或接地之间可能出现的电压、电流或能量，通过检查或计算或在必要时通过在相关条件下的测量来确定。

8.5.2 Separation of PATIENT CONNECTIONS 患者联系分离

8.5.2.1 * F-TYPE APPLIED PARTS *F-TYPE应用部件

The PATIENT CONNECTION(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means

equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE
任何F-TYPE应用部分的患者连接应与所有其他部分分开，包括其他应用部分的患者连接，其方式相当于工作电压等于最大电源电压的一种患者保护装置

and shall comply with the specified limit for PATIENT LEAKAGE CURRENT with 110 % of the
并应符合规定的患者泄漏电流限值
MAXIMUM MAINS VOLTAGE applied.
施加的最大电源电压。

A single F-TYPE APPLIED PART may include multiple functions, in which case separation between such functions is not required.
单个F-TYPE应用部件可包括多个功能，在这种情况下，这些功能之间不需要分离。

If there is no electrical separation between PATIENT CONNECTION(S) of the same or another function (e.g. between ECG electrode and pressure catheter), then these PATIENT CONNECTION(S) are treated as one APPLIED PART.
如果相同或其他功能的患者连接之间没有电分离（例如，心电图电极和压力导管之间），则这些患者连接被视为一个应用部分。

Whether multiple functions are to be considered as all within one APPLIED PART or as multiple
多个功能是在一个应用部分中被视为全部功能还是多个功能
APPLIED PARTS is as defined by the MANUFACTURER.
应用部件由制造商定义。

The classification as TYPE BF, TYPE CF or DEFIBRILLATION-PROOF applies to the whole of one
BF型、CF型或防除颤型的分类适用于其中的全部
APPLIED PART.
应用部分。

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3 and by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES.
通过检查、8.7.4中的泄漏电流试验、8.8.3中的介电强度试验以及相关爬电距离和空气间隙的测量来检查是否符合要求。

NOTE The separation means between an F-TYPE APPLIED PART and other parts are subject both to these tests, related to the MAXIMUM MAINS VOLTAGE, and to tests related to the voltages present within the respective circuits as specified in 8.5.4. Depending on the magnitude of the latter voltages, one set of tests or the other could be more stringent.
注：F-TYPE应用部件与其他部件之间的分离装置应进行与最大电源电压相关的试验，以及与8.5.4中规定的各电路内电压相关的试验。根据后一种电压的大小，一套或另一套可能更严格。

Any protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.
任何连接在F-TYPE应用部件的患者连接和外壳之间的保护装置，用于提供过电压保护，不得低于500 V r.m.s。

Compliance is checked by testing the operating voltage of the protective device.
通过测试保护装置的工作电压来检查合规性。

8.5.2.2 * TYPE B APPLIED PARTS

*B型应用部件

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall

未进行保护接地的B型应用部件的患者连接应

be separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS that are not

用一种保护患者的方法将其与不可触及的金属部件分开

PROTECTIVELY EARTHED, unless:

保护接地，除非：

- the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and
所述金属可触及部分与所述应用部分物理上相邻，并且可被视为所述应用部分的一部分；以及
- the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or
金属可触及部分接触电压源或
LEAKAGE CURRENT above permitted limits is acceptably low.
超出允许限值的泄漏电流低得可以接受。

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES, and by reference to the RISK MANAGEMENT FILE.
通过检查、8.7.4中的泄漏电流测试、8.8.3中的介电强度测试、相关爬电距离和空气间隙的测量以及参考风险管理文件来检查合规性。

8.5.2.3 * PATIENT leads or PATIENT cables

*病人导线或病人电缆

Any connector for electrical connections on a PATIENT lead that:

患者导线上用于电气连接的任何连接器：

- is at the end of the lead or cable that is remote from the PATIENT; and
位于远离患者的导线或电缆末端；以及
- contains a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE.
包含一个导电部分，该导电部分不通过一种保护患者的方式与所有患者连接分离，工作电压等于最大电源电压。

shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTION(S) contact the PATIENT.

其构造应确保当患者连接与患者接触时，所述部件不会接地或可能的危险电压。

NOTE Where the phrase “said part” is mentioned in this subclause, it refers to the “...conductive part of the connector that is not separated from all PATIENT CONNECTIONS...” from the first sentence of this subclause.

注：本款中所述的“所述部件”指的是本款第一句中的“.....连接器的导电部分，未与所有患者连接分开.....”。

In particular:

特别地：

- the said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter;
所述部件不得与直径不小于100mm的扁平导电板接触；
- the AIR CLEARANCE between connector pins and a flat surface shall be at least 0,5 mm;
连接器插脚和平面之间的空气间隙应至少为0.5 mm；

- if able to be plugged into a mains socket, the said part shall be protected from making contact with parts at MAINS VOLTAGE by insulating means providing a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of 1 500 V and complying with 8.8.4.1;
如果能够插入电源插座，则应通过提供至少1.0 mm的爬电距离和1500 V的介电强度，并符合第8.8.4.1条的绝缘方式，保护所述部件不与电源电压下的部件接触；
- the straight unjointed test finger with the same dimensions as the standard test finger of Figure 6 shall not make electrical contact with the said part if applied in the least favourable position against the access openings with a force of 10 N, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with objects other than a mains socket or a flat surface (e.g. corners or edges).
与图6中的标准测试指尺寸相同的直的未连接测试指，如果以10 N的力施加在最不利的位置上，则不得与所述部件发生电接触，除非风险管理过程证明接触不存在不可接受的风险电源插座或平面以外的物体（例如角落或边缘）。

Compliance is checked by inspection and test as required.

按要求通过检验和试验检查是否符合要求。

8.5.3 * MAXIMUM MAINS VOLTAGE

*最大电源电压

The MAXIMUM MAINS VOLTAGE shall be determined as follows:

最大电源电压应确定如下：

- for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, including INTERNALLY POWERED ME EQUIPMENT that also has a means of connection to a SUPPLY MAINS, the MAXIMUM MAINS VOLTAGE is the highest RATED supply voltage; unless this is less than 100 V, in which case the MAXIMUM MAINS VOLTAGE is 250 V;
对于单相或直流电源供电的医用电气设备，包括内部供电的医用电气设备（也有连接电源的方式），最大电源电压为最高额定电源电压；除非低于100伏，在这种情况下，最大电源电压为250伏；
- for polyphase ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is the highest RATED phase to neutral supply voltage;
对于多相医用电气设备，最大电源电压为最高额定相对中性点供电电压；
- for other INTERNALLY POWERED ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is 250 V.
对于其他内部供电的医用电气设备，最大电源电压为250伏。

8.5.4 * WORKING VOLTAGE

*工作电压

The WORKING VOLTAGE for each MEANS OF PROTECTION shall be determined as follows:

每种保护装置的工作电压应确定如下：

- The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value.
医用电气设备的输入电源电压应为额定电压或额定电压范围内产生最高测量值的电压。

- For d.c. voltages with superimposed ripple, the WORKING VOLTAGE is the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value.
对于具有叠加纹波的直流电压，如果峰间纹波不超过平均值的10%，则工作电压为平均值；如果峰间纹波超过平均值的10%，则为峰值电压。
- The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected.
形成双重绝缘的每种保护装置的工作电压是双重绝缘作为一个整体所承受的电压。
- For WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.
对于涉及病人连接未接地的的工作电压，病人接地（有意或无意）的情况被视为正常情况。
- The WORKING VOLTAGE between the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART and F-TYPE应用部件的患者连接与 the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. See also 8.5.2.1.
外壳被视为正常使用时绝缘层上出现的最高电压，包括应用部件任何部分的接地。另见 8.5.2.1。
- For DEFIBRILLATION-PROOF APPLIED PARTS, the WORKING VOLTAGE is determined without regard to the possible presence of defibrillation voltages. See also 8.5.5 and 8.9.1.15.
对于防除颤应用部件，确定工作电压时不考虑可能存在的除颤电压。另见8.5.5和8.9.1.15。
- In the case of motors provided with capacitors where a resonance voltage can occur between the point where a winding and a capacitor are connected together on the one hand and any terminal for external conductors on the other hand, the WORKING VOLTAGE shall be equal to the resonance voltage.
如果电容器的一个绕组和另一个电容器的工作点之间的电压相等，则电容器的一个工作点和另一个电容器之间的电压应相等。

8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS 防除颤应用部件

8.5.5.1 * Defibrillation protection *除颤保护

The classification DEFIBRILLATION-PROOF APPLIED PART shall apply to the whole of one APPLIED PART.

防除颤应用部分的分类应适用于一个应用部分的整体。

NOTE 1 This requirement does not apply to separate functions of the same APPLIED PART but the possibility of an

注1：本要求不适用于同一应用部件的单独功能，但是

OPERATOR receiving a shock from such parts should be considered in the RISK MANAGEMENT PROCESS.

在风险管理过程中，应考虑受到此类部件冲击的操作员。

See 8.9.1.15 for the requirements for CREEPAGE DISTANCES and AIR CLEARANCES associated with a DEFIBRILLATION-PROOF APPLIED PART.

有关防除颤应用部件的爬电距离和空气间隙要求，见8.9.1.15。

Arrangements used to isolate the PATIENT CONNECTION(S) of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT shall be so designed that:
用于将除颤应用部件与医用电气设备其他部件隔离的装置应设计为：

a) During a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION- PROOF APPLIED PART, hazardous electrical energies, as determined by the peak voltage measured between the points Y1 and Y2 of Figure 9 and Figure 10 exceeding 1 V, do not appear on:
在心脏除颤器向连接到防除颤应用部件的患者放电期间，由图9和图10的Y1和Y2点之间测得的超过1v的峰值电压确定的危险电能不会出现在：

- the ENCLOSURE, including connectors in PATIENT leads and cables when connected to the ME EQUIPMENT;
外壳，包括连接到医用电气设备时患者引线和电缆中的连接器；

NOTE 2 1 This requirement does not apply to a connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it is disconnected from the ME EQUIPMENT.

注2 1：当从医用电气设备上断开时，本要求不适用于来自除颤应用部件或其连接器的连接导线。

- any SIGNAL INPUT/OUTPUT PART;
任何信号输入/输出部分；
- metal foil for test on which the ME EQUIPMENT is placed and which has an area at least equal to the base of the ME EQUIPMENT; or
放置医用电气设备的试验用金属箔，其面积至少等于医用电气设备的底座；或
- PATIENT CONNECTIONS of any other APPLIED PART (whether or not classified as a 任何其他应用部分的患者连接（无论是否归类为 DEFIBRILLATION-PROOF APPLIED PART); or 防除颤应用部件）；或
- any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.
受试应用部件的任何未使用或断开连接或同一应用部件的任何功能。完全穿戴的医用电气设备（如Holter监视器）不受此要求的约束。

b) Following exposure to the defibrillation voltage, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

在暴露于除颤电压后，以及随附文件中规定的任何必要恢复时间后，医用电气设备应符合本标准的相关要求，并应继续提供基本安全和基本性能。

Compliance is checked by the following tests, for each DEFIBRILLATION-PROOF APPLIED PART in turn.

通过以下试验，依次检查每个防除颤应用部件的合规性。

- **Common-mode test**

- 共模试验**

The ME EQUIPMENT is connected to the test circuit as shown in Figure 9. The test voltage is applied to all the PATIENT CONNECTIONS of the DEFIBRILLATION-PROOF APPLIED PART connected together, excluding any that are PROTECTIVELY EARTHED or functionally earthed. If an APPLIED PART has multiple functions, the test voltage is applied to all the PATIENT CONNECTIONS of one function at a time with the other functions disconnected. 医用电气设备连接至测试电路，如图9所示。测试电压应用于连接在一起的除颤应用部分的所有患者连接，不包括任何保护性接地或功能性接地。如果一个应用部件具有多个功能，则在断开其他功能的情况下，一次对一个功能的所有患者连接施加测试电压。

spl
ay
evic
e
八
字
形
装
置

n > 1 M□
n>1米□

IEC 1404/12

IEC 1404/12标准

For legends, see Table 5.
图例见表5。

Components
组件

VT Test voltage
VT试验电压

S Switch for applying
the test voltage
施加试验电压的S开
关

R1, R2 Tolerance at ± 2 %,
not less than 2 kV
R1, R2公差为±2%，不小
于2kV

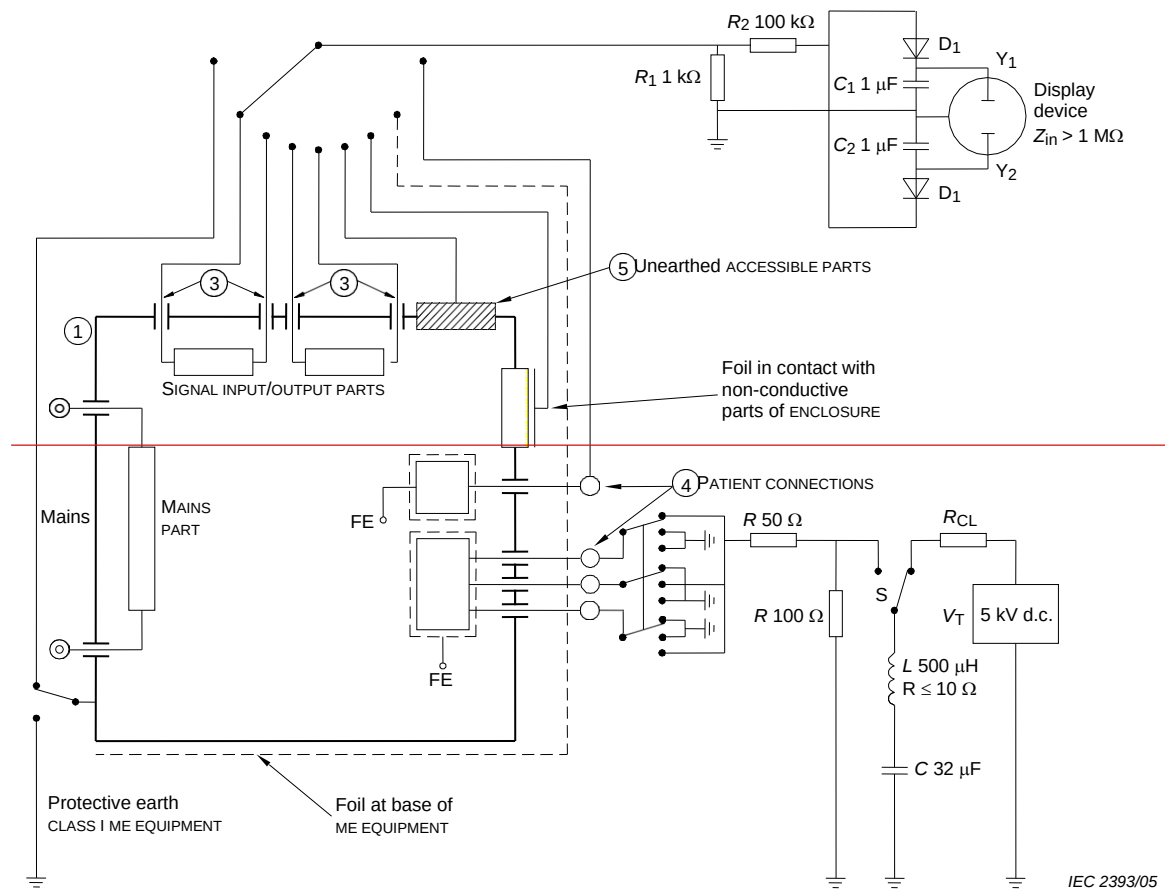
RCL Current limiting
resistor D1, D2 Small signal

silicon diodes

限流电阻D1，D2小信号硅二
极管

Other components toleranced at $\pm 5\%$
其他部件公差为 $\pm 5\%$

Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS
图9-测试电压对桥接患者连接的应用
for DEFIBRILLATION-PROOF APPLIED PARTS
用于防除颤应用部件
(see 8.5.5.1)
(见8.5.5.1)



R2 100
R1 1 k□
R1 1 k□
R2 100 k□
C1 1 □F
C1 1 华氏度
C2 1 □F
C2 1 华氏度
D1 Y1
D1和Y1
Display device
显示设备
Zin > 1 M□
锌>1 M□
Y2
Y2年
D1
D1

5 Unearthed ACCESSIBLE PARTS
5出土可触及部分

3 3
3 3个

1
1

SIGNAL
INPUT/OUTPUT
PARTS
信号输入/输出部
件

Foil in contact with
non-conductive parts
of ENCLOSURE
与外壳非导电部件接
触的箔材

4 PATIENT CONNECTION of another APPLIED
PART

4另一应用部位的病人连接

PATIENT CONNECTION of another function
其他功能的患者连接
4 of the same APPLIED PART
同一应用部件的4个

Mains
NS
主电源
PART
零件

MAI

FE
铁

R 50
□
R 50□
of the same
同样的
APPLIED PART
应用部分

R
100 □
R 100□

Foil at base of
底部箔材
ME
EQUIPMENT
医用电气设备

Protective
earth
保护接地
CLASS I ME
EQUIPMENT
一类医用电气
设备

FE
铁

4
4
All
PATIEN
T
CONNE
CTIONS
所有患
者关系
of one function
一个函数的

	S	压。	R□10□
RCL	VT 5	L 500 □H	C 32 □F
RCL公司	kV d.c.	长500μH	摄氏32度
	5千伏	R □ 10 □	
	直流电		
S			
			IEC 1405/12
			IEC 1405/12标准

For legends, see Table 5.
图例见表5。

Components
组件

VT Test voltage
VT试验电压

S Switch for applying
the test voltage
施加试验电压的S开
关

R1, R2 Tolerance at $\pm 2\%$,
not less than 2 kV
R1, R2公差为 $\pm 2\%$, 不小
于2kV

RCL Current limiting
resistor D1, D2 Small signal
silicon diodes
限流电阻D1, D2小信号硅二
极管

Other components toleranced at $\pm 5\%$
其他部件公差为 $\pm 5\%$

Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS
for

图10-将测试电压应用于
DEFIBRILLATION-PROOF APPLIED PARTS
防除颤应用部件
(see 8.5.5.1)
(见8.5.5.1)

• **Differential-mode test**
差模试验

The ME EQUIPMENT is connected to the test circuit as shown in Figure 10. The test voltage is applied to each PATIENT CONNECTION of the DEFIBRILLATION-PROOF APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART being connected to earth.
医用电气设备连接至测试电路，如图10所示。测试电压依次施加在防除颤应用部件的每个患者连接上，同一除颤应用部件的所有剩余患者连接均接地。

NOTE 2 The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

注2：当应用部分由单个患者连接组成时，不使用差模试验。

During the above tests:
在上述试验期间：

– except for PERMANENTLY INSTALLED ME EQUIPMENT, the ME EQUIPMENT is to

be tested with and without the PROTECTIVE EARTH CONDUCTOR connected (i.e. two separate tests);

除永久性安装的医用电气设备外，医用电气设备应在有或无保护接地导体连接的情况下进行测试（即两个单独的测试）；

- insulating surfaces of APPLIED PARTS are covered with metal foil or, where appropriate, immersed in a 0.9 % saline solution;
–应用部件的绝缘表面覆盖金属箔，或在适当的情况下，浸入0.9%盐水中；
- any external connection to a FUNCTIONAL EARTH TERMINAL is removed;
移除与功能性接地端子的任何外部连接；

- parts specified 8.5.5.1 a) that are not PROTECTIVELY EARTHED are connected in turn to a display device;
8.5.5.1 a) 中规定的未进行保护接地的部件依次连接至显示装置;
- the ME EQUIPMENT is connected to the SUPPLY MAINS and operated in accordance with the instructions for use.
– 医用电气设备连接至电源, 并按照使用说明进行操作。

After the operation of S, the peak voltage between the points Y1 and Y2 is measured. Each test is repeated with VT reversed.

运行S后, 测量Y1点和Y2点之间的峰值电压。每次试验重复进行, VT颠倒。

After any recovery time stated in the ACCOMPANYING DOCUMENTS, determine that the ME EQUIPMENT continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.
在随附文件中规定的任何恢复时间后, 确定
医用电气设备继续提供基本安全和基本性能。

8.5.5.2 Energy reduction test 能量降低试验

DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF
防患者除颤连接或除颤部分

APPLIED PARTS shall incorporate a means so that the defibrillator energy delivered to a 100 □
应用部件应包括一种方法, 以便将除颤器能量传输至100□
load is at least 90 % of the energy delivered to this load with the ME EQUIPMENT disconnected.
在医用电气设备断开的情况下, 负荷至少为该负荷的90%。

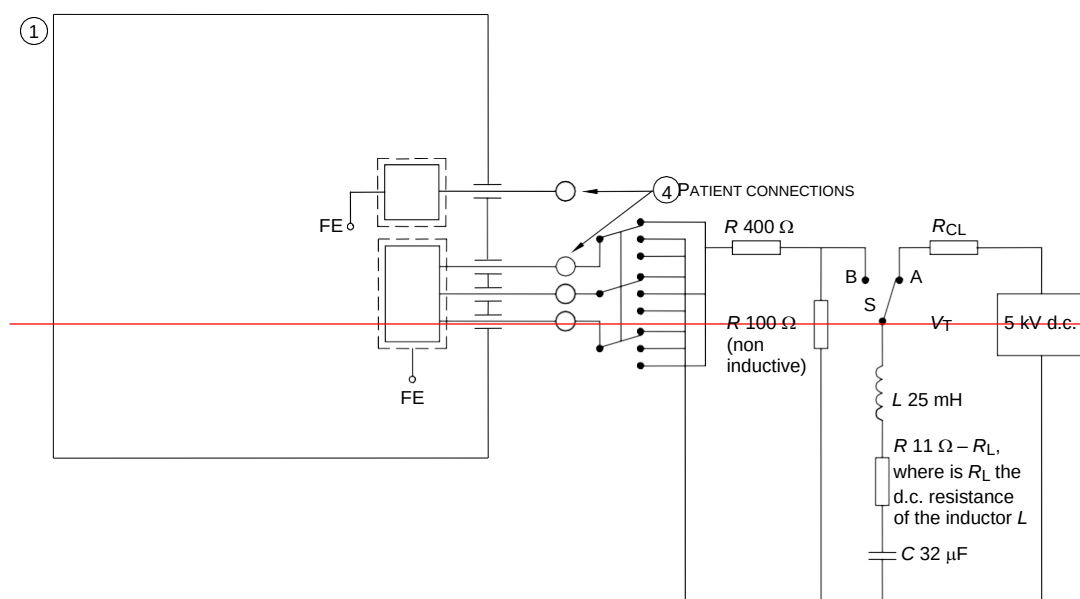
Compliance is checked by the following test:
通过以下试验检查合规性:

The test circuit is shown in Figure 11. For this test, the ACCESSORIES such as cables, electrodes and transducers that are recommended in the instructions for use (see 7.9.2.14) are used. The test voltage is applied to each PATIENT CONNECTION or APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same APPLIED PART being connected to earth (differential mode). Other DEFIBRILLATION PROOF APPLIED PARTS, if any, are tested separately, in turn.
测试电路如图11所示。对于本试验, 使用使用说明书(见7.9.2.14)中推荐的附件, 如电缆、电极和传感器。测试电压依次施加到每个患者连接或应用部分, 同一应用部分的所有剩余患者连接均接地(差模)。其他防除颤应用部件(如有)依次单独测试。

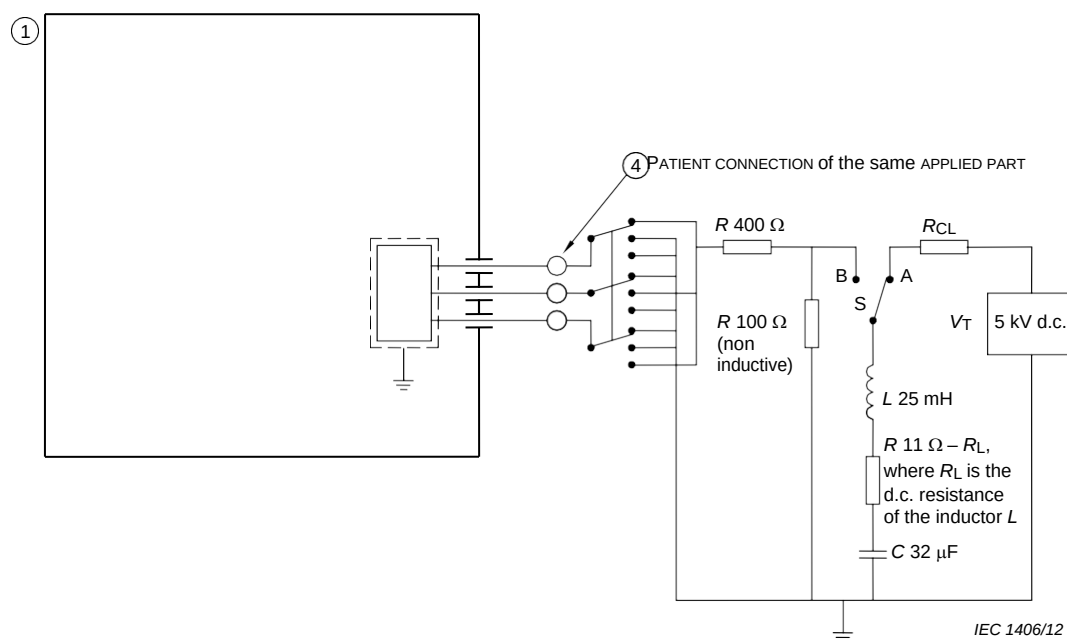
The PROCEDURE is as follows.
程序如下。

- a) Connect the APPLIED PART or PATIENT CONNECTION to the test circuit. The parts described in 8.5.5.1 a) are connected to earth.
将应用部件或患者连接件连接到测试电路。中描述的部件
8.5.5.1 a) 接地。
- b) Charge capacitor C to 5 kV d.c. with switch S in position A.
将电容器C充电至5 kV直流, 开关S位于位置A。
- c) Discharge capacitor C by actuating the switch S to position B, and measure the energy E1 delivered to the 100 □ load.
将开关S拨到位置B, 对电容器C放电, 测量能量E1
输送至100□负载。
- d) Remove the ME EQUIPMENT under test from the test circuit and repeat steps b) and c) above, measuring the energy E2 delivered to the 100 □ load.
从测试电路中移除被测医用电气设备, 并重复上述步骤b)和c), 测量传送到100□负载的能量E2。

- e) Verify that the energy E_1 is at least 90 % of E_2 .
确认能量 E_1 至少为 E_2 的90%。
- f) Repeat the test with VT reversed.
在VT反转的情况下重复测试。



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For legends, see Table 5.

图例见表5。

Components

组件

S Switch for applying the test energy A, B Switch positions

S开关，用于施加试验能量A、B开关位置

RCL Current limiting resistor Components toleranced at $\pm 5\%$

RCL限流电阻元件公差为 $\pm 5\%$

(见8.5.5.2)

ME
EQUIPMEN
T
医用电气设
备

The requirements of 8.6.2 to 8.6.8 (inclusive) apply unless the parts concerned comply with the requirements and tests of IEC 60950-1 for protective earthing and serve as MEANS OF OPERATOR PROTECTION but not as MEANS OF PATIENT PROTECTION. 8.6.2至8.6.8（含8.6.8）的要求适用，除非相关部件符合IEC 60950-1的保护接地要求和试验，并作为操作员保护的手段，而不是作为病人保护的手段。

8.6.2 * PROTECTIVE EARTH TERMINAL

*保护接地端子

The PROTECTIVE EARTH TERMINAL of ME EQUIPMENT shall be suitable for connection to an external protective earthing system either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a FIXED PROTECTIVE EARTH CONDUCTOR.

医用电气设备的保护接地端子应适用于通过电源线中的保护接地导体连接到外部保护接地系统,并在适当的情况下,通过合适的插头或固定的保护接地导体进行连接。

The clamping means of the PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS shall comply with the requirements of 8.11.4.3. It shall not be possible to loosen the clamping means without the aid of a TOOL.

医用电气设备用于固定电源导线或电源线的保护接地端子的夹紧方式应符合8.11.4.3的要求。在没有工具的帮助下,不可能松开夹紧装置。

Screws for internal PROTECTIVE EARTH CONNECTIONS shall be completely covered or protected against accidental loosening from the outside of ME EQUIPMENT.

内部保护接地连接的螺钉应完全覆盖或保护,以防从医用电气设备外部意外松动。

Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the 如果电器插座构成医用电气设备的电源连接,则

APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

电器插座应视为保护接地端子。

The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the ME EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

保护接地端子不得用于医用电气设备不同部件之间的机械连接或固定与保护接地或功能接地无关的任何部件。

Compliance is checked by inspection of materials and construction, by manual tests, and by the test of 8.11.4.3.

通过材料和结构检查、手动试验和8.11.4.3中的试验检查合规性。

8.6.3 * Protective earthing of moving parts

*运动部件的保护接地

Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connection will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

任何保护性接地连接不得用于移动部件,除非制造商证明在医用电气设备的预期使用寿命期间,该连接将保持可靠。

Compliance is checked by inspection of the ME EQUIPMENT and if necessary inspection of the 通过检查医用电气设备和必要时检查

RISK MANAGEMENT FILE.

风险管理文件。

8.6.4 Impedance and current-carrying capability

阻抗和载流能力

a) * PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.

*保护接地连接应能够可靠地承载故障电流,且不会出现过大的电压降。

For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVELY EARTHED shall

not exceed 100 m Ω , except as allowed by 8.6.4 b).
对于永久安装的医用电气设备，保护接地端子与任何保护接地部件之间的阻抗不得超过100 m Ω ，8.6.4 b) 允许的情况除外。

For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 m Ω , except as allowed by 8.6.4 b).
对于带有器具插孔的医用电气设备，电器插座中的接地针脚与任何保护性接地部件之间的阻抗不得超过100 m Ω ，8.6.4 b) 允许的情况除外。

For ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 m Ω , except as allowed by 8.6.4 b).
对于带有不可拆卸电源线的医用电气设备，电源插头中的保护接地引脚与任何保护接地部件之间的阻抗不得超过200 m Ω ，8.6.4 b) 允许的情况除外。

Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 m Ω , except as allowed by 8.6.4 b).
此外，当连接到医用电气设备时，制造商提供或规定的任何可拆卸电源线的电源插头中的保护接地引脚与医用电气设备的任何保护接地部分之间的阻抗不得超过200 m Ω ，8.6.4 b) 允许的情况除外。

Where a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, testing shall be carried out using a 3 m long cord of appropriate cross sectional area based on 8.11.3.3 and Table 17.
如果既没有提供也没有规定可拆卸电源线，则应根据8.11.3.3和表17，使用具有适当横截面积的3m长电源线进行试验。

Compliance is checked by the following test:
通过以下试验检查合规性：

A current of 25 A or 1.5 times the highest RATED current of the relevant circuit(s), whichever is greater (□ 10 %), from a current source with a frequency of 50 Hz or 60 Hz and with a no-load voltage not exceeding 6 V, is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each PROTECTIVELY EARTHED part.

电流为25A或相关电路最高额定电流的1.5倍, 取较大值(±10%), 来自频率为50 Hz或60 Hz且空载电压不超过6 V的电流源, 通过保护接地端子或电器插座中的保护接地触点或电源插头和每个保护接地部件中的保护接地引脚持续5到10秒。

Alternatively, d.c. may be used for this test.
或者, 本试验可使用直流电。

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop.
测量所述部件之间的电压降, 并根据电流和电压降确定阻抗。

Where the product of the test current as specified above and the total impedance (i.e. the impedance being measured plus the impedance of the test leads and the contact impedances) would exceed 6 V, the impedance is first measured with a no-load voltage not exceeding 6 V.

如果上述规定的试验电流与总阻抗(即被测阻抗加上测试引线的阻抗和接触阻抗)的乘积将超过6V, 则首先在不超过6V的空载电压下测量阻抗。

If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross sectional area is at least equal to that of the relevant current-carrying conductors.

如果测量的阻抗在允许范围内, 则使用一个空载电压足以将规定电流输入总阻抗的电流源重复进行阻抗测量, 或者通过以下方式确认相关保护接地导体和保护接地连接的载流能力检查其横截面积是否至少等于相关载流导体的横截面积。

- b) * The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed the values specified above if the relevant circuits have limited current capability such that, in case of short circuit of relevant insulation, the allowable values of the TOUCH CURRENT and the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION are not exceeded.

*如果相关电路的电流容量有限, 则允许保护接地连接的阻抗超过上述规定值, 以便在相关绝缘短路的情况下不会超过接触电流和单个故障条件下的患者泄漏电流的允许值。

Compliance is checked by inspection and if necessary by measurement of LEAKAGE CURRENT in the relevant SINGLE FAULT CONDITION. Transient currents occurring during the first 50 ms following the short circuit are disregarded.
通过检查和必要时测量相关单一故障条件下的泄漏电流来检查合规性。短路后前50 ms内出现的瞬态电流不考虑在内。

8.6.5 Surface coatings 表面涂层

Conductive elements of ME EQUIPMENT that have surface coatings of poorly conducting material such as paint, and between which electrical contact is essential to a PROTECTIVE EARTH CONNECTION, shall have the coatings removed at the point of contact unless an investigation of the joint construction and the manufacturing PROCESS has demonstrated that the requirements for impedance and current-carrying capacity are assured without the removal of the surface coating.
医用电气设备的导电元件, 其表面涂层为低导电材料, 如油漆, 其之间的电气接触对保护接地连接至关

重要，除非对接头结构和制造工艺的调查表明，在不去除表面涂层的情况下，能够保证阻抗和载流能力的要求，否则应在接触点清除涂层。

Compliance is checked by inspection.
通过检查检查合规性。

8.6.6 Plugs and sockets **插头和插座**

Where the connection between the SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT that can be operated by persons other than SERVICE PERSONNEL is made via a plug and socket device, the PROTECTIVE EARTH CONNECTION shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are PROTECTIVELY EARTHED.

如果电源干线和医用电气设备之间或医用电气设备的独立部件之间的连接是通过插头和插座装置进行的，则保护性接地连接应在电源连接接通或中断之前进行，并在电源连接断开后中断。这也适用于可互换部件的保护接地。

Compliance is checked by inspection.
通过检查检查合规性。

8.6.7 * POTENTIAL EQUALIZATION CONDUCTOR ***电位均衡导体**

If ME EQUIPMENT is provided with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR, the following requirements apply.

如果医用电气设备配备有用于连接电位均衡导体的端子，则以下要求适用。

- The terminal shall be accessible to the OPERATOR with the ME EQUIPMENT in any position of
当医用电气设备位于
NORMAL USE.
正常使用。
- The RISK of Accidental disconnection shall be minimized avoided in NORMAL USE.
正常使用时应尽量避免意外断开的风险。
- The terminal shall allow the conductor to be detached without the use of a TOOL.
端子应允许在不使用工具的情况下分离导线。

- The terminal shall not be used for a PROTECTIVE EARTH CONNECTION.
端子不得用于保护接地连接。
- The terminal shall be marked with symbol IEC 60417-5021 (DB:2002-10) (see Table D.1, symbol 8).
端子应标有符号IEC 60417-5021 (DB:2002-10) (见表D.1, 符号8)。
- The instructions for use shall contain information on the function and use of the POTENTIAL EQUALIZATION CONDUCTOR together with a reference to the requirements of this standard for ME SYSTEMS.
使用说明应包含电位均衡导体的功能和使用信息, 并参考本标准对医用电气系统的要求。

The POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR.
电源线不得包含电位均衡导体。

Compliance is checked by inspection.
通过检查检查合规性。

8.6.8 FUNCTIONAL EARTH TERMINAL 功能接地端子

A FUNCTIONAL EARTH TERMINAL of ME EQUIPMENT shall not be used to provide a PROTECTIVE EARTH CONNECTION.
医用电气设备的功能性接地端子不得用于提供保护性接地连接。

Compliance is checked by inspection.
通过检查检查合规性。

8.6.9 * CLASS II ME EQUIPMENT *II类医用电气设备

If CLASS II ME EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only as the functional earth connection to a FUNCTIONAL EARTH TERMINAL for these screens and shall be coloured green and yellow. In such a case, the ACCOMPANYING DOCUMENTS shall state that the third conductor in the POWER SUPPLY CORD is only a functional earth.
如果带有隔离内部屏蔽的II类医用电气设备配备有三根导线的电源线, 则第三根导线(连接到电源插头的保护接地触点)应仅用作这些屏蔽的功能接地端子的功能接地连接, 并应涂上绿色和黄色。在第三种情况下, 电源线只能是功能性的电源线。

The insulation of such internal screens and all internal wiring connected to them shall provide two MEANS OF PROTECTION. In such case, there shall be an explanation in the technical description.
此类内部屏蔽层的绝缘和所有连接到它们的内部接线应提供两种保护方法。在这种情况下, 应在技术说明书中予以说明。

The insulation between internal screens, including internal wiring connected to them and ACCESSIBLE PARTS, shall provide two MEANS OF PROTECTION.
内部屏蔽之间的绝缘, 包括连接到它们的内部布线和可触及部件应提供两种保护方法。

Compliance is checked by inspection and measurement. The insulation is tested as described in 8.8.
通过检查和测量来检查符合性。绝缘测试如8.8所述。

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS 漏电流和病人辅助电流

8.7.1 General requirements

一般要求

- a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.
提供电击保护的电气隔离装置的质量应确保流经其的电流限制在8.7.3中规定的值。
- b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:
接地漏电电流、接触电流、患者漏电电流和患者辅助电流的规定值适用于以下条件的任何组合：
- at operating temperature and following the humidity preconditioning treatment, as described in 5.7;
按照5.7所述，在工作温度下并在湿度预处理之后；
 - after any required sterilization PROCEDURE (see 11.6.7);
在任何要求的灭菌程序后（见11.6.7）；
 - in NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2;
正常工况和8.7.2规定的单一故障工况；
 - with ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position;
医用电气设备在待机状态下通电并完全运行，电源部分的任何开关处于任何位置；
 - with the highest RATED supply frequency;
最高额定供电频率；
 - with a supply equal to 110 % of the highest RATED MAINS VOLTAGE.
电源等于最高额定电源电压的110%。

8.7.2 * SINGLE FAULT CONDITIONS

*单一故障条件

The allowable values specified in 8.7.3 apply in the SINGLE FAULT CONDITIONS specified in 8.7.3中规定的允许值适用于

8.1 b) except that:

8.1 b) 除了:

- where insulation is used in conjunction with a PROTECTIVE EARTH CONNECTION, short circuit of the insulation applies only in the circumstances specified in 8.6.4 b); 如果绝缘与保护接地连接一起使用, 绝缘短路仅适用于8.6.4 b) 中规定的情况;
- the only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time; 接地泄漏电流的唯一单一故障条件是一次中断一根电源导线;
- LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT are not measured in the SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION.

在双重绝缘的一个组成部分短路的单一故障情况下, 不测量泄漏电流和病人辅助电流。

SINGLE FAULT CONDITIONS shall not be applied at the same time as the special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS (8.7.4.7 b)) and non-PROTECTIVELY EARTHED parts of the ENCLOSURE (8.7.4.7 d)). 单一故障条件不得与外壳应用部件 (8.7.4.7 b)) 和非保护接地部件 (8.7.4.7 d)) 上最大电源电压的特殊试验条件同时应用。

8.7.3 * Allowable values

*允许值

- a) The allowable values specified in 8.7.3 b), c) and d) apply to currents flowing through the network of Figure 12 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 12 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s. 8.7.3 b)、c) 和d) 中规定的允许值适用于流经图12a) 网络的电流, 并按本图所示进行测量 (或通过测量图12b中定义的电流频率含量的装置测量)。这些值适用于直流和交流以及复合波形。除非另有说明, 否则它们可能是直流电或永磁同步电动机。
- b) The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 3 and Table 4. The values of a.c. apply to currents having a frequency not less than 0,1 Hz. 病人漏电流和病人辅助电流的允许值见表3和表4。交流值适用于频率不小于0.1Hz的电流。
- c) The allowable values of the TOUCH CURRENT are 100 □A in NORMAL CONDITION and 500 □A in SINGLE FAULT CONDITION. 正常情况下, 接触电流的允许值为100μA, 500μA in SINGLE FAULT CONDITION. 单一故障状态。
- d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed. 接地漏泄电流允许值在正常情况下为5ma, 在单一故障情况下为10ma。对于连接至仅为该医用电气设备供电的供电电路的永久性安装医用电气设备, 允许较高的接地漏电电流值。

NOTE 1 Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710 [10].

注1：当地法规可规定装置保护接地电流的限值。另见IEC 60364-7-710[10]。

NOTE 2 The EARTH LEAKAGE CURRENT in NORMAL CONDITION can become TOUCH CURRENT in SINGLE FAULT

单点接地故障时2号接地电流正常时能变为漏电

CONDITION unless the ME EQUIPMENT is PERMANENTLY INSTALLED or the protective earth is not accessible from outside the ME EQUIPMENT.

除非医用电气设备是永久性安装的或不能从医用电气设备外部接近保护接地。

- e) Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.

此外，无论波形和频率如何，使用非频率加权装置测量时，在正常条件下或在单一故障条件下，泄漏电流不得超过10 mA r.m.s。

- f) *. The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

*. 在非永久性安装的医用电气设备中，可在功能性接地导体中流动的泄漏电流允许值在正常情况下为5毫安，在单一故障条件下为10毫安。

NOTE 3 Subclause 16.6.1 requires that when ME EQUIPMENT is included in an ME SYSTEM, the TOUCH CURRENTS from any part of the ME SYSTEM cannot exceed 100 μ A in NORMAL CONDITION and 500 μ A in SINGLE FAULT CONDITION.

注3：子条款16.6.1要求当医用电气设备包含在医用电气系统中时，医用电气系统任何部分的接触电流在正常情况下不得超过100 μ A，在单一故障条件下不得超过500 μ A。

R1
 R1
 Z R2
 C1
 Z R2 C1
 R1 10 k $\square$ $\pm$ 5 %a)
 R1 10 k $\square$ $\pm$ 5 %a)
 R2 1 k $\square$ $\pm$ 5 %a)
 R2 1 k $\square$ $\pm$ 5 %a)
 C1 0,015 $\square$ F $\pm$ 5 %
 C1 0015 μ F $\pm$ 5 %
 Voltage
 电压
 V
 measuri
 ng
 V测量
 instrum
 ent b)
 仪 器 b)
 +20
 +20个
 8
 -40
 -40岁
 -60
 -60岁
 -20
 -20岁
 101 102 103 104 105 106
 101 102 103 104 105 106
 Frequency f Hz
 频率 f Hz

a) Measuring device characteristics
测量装置b) 频率特性

b) Frequency

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			+20 +20个
	R1		8
Z		C1	
2 R		V	
Z R2		C1 V型	
型			
	Voltage measuring instrument b)		
	电压测量仪表b)		
	-20 -20岁		
	-40 -40岁		
		1 %a)	□
R1 10 k□ ±	R2 1	F	0015μF±5%
5 %a)	k□±1%	±	
R1 10	a)	5 %	
k□±5%a)	C1	C	
R2 1 k□ ±	0,015	1	

IEC 1407/12
IEC 1407/12
标准

-60
-60岁

1
0

1
0
3

1
0
4

1
0
5

1
0
6

1
0

1
0
2

1
0
3

1
0
4

1
0
5

1
0
6

F
r
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q
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f

(
H

z
)
频
率
f
(
H
z
)

a) Measuring device
characteristics
测量装置b) 频率特性

b) Frequency

IEC 1408/12标准

NOTE The network and voltage measuring instrument above are replaced by the symbol in the following figures.

注：上述网络和电压测量仪表用下图中的符号代替。

a) Non-inductive components

a) 无感元件

b) Resistance $\geq 1\text{ M}\Omega$ and capacitance $\leq 150\text{ pF}$

b) 电阻 $\geq 1\text{ M}\Omega$ 和电容 $\leq 150\text{ pF}$

c) $Z(f)$ is the transfer impedance of the network, i.e. V_{out}/I_{in} , for a current of frequency f .

c) 电流传输的阻抗 (i/Z) 为网络阻抗。

Figure 12 – Example of a measuring device and its frequency characteristics

图12——测量装置及其频率特性示例

(see 8.7.3)

(见8.7.3)

Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

表3—*正常和单一故障条件下的患者漏电流和患者辅助电流的允许值

Current in □A
 电流（单位：A）

Current 当前	Description 说明	Referenc e 参考文献	Measurin g Circuit 测量电 路		TYPE B APPL IED PART B型应 用部 件		TYPE BF APPL IED PART BF型 应用 部件		TYPE CF APPL IED PART CF型 应用 部件	
					N C 北 卡 罗 来 纳 州	SFC 燃油 消耗 率	N C 北 卡 罗 来 纳 州	SFC 燃油 消耗 率	NC 北 卡 罗 来 纳 州	SF C 燃 油 消 耗 率
PATIE NT AUXILI ARY CURR ENT 病人辅 助电流		8.7.4.8 8.7.4.8 条	Figure 19 图19	d.c. d、 c。	10 10	50 50	10 10	50 50	10 10	50 50
				a.c. a、 c。	10 0 10 0	500 500	10 0 10 0	500 500	10 10	50 50
PATIE NT LEAK AGE CURR ENT 病人漏 电流	From PATIENT CONNECTI ON to 从患者连接 到 earth 地球	8.7.4.7 a) 8.7.4.7 a) 条)	Figure 15 图15	d.c. d、 c。	10 10	50 50	10 10	50 50	10 10	50 50
				a.c. a、 c。	10 0 10 0	500 500	10 0 10 0	500 500	10 10	50 50
	Caused by an external voltage on a SIP/SOP 由SIP/SOP	8.7.4.7 c) 8.7.4.7 c)	Figure 17 图17	d.c. d、 c。	10 10	50 50	10 10	50 50	10 10	50 50
				a.c.	10	500	10	500	10	50

	上的外部电压引起			a、c。	0 10 0	500	0 10 0	500	10	50
Total PATIENT LEAKAGE 病人总漏电流a	With the same types of APPLIED PART connected together 将相同类型的应用部件连接在一起	8.7.4.7 a) and 8.7.4.7 a) 和 8.7.4.7 h) 8.7.4.7小时)	Figure 15 and 图15和 Figure 20 图20	d.c. d、c。	50 50	100 100	50 50	100 100	50 50	10 0 10 0
				a.c. a、c。	50 0 50 0	1 000 100 0个	50 0 50 0	1 000 100 0个	50 50	10 0 10 0
	Caused by an external voltage on a SIP/SOP 由SIP/SOP上的外部电压引起	8.7.4.7 c) and 8.7.4.7 c) 和 8.7.4.7 h) 8.7.4.7小时)	Figure 17 and 图17和 Figure 20 图20	d.c. d、c。	50 50	100 100	50 50	100 100	50 50	10 0 10 0
				a.c. a、c。	50 0 50 0	1 000 100 0个	50 0 50 0	1 000 100 0个	50 50	10 0 10 0

Key
钥匙

NC = NORMAL CONDITION
NC=正常状态

SFC = SINGLE FAULT CONDITION
SFC=单一故障条件

NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 d). NOTE 2 For TOUCH CURRENT see 8.7.3 c).

注1：接地漏电电流见8.7.3 d)。注2：接触电流见8.7.3 c)。

a Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 患者总泄漏电流值仅适用于具有多个应用部件的设备。看到了吗

8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.
8.7.4.7小时)。单个应用部件应符合患者泄漏电流值。

Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7

表4—*在8.7.4.7中确定的特殊试验条件下，病人漏电电流的允许值

Current in □A
电流（单位：A）

Current 当前	Description a 说明a	Reference 参考文献	Measuring Circuit 测量电路	TYPE B APPL IED PART B型应 用部 件	TYPE BF APPL IED PART BF型 应用 部件	TYPE CF APPL IED PART CF型 应用 部件
PATIE NT LEAK AGE CURR ENT 病人漏 电流	Caused by an external voltage on the PATIENT 由病人的外部 电压引起的 CONNECTION of an F- TYPE APPLIED PART F型应用部件的 连接	8.7.4.7 b) 8.7.4.7 b)	Figure 16 图16	Not 不是 applicab le 可应用的	5 000 5000个	50 50
	Caused by an external voltage on a metal ACCESSIBLE 由可触及的金属 上的外部电压引 起的 PART not 零件不 PROTECTIVE LY EARTHED 保护接地	8.7.4.7 d) 8.7.4.7 d)	Figure 18 图18	500 500	500 500	– c –c
Total PATIE NT LEAK AGE 病人总 漏电流 CURR ENT b 电流b	Caused by an external voltage on the PATIENT 由病人的外部 电压引起的 CONNECTION of an F- TYPE APPLIED PART F型应用部件的 连接	8.7.4.7 b) and 8.7.4.7 b) 和 8.7.4.7 h) 8.7.4.7小 时)	Figure 16 and 图16和 Figure 20 图20	Not 不是 applicab le 可应用的	5 000 5000个	100 100

Caused by an external voltage on a metal ACCESSIBLE 由可触及的金属上的外部电压引起的 PART not 零件不 PROTECTIVELY EARTHED 保护接地	8.7.4.7 d) and 8.7.4.7 d) 和 8.7.4.7 h) 8.7.4.7小时)	Figure 18 and 图18和 Figure 20 图20	1 000 1000个	1 000 1000个	— c —c
a The condition referred to in Table IV of the second edition as “MAINS VOLTAGE on APPLIED PART”, and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See also the rationales for 8.5.2.2 and a第二版表四中所指的“应用部件上的电源电压”，在该版本中被视为单一故障条件，在本版中被视为特殊试验条件。在无保护接地的可触及部分进行的最大市电电压试验也是一种特殊试验条件，但允许值与单一故障条件下的试验值相同。另见8.5.2.2和 8.7.4.7 d). 8.7.4.7 d) 。 b Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See b患者总泄漏电流值仅适用于具有多个应用部件的设备。看到了吗 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values. 8.7.4.7小时)。单个应用部件应符合患者泄漏电流值。 c This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d). c该条件不使用CF型应用部件进行测试，因为它包含在应用部件上最大电源电压的测试中。另见8.7.4.7 d) 的基本原理。					

8.7.4 Measurements
测量

8.7.4.1

8.7.4.1概述

The LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT test figures referenced in 8.7.4.5 to 8.7.4.5至

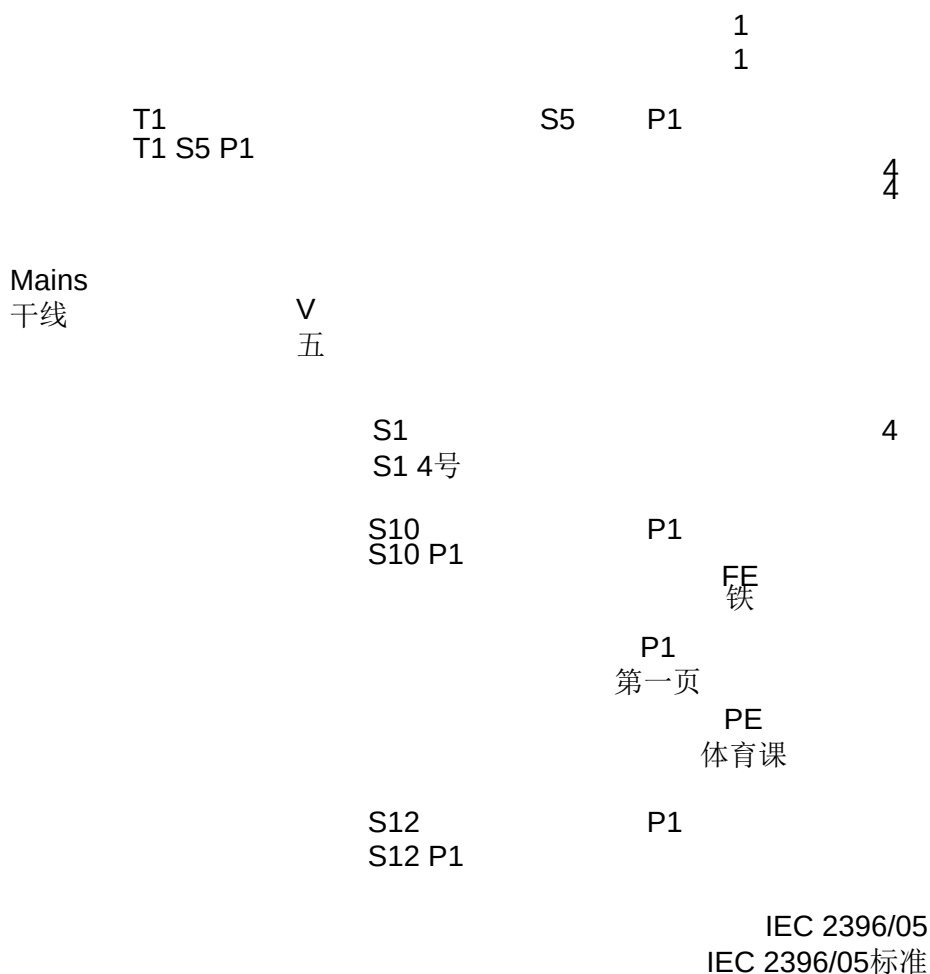
8.7.4.8 (Figure 13 to Figure 19 inclusive) show suitable test configurations for use in conjunction with the test PROCEDURES specified in these subclauses. It is recognized that other test figures can yield accurate results. However if the test results are close to the allowed values or if there is any doubt as to the validity of the test results, the applicable test figure is to be used as the deciding factor. 8.7.4.8（包括图13至图19）显示了与这些子条款中规定的试验程序一起使用的适当试验配置。一般认为，其他试验数据可以得出准确的结果。但是，如果试验结果接近允许值或对试验结果的有效性有任何疑问，则应使用适用的试验数据作为决定因素。

a) The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to operating temperature in accordance with the requirements of 11.1.3 c). 根据11.1.3 c) 的要求，在医用电气设备达到工作温度后，测量接地漏电电流、接触电流、病人漏电电流和病人辅助电流。

b) Where examination of the circuit arrangement and the arrangement of components and

General

material of the ME EQUIPMENT shows no possibility of any HAZARDOUS SITUATION described in 13.1, the number of tests can be reduced. 如果对医用电气设备的电路布置、部件和材料的布置进行检查，表明不可能出现13.1中所述的任何危险情况，则可减少试验次数。



For legends, see Table 5.

图例见表5。

Key

钥匙

Measure in all possible combinations of positions of S5, S10 and S12 with:

在S5、S10和S12位置的所有可能组合中测量:

S1 closed (NORMAL CONDITION), and S1 open (SINGLE FAULT CONDITION).

S1关闭（正常状态），S1打开（单一故障状态）。

Example with the measuring supply circuit of Figure F.1

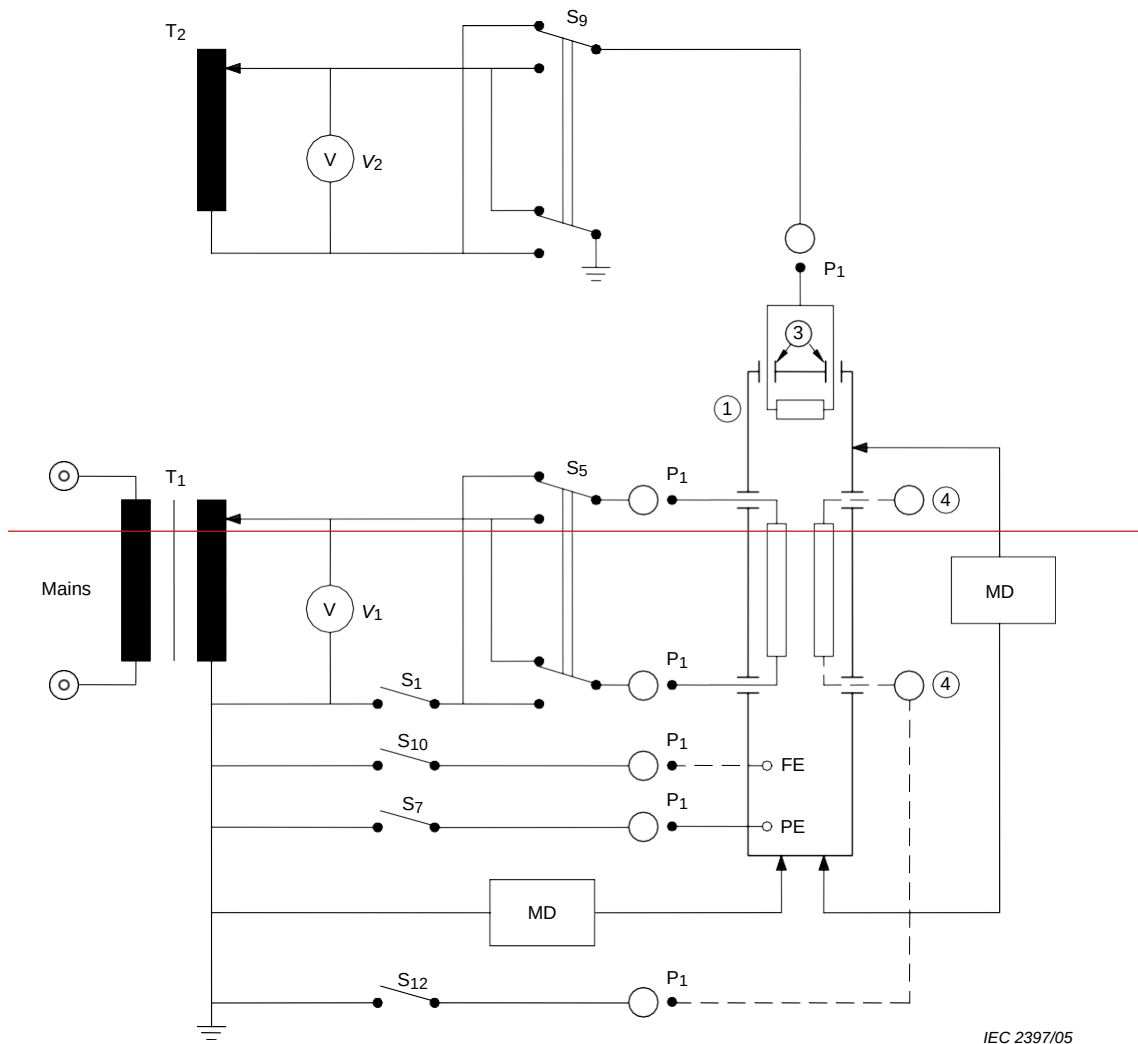
图F.1测量电源电路示例

Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART

图13-I类医用电气设备（有或无应用部件）的接地漏电流测量电路

(see 8.7.4.5)

(见8.7.4.5)



T2
T2型

T1
T1

IEC 1409/12
IEC 1409/12标准

For legends, see Table 5.
图例见表5。

Key
钥匙

Measure (with S7 closed if CLASS I ME equipment)
under all possible combinations of positions of S1, S5,
S9, S10, and S12.
在S1、S5、S9、S10和S12位置的所有可能组合下进行
测量（如果I类医用电气设备，则关闭S7）。

S1 open is SINGLE FAULT CONDITION.
S1开路为单一故障状态。

CLASS I ME equipment only:
仅I类医用电气设备：
Measure with S7 open (SINGLE FAULT CONDITION)
and with S1 closed under all possible combinations of
S5, S9, S10 and S12.
在S5、S9、S10和S12的所有可能组合下，在S7打开
（单一故障条件）和S1关闭的情况下进行测量。

For CLASS II ME equipment, the PROTECTIVE EARTH CONNECTION and S7
对于II类医用电气设备，保护接地连接和S7
are not used.
未使用。

Transformer T2 is used if required (see 8.1 a))

如果需要，使用变压器T2（见8.1 a））

Example with the measuring supply circuit of Figure F.1.

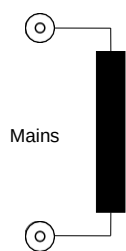
图F.1测量电源电路示例。

Figure 14 – Measuring circuit for the TOUCH CURRENT

图14—接触电流测量电路

(see 8.7.4.6)

（见8.7.4.6）



IEC 2398/05
IEC 2398/05标准

T1
T1

IEC 1410/12
IEC 1410/12标准

For legends, see Table 5.
图例见表5。

Key
钥匙

Measure (with S7 closed if CLASS I ME EQUIPMENT)
under all possible combinations of positions of S1, S5,
S10, S13 and S15.

在S1、S5、S10、S13和S15的所有可能位置组合下进
行测量（如果I类医用电气设备，则关闭S7）。

S1 open is SINGLE FAULT
CONDITION. CLASS I ME
EQUIPMENT only:

S1开路为单一故障状态。仅I
类医用电气设备：

Measure with S7 open (SINGLE FAULT CONDITION) and
with S1 closed under all possible combinations of S5, S10,
S13 and S15.

在S5、S10、S13和S15的所有可能组合下，在S7打开（单
一故障条件）和S1关闭的情况下进行测量。

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S7 are
not used.
对于II类医用电气设备，保护接地连接和S7为
未使用。

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the
图15—患者漏电电流的测量电路
PATIENT CONNECTION to earth
病人接地
(see 8.7.4.7 a))

(见8.7.4.7a)

T1
T1

Mains
干线

V V1
第1版

S1
S1

1

1

5

5

S5

P1
S5第1
页

4

4

4

4

S10
S10第3页

§7第1页

P1

3

FE
铁

P1

PE 体育课3

3

P1
第一页

$$\begin{pmatrix} L \\) \\ N \\ (\\ L \\) \end{pmatrix}$$

电压V2

$$\begin{array}{l} L(N) \\ L(N) \end{array}$$

T2
T2型

M a i n s

干线

N
(

V V2

S9 R
S9 R系列

MD
医学博士

P1
第一页

S13
第13节

IEC
2399/05
IEC 2399
标准

干线

N(L)
N (L)

S9

MD

P1

第一页

医学博士

R

S9 R系
列

V V2
电压
V2

S13

第13节

IEC 1411/12

IEC 1411/12标准

For legends, see Table 5.

图例见表5。

Key

钥匙

Measure (with S7 closed, if CLASS I ME EQUIPMENT)

WITH S1 closed under all possible combinations of
positions of S5, S9, S10 and S13.

在S5、S9、S10和S13的所有可能位置组合下，在S1闭
合的情况下测量（若I类医用电气设备，则关闭S7）。

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S7 are
not used.
对于II类医用电气设备，保护接地连接和S7为
未使用。

Example with the measuring supply circuit of Figure F.1.

图F.1测量电源电路示例。

Figure 16 – Measuring circuit for the PATIENT LEAKAGE CURRENT via the PATIENT

图16—通过患者的患者漏电流测量电路

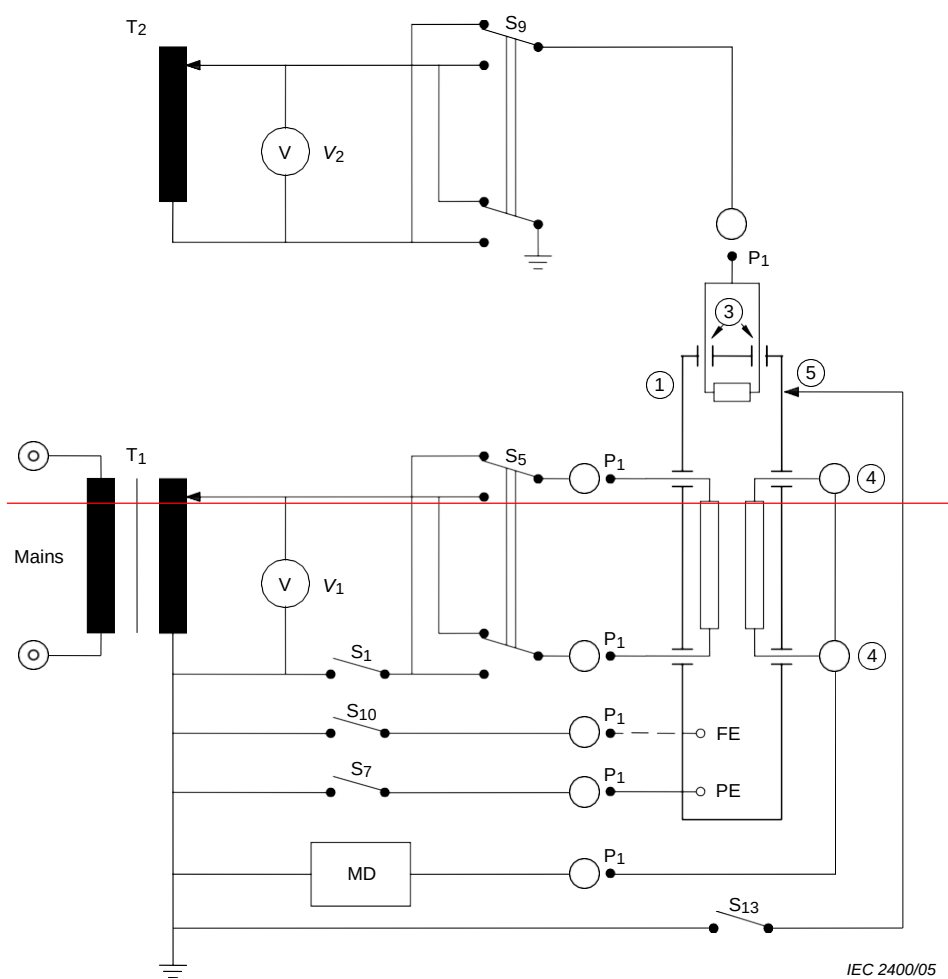
CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the
由外部电压引起的F-TYPE应用部件接地连接

PATIENT CONNECTION(S)

患者连接

(see 8.7.4.7 b))

(见8.7.4.7 b))



IEC 2400/05

T2
T2型

T1
T1

IEC 1412/12
IEC 1412/12标准

For legends, see Table 5.
图例见表5。

Key
钥匙

Measure (with S7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S1, S5, S9, S10 and S13 (S1 open is SINGLE FAULT CONDITION).
在S1、S5、S9、S10和S13位置的所有可能组合（S1打开为单一故障条件）下进行测量（若I类医用电气设备，则关闭S7）。

CLASS I ME EQUIPMENT only:
仅I类医用电气设备：

Measure with S7 open (SINGLE FAULT CONDITION) and with S1 closed under all possible combinations of S5, S9, S10 and S13.
在S5、S9、S10和S13的所有可能组合下，在S7打开（单一故障条件）和S1关闭的情况下进行测量。

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S7 are not used.
对于II类医用电气设备，不使用保护接地连接和S7。

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

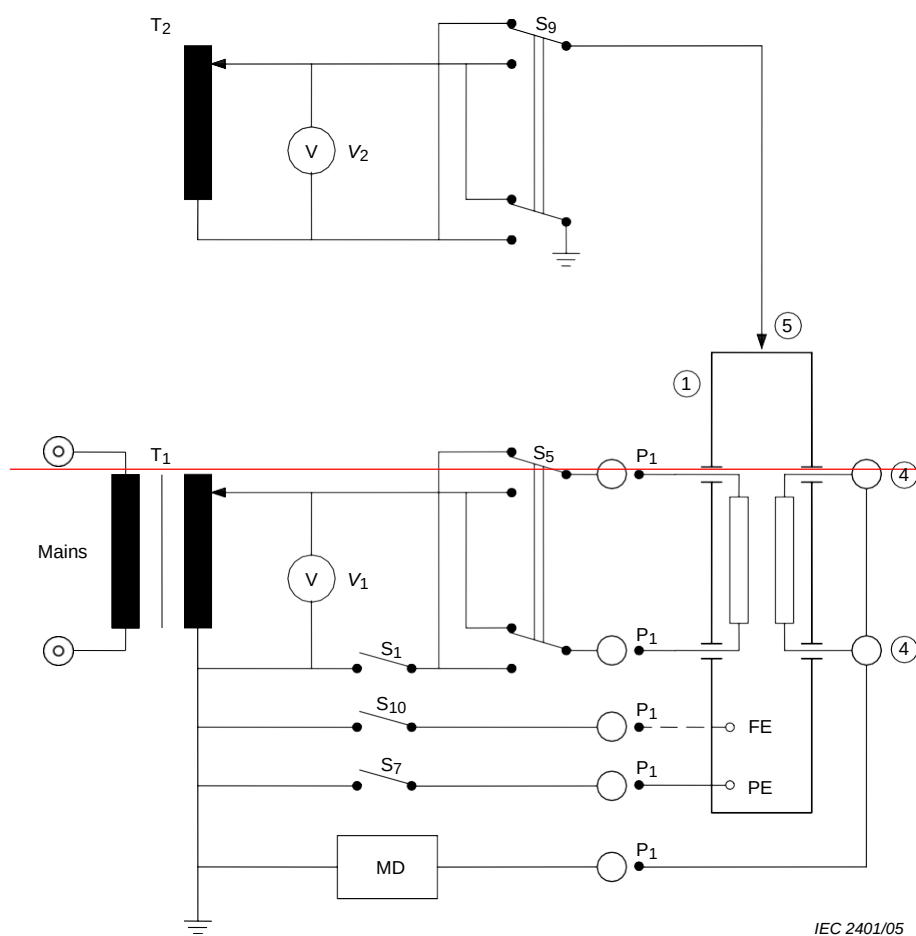
Figure 17 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT

图17—患者泄漏电流的测量电路

CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART
信号输入/输出部分的外部电压引起的接地连接

(see 8.7.4.7 c))

(见8.7.4.7 c))



T2
T2型

T1
T1

IEC 1413/12
IEC 1413/12标准

For legends, see Table 5.
图例见表5。

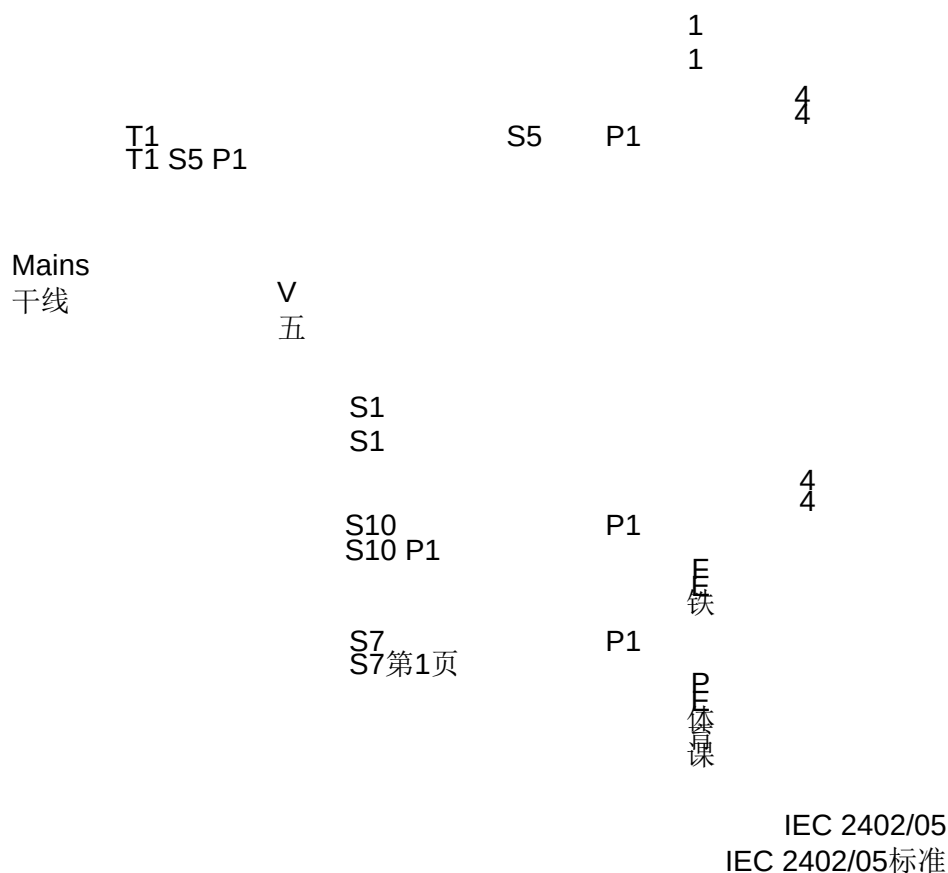
Key
钥匙

Measure with S1 closed (and with S7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S5, S9 and S10
在S5、S9和S10的所有可能位置组合下，在S1关闭（若为I类医用电气设备，则关闭S7）的情况下进行测量

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S7 are not used.
对于II类医用电气设备，不使用保护接地连接和S7。

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure 18 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT
图18–患者泄漏电流的测量电路
CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED
由未进行保护性接地的金属可触及部件上的外部电压引起的接地连接
(see 8.7.4.7 d))
(见8.7.4.7 d))



For legends, see Table 5.

图例见表5。

Key

钥匙

Measure (with S7 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S1, S5, and S10.

在所有可能的S1、S5和S10位置组合下进行测量（若I类医用电气设备，则关闭S7）。

S1 open is a SINGLE FAULT CONDITION.

CLASS I ME EQUIPMENT only:

S1开路为单一故障状态。仅I类医用电气设备:

Measure with S7 open (SINGLE FAULT CONDITION) and with S1 closed under all possible combinations of positions of S5, and S10.

在所有可能的S5和S10位置组合下，在S7打开（单一故障条件）和S1关闭的情况下进行测量。

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S7 are not used.
对于II类医用电气设备，不使用保护接地连接和S7。

Example with the measuring supply circuit of Figure F.1.

图F.1测量电源电路示例。

Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT

图19-患者辅助电流测量电路

(see 8.7.4.8)

(见8.7.4.8)

See Figure 17
见图17

T1
T1



IEC 2403/05
IEC 2403/05标准

For legends, see Table 5.
图例见表5。

Key
钥匙

For the position of S1, S5, S7 and S10, see Figure 15, Figure 16, Figure 17 or Figure 18
S1、S5、S7和S10的位置见图15、图16、图17或图18

Figure 20 – Measuring circuit for the total PATIENT LEAKAGE CURRENT with all
PATIENT
图20–所有患者的总泄漏电流测量电路
CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF
APPLIED

同一类型的所有应用部件的连接（B型应用部件，BF型应用部件
PARTS or TYPE CF APPLIED PARTS) connected together
部件或CF型应用部件）连接在一起
(see 8.7.4.7 h))
(见8.7.4.7 h)

Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F
表5——图9至图11、图13至图20、图A.15、附件E和F的符号图例

1	ME EQUIPMENT ENCLOSURE 医用电气设备外壳
	Separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see 5.5 g f) and Annex F)
2	ME EQUIPMENT (see 5.5 g f) and Annex F) 医用电气设备（见5.5 g f）和附录f）
3	SIGNAL INPUT/OUTPUT PART short circuited or loaded 信号输入/输出部分短路或负载
4	PATIENT CONNECTIONS 患者关系
	Metal ACCESSIBLE PART not PROTECTIVELY EARTHED 金属可触及部分未进行保护接地
5	In case of a non-conductive ENCLOSURE and PATIENT LEAKAGE CURRENT measurement, connection is replaced by a metal foil of maximum 20 cm □ 10 cm in intimate contact with the ENCLOSURE or relevant parts of the ENCLOSURE and connected to the reference earth 如果是非导电外壳和患者泄漏电流测量，应使用与外壳紧密接触的最大20 cm×10 cm的金属箔代替连接，或外壳的相关部件并连接至参考接地
6	PATIENT circuit 病人回路
7	Metal plate under a non-conductive ENCLOSURE with dimensions at least equal to the plan projection of the ENCLOSURE connected to the reference earth 非导电外壳下的金属板，其尺寸至少等于连接至基准接地的外壳的平面投影
T, T	Single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (See also the rationale for 8.7.4.2 and 8.7.4.3) 具有足够额定功率和可调输出电压的T、T单相或多相隔离变压器（另见8.7.4.2和8.7.4.3的基本原理。）
V(1,2,3)	Voltmeter indicating r.m.s. value, using, if relevant and possible, one meter with a commutator
V (1,2,3)	伏特计，指示r.m.s.值，如果相关和可能，使用一个带换向器的仪表
S, S, S	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION) (See Annex F) S、S、S单极开关，模拟电源导线的中断（单一故障条件）（见附录F）
S5, S9	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S5、S9	换向器开关，以反转电源电压的极性
S	Single-pole switch, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to the ME EQUIPMENT (SINGLE FAULT CONDITION) 单极接地保护开关，模拟单极接地开关 医用电气设备（单一故障状态）
	Single pole switch simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to a separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT 模拟单个保护接地导体对独立电源的中断的单极开关
S8	supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT
S8	医用电气系统中为医用电气设备供电的供电装置或其他电气设备 (SINGLE FAULT CONDITION) (see Figure F.5) （单一故障条件）（见图F.5）
S	Switch for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply system S开关，用于将功能接地端子连接到测量电源系统的接地点

S12 Switch for connecting a PATIENT CONNECTION to the earthed point of the measuring supply circuit S13 Switch for connecting to earth a metal

ACCESSIBLE PART not PROTECTIVELY EARTHED

S12用于将患者连接连接至测量电源电路的接地点的开关S13用于将未进行保护性接地的金属可触及部分接地的开关

S14 Switch to connect/disconnect PATIENT CONNECTION to/from earth
S14开关，用于连接/断开患者与接地的连接

S15 Switch for connecting to earth a metal plate under a non-conductive ENCLOSURE
S15开关，用于将非导电外壳下的金属板接地

P1 Sockets, plugs or terminals for the supply connection of the ME EQUIPMENT
医用电气设备电源连接用P1插座、插头或端子

P Sockets, plugs or terminals for the connection to a separate power supply or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see Figure F.5)
P插座、插头或端子，用于连接到为医用电气设备供电的医用电气系统中的独立电源或其他电气设备（见图F.5）

MD Measuring device (see

Figure 12) FE FUNCTIONAL

EARTH TERMINAL

MD测量装置（见图12）FE功能接

地端子

PE PROTECTIVE EARTH TERMINAL
PE保护接地端子

R Impedance to protect the circuitry and the person performing the test, but low enough to accept currents higher than the allowable values of the LEAKAGE CURRENT to be measured (optional)
R保护电路和测试人员的阻抗，但足够低以接受高于待测泄漏电流允许值的电流（可选）

Optional connection
可选连接

Reference earth (for LEAKAGE CURRENT and PATIENT AUXILLARY CURRENT measurements and for

参考接地（用于泄漏电流和患者辅助电流测量，以及
R testing of DEFIBRILLATION-PROOF APPLIED PARTS, not connected to protective earth of the SUPPLY MAINS)
R测试未连接电源保护接地的除颤应用部件）

SUPPLY MAINS voltage source
电源电压源

8.7.4.2 * Measuring supply circuits

*测量电源电路

ME EQUIPMENT specified for connection to a SUPPLY MAINS is connected to an appropriate power source. For single-phase ME EQUIPMENT, the polarity of the supply is reversible and tests are conducted at both polarities. INTERNALLY POWERED ME EQUIPMENT is tested without any connection to a measuring supply circuit. 指定用于连接电源的医用电气设备连接至适当的电源。对于单相医用电气设备，电源的极性是可逆的，并且在两个极性下进行试验。内部供电的医用电气设备在没有任何测量电源电路连接的情况下进行测试。

NOTE Figure F.1 to Figure F.5 (inclusive) show some suitable arrangements but do not cover all possibilities, for example, delta-connected 3-phase supplies.

注：图F.1至图F.5（包括图F.1）显示了一些适当的布置，但并未涵盖所有可能性，例如三角形连接的三相电源。

8.7.4.3 * Connection to the measuring supply circuit

*连接到测量电源电路

a) ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.

配备电源线的医用电气设备使用该电源线进行测试。

b) ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified in the instructions for use. 当医用电气设备通过3米长的可拆卸电源线或使用说明中规定的长度和类型连接到测量电源电路时，对配备有器具插孔的医用电气设备进行测试。

c) PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection. 对永久安装的医用电气设备进行测试，同时通过尽可能短的连接与测量电源电路连接。

d) Measuring arrangement

测量装置

1) APPLIED PARTS, including PATIENT cables (when present), are placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface. 应用部件，包括病人电缆（如有）放置在介电常数约为1（例如，发泡聚苯乙烯）的绝缘表面上，并高于接地金属表面约200 mm。

NOTE 1 The measuring supply circuit and the measuring circuit should be positioned as far as possible away from unscreened power source leads. Placing the ME EQUIPMENT on or near a large earthed metal surface should be avoided. 注1：测量电源电路和测量电路应尽可能远离未屏蔽的电源线。应避免将医用电气设备放置在大型接地金属表面上或附近。

NOTE 2 Where APPLIED PARTS are such that the test results can depend upon how they are placed on the insulating surface, the test is repeated as necessary to determine the worst possible positioning. 注2：如果应用部件的试验结果取决于其在绝缘表面上的放置方式，则应根据需要重复试验，以确定最差的可能位置。

2) If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME EQUIPMENT), the reference earth of the measuring circuits is connected to protective earth of the

SUPPLY

MAINS.

如果不使用隔离变压器测量泄漏电流（例如，在测量输入功率极高的医用电气设备的泄漏电流时），测量电路的参考接地应连接至电源干线的保护接地。

8.7.4.4 Measuring device (MD) 测量装置 (MD)

a) The measuring device loads the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately $1\ 000\ \Omega$ for d.c., a.c. and composite waveforms with frequencies up to and including 1 MHz. 对于频率高达1 MHz（含1 MHz）的直流、交流和复合波形，测量装置加载的泄漏电流源或患者辅助电流的电阻阻抗约为 $1\ 000\ \Omega$ 。

b) The evaluation of current or current components according to 8.7.3 a) is obtained automatically if a measuring device according to Figure 12 a) or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument. 如果使用图12a)所示的测量装置或具有相同频率特性的类似电路，则可自动根据8.7.3a)对电流或电流分量进行评估。这允许用一台仪器测量所有频率的总影响。

If currents or current components with frequencies exceeding 1 kHz might exceed the 10 mA limit specified in 8.7.3 e), these are measured by other appropriate means such as a $1\ k\Omega$ non-inductive resistor and suitable measuring instrument. 如果频率超过1 kHz的电流或电流分量可能超过8.7.3 e)中规定的10 mA限值，则应采用其他适当的方法进行测量，如 $1\ k\Omega$ 无感电阻和合适的测量仪器。

c) The voltage measuring instrument as shown in Figure 12 a) has an input resistance of at least $1\ M\Omega$ and input capacitance of no more than 150 pF. It indicates the true r.m.s. value of the voltage being d.c., a.c. or a composite waveform having components with frequencies from 0,1 Hz up to and including 1 MHz, with an indicating error not exceeding 如图12a)所示的电压测量仪表的输入电阻至少为 $1\ M\Omega$ ，输入电容不超过150 pF。它表示电压的真实r.m.s.值为直流、交流或具有频率为0.1hz至1mhz（包括1mhz）的复合波形，指示误差不超过 $\pm 5\%$ of the indicated value. 指示值的 $\pm 5\%$ 。

The scale can indicate the current through the measuring device including automatic evaluation of components with frequencies above 1 kHz so as to enable direct comparison of the reading with the limit values specified in 8.7.3. 电子秤可以指示通过测量装置的电流，包括频率超过1 kHz的部件的自动评估，以便能够直接将读数与8.7.3中规定的限值进行比较。

These requirements can be limited to a frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies above such an upper limit do not occur in the measured current. 如果能够证明（例如，通过使用示波器）在测量电流中不会出现高于此上限的频率，则这些要求可以限制在上限低于1兆赫的频率范围内。

8.7.4.5 * Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection
*漏电电流和功能接地电流的测量

- a) CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.

根据图13测试I类医用电气设备。按照第8.6.9节的要求，对具有功能性接地连接的II类医用电气设备进行试验，将其视为一类医用电气设备。

- b) If ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example, one connected to the main ENCLOSURE and one to a separate power supply unit), then the current to be measured is the aggregate current that would flow into the protective earthing system of the installation. 如果医用电气设备有一个以上的保护接地导体（例如，一个连接到主外壳，另一个连接到单独的电源装置），则要测量的电流是流入装置保护接地系统的总电流。

- c) For FIXED ME EQUIPMENT that can have connections to earth through the building structure, the MANUFACTURER specifies a suitable test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT. 对于可通过建筑结构接地的固定式医用电气设备，制造商规定了测量接地漏电电流的适当试验程序和配置。

8.7.4.6 * Measurement of the TOUCH CURRENT
*接触电流测量

- a) ME EQUIPMENT is tested according to Figure 14, using an appropriate measuring supply circuit.

根据图14，使用适当的测量电源电路对医用电气设备进行测试。

Measure with MD between earth and each part of the ENCLOSURE(S) that is not PROTECTIVELY EARTHED.
用MD测量接地和外壳各部分之间的距离
保护接地。

Measure with MD between parts of the ENCLOSURE(S) that are not PROTECTIVELY EARTHED.
用MD测量未接地的外壳部分之间的MD。

In the SINGLE FAULT CONDITION of interruption of any one PROTECTIVE EARTH CONDUCTOR (when applicable, see 8.1 b)), measure with MD between earth and any part of the ENCLOSURE(S) that is normally PROTECTIVELY EARTHED. 在任何一个保护接地导体中断的单一故障条件下（如适用，见8.1 b）），用MD测量接地和外壳任何部分之间的正常保护接地。

NOTE It is not necessary to make separate measurements from more than one part that is PROTECTIVELY EARTHED.

注：不必对多个保护接地部件进行单独测量。

INTERNALLY POWERED ME EQUIPMENT is investigated for TOUCH CURRENT but only between parts of the ENCLOSURE, not between the ENCLOSURE and earth unless

8.7.4.6

c)

applies.

对内部供电的医用电气设备进行接触电流调查，但仅限于外壳部件之间的接触电流，不包括外壳和接地之间的接触电流，除非8.7.4.6 c) 适用。

- b) If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE. 如果医用电气设备有由绝缘材料制成的外壳或外壳的一部分，则应在与外壳或外壳相关部分紧密接触时使用最大20 cm x 10 cm的金属箔。

The metal foil is shifted, if possible, to determine the highest value of the TOUCH CURRENT. The metal foil should not touch any metal parts of the ENCLOSURE that are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE that are not PROTECTIVELY EARTHED can be covered partly or totally by the metal foil. 如果可能的话，金属箔会移动，以确定接触电流的最高值。金属箔不应接触外壳中可能有保护性接地的任何金属部件；但是，外壳中未进行保护性接地的金属部件可以部分或全部被金属箔覆盖。

Where it is intended to measure the TOUCH CURRENT in the SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR, the metal foil is arranged to contact parts of the ENCLOSURE that are normally PROTECTIVELY EARTHED.

通常情况下，金属箔的保护性接地部分是在保护性接地的情况下进行的。

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR is larger than 20 cm x 10 cm, the size of the foil is increased corresponding to the area of contact.

如果患者或操作员接触的外壳表面大于20 cm x 10 cm，则箔材的尺寸根据接触面积增加。

- c) ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T2. 当需要时，带有信号输入/输出部分的医用电气设备（见8.1A）），使用变压器T2进行额外测试。

The value of the voltage set at the transformer T2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is determined to be worst case based on testing or circuit analysis. 变压器T2处设置的电压值等于最大电源电压的110%。根据测试或电路分析，施加外部电压时使用的特定引脚配置被确定为最坏情况。

8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

病人漏电流测量

See Annex K, which contains simplified PATIENT LEAKAGE CURRENT diagrams, for supplemental explanatory detail.

关于补充说明细节，见附录K，其中包含简化的患者漏电流图。

a) ME EQUIPMENT with an APPLIED PART is tested according to Figure 15.

根据图15测试带有应用部件的医用电气设备。

An ENCLOSURE, other than an APPLIED PART, made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE. 由绝缘材料制成的外壳（应用部件除外）放置在接地的平坦金属表面上任何正常使用的位置，其尺寸至少等于外壳的平面投影。

b) * ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 16.

*根据图16对带有F-TYPE应用部件的医用电气设备进行额外测试。

SIGNAL INPUT/OUTPUT PARTS are connected to earth, if not already permanently earthed in the ME EQUIPMENT. 如果医用电气设备中尚未永久接地，信号输入/输出部件应接地。

The value of the voltage to be set at the transformer T2 in Figure 16 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. 图16中变压器T2处设置的电压值等于最大电源电压的110%。

For this measurement, non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including 对于该测量，非保护性接地金属可触及部件包括
PATIENT CONNECTIONS of other APPLIED PARTS (if present) are connected to earth. 其他应用部件（如有）的患者接头连接至接地。

c) * ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 17. *医用电气设备带有应用部分和信号输入/输出部分，如有需要（见8.1 a）），根据图17进行额外测试。

The value of the voltage set at the transformer T2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is to be worst case based on testing or circuit analysis. 变压器T2处设置的电压值等于最大电源电压的110%。根据测试或电路分析，施加外部电压时使用的特定引脚配置是最坏情况。

d) * ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 18. *根据图18对医用电气设备进行额外测试，该医用电气设备的患者连接为B型应用部件，或BF型应用部件，以及未进行保护性接地的金属可触及部件。

The value of the voltage set at the transformer T2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. 变压器T2处设置的电压值等于最大电源电压的110%。

This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved.

如果能够证明所涉及的零件已充分分离，则无需进行该试验。

- e) An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution is used in which the APPLIED PART is immersed.
使用8.7.4.6中所述的金属箔对由绝缘材料制成的表面组成的应用部件进行试验。或者使用0.9%的盐水溶液，将应用部分浸入其中。

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil is increased to correspond to the area of contact.
如果拟接触患者的应用部分的表面比20 cm x 10 cm的箔材的表面大得多，则应增加箔材的尺寸，以符合接触面积。

Such metal foil or saline solution is considered as the only PATIENT CONNECTION for the
这种金属箔或盐水溶液被认为是
APPLIED PART concerned.
相关应用部分。

- f) Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline solution and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.

如果患者连接由与患者接触的流体形成，则用0.9%的盐水代替液体，将电极置于盐水中，并且该电极被视为相关应用部分的患者连接。

- g) The PATIENT LEAKAGE CURRENT is measured (see also Annex E):

测量病人漏电流（另见附录E）：

- for TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE;
对于B型应用部件和BF型应用部件，从所有患者到所有患者单个函数的连接，可以直接连接在一起，也可以像正常使用；
- for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together.
对于B型应用部件，从所有直接连接在一起的病人连接处。

- for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE.
对于BF型应用部件, 单个功能的所有患者连接件之间或直接连接在一起, 或按正常使用方式加载。
- infor TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.
信息型CF应用部件, 依次从每个患者连接到每个患者连接。

If the instructions for use specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT leads or PATIENT cables and electrodes), the PATIENT LEAKAGE CURRENT measurements are made with the least favourable specified detachable part. See also 7.9.2.14.

如果使用说明书规定了应用部件的可拆卸部件的替代品(例如, 患者导线或病人电缆和电极), 则应使用最不利指定的可拆卸部件进行患者泄漏电流测量。另见7.9.2.14。

- h) * The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together. See Figure 20. If necessary, a functional earth may be disconnected before conducting this test.

*患者总漏电流测量的是连接在一起的同一类型的所有应用部件(B型应用部件、BF型应用部件或CF型应用部件)的所有患者连接。见图20。如有必要, 可在进行该试验前断开功能接地。

NOTE Measurement of total PATIENT LEAKAGE CURRENT of TYPE B APPLIED PARTS is only necessary if there are two or more PATIENT CONNECTION that belong to different functions and that are not electrically connected directly together.

注: 仅当有两个或两个以上属于不同功能且未直接电连接在一起的患者连接时, 才需要测量B型应用部件的患者总泄漏电流。

- i) If the PATIENT CONNECTIONS of the APPLIED PART are loaded in NORMAL USE, the measuring device is connected to each PATIENT CONNECTION in turn.
如果正常使用时, 应用部件的患者连接件被加载, 则测量设备依次连接到每个患者连接件上。

8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT 病人辅助电流的测量

ME EQUIPMENT with an APPLIED PART is tested according to Figure 19, using an appropriate measuring supply circuit unless the ME EQUIPMENT has only a single PATIENT CONNECTION.

除非医用电气设备只有一个病人连接, 否则应根据图19使用适当的测量电源电路对医用电气设备进行测试。

The PATIENT AUXILIARY CURRENT is measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS, either connected directly together or loaded as in NORMAL USE (see also Annex E).
患者辅助电流是在任何单个患者连接和所有其他患者连接之间测量的, 这些患者连接要么直接连接在一起, 要么在正常使用中加载(另见附录E)。

8.7.4.9 * ME EQUIPMENT with multiple PATIENT CONNECTIONS *具有多个患者连接的医用电气设备

ME EQUIPMENT with multiple PATIENT CONNECTIONS is investigated to ensure that the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values for NORMAL CONDITION while one or more PATIENT CONNECTIONS are:

研究具有多个患者连接的医用电气设备，以确保患者漏电流和患者辅助电流不超过正常情况下的允许值，而一个或多个患者连接为：

- disconnected from the PATIENT; and
与患者断开联系；以及
- disconnected from the PATIENT and earthed.
与病人断开并接地。

Testing is performed if an examination of the ME EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT can increase to excessive levels under the above conditions. Actual measurements should be limited to a representative number of combinations.
如果医用电气设备电路的检查表明，在上述条件下，患者泄漏电流或患者辅助电流可能增加到过高水平，则进行测试。实际测量应限于具有代表性的组合数量。

8.8 Insulation 绝缘

8.8.1 * *总则

General

Only the following insulation shall be subject to testing:
仅对以下绝缘进行测试：

- insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION;
作为保护手段的绝缘，包括加强绝缘；
- insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, which shall be tested as one MEANS OF PROTECTION.
任何电源保险丝或过电流脱扣器电源侧电源部分相反极性部件之间的绝缘，应作为一种保护手段进行测试。

Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION, shall be subject to testing.

只有作为保护手段的绝缘（包括加强绝缘）才应接受测试。

Insulation forming part of a component is exempt provided that the component complies with 4.8.
如果部件符合4.8的要求，则构成部件的绝缘部件可免除。

Insulation forming MEANS OF OPERATOR PROTECTION is exempt from the tests of 8.8 if it complies with the requirements and tests of IEC 60950-1 for INSULATION CO-ORDINATION.

如果符合IEC 60950-1关于绝缘配合的要求和试验，操作人员保护的绝缘成型装置可免于进行8.8的试验。

8.8.2 * Distance through solid insulation or use of thin sheet material

*通过固体绝缘或使用薄板材料的距离

Solid insulation which forms SUPPLEMENTARY INSULATION or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V shall either:

对于峰值工作电压大于71V的补充绝缘或加强绝缘的固体绝缘应：

- a) have a distance through insulation of at least 0,4 mm, or
通过绝缘层的距离至少为0.4 mm，或
- b) not form part of an ENCLOSURE and not be subject to handling or abrasion during NORMAL USE, and comprise:
不构成外壳的一部分，在正常使用期间不会受到搬运或磨损，包括：
 - at least two layers of material, each of which will pass the appropriate dielectric strength test; or
至少两层材料，每层都将通过适当的介电强度试验；或
 - three layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test.
三层材料，两层材料的所有组合将通过适当的介电强度测试。

The appropriate dielectric strength test for the one or two layers is the test for one MEANS OF PROTECTION in the case of SUPPLEMENTARY INSULATION or the test for two MEANS OF PROTECTION in the case of REINFORCED INSULATION, respectively.
对于一层或两层，适当的介电强度试验分别是在附加绝缘的情况下对一种保护方式的试验，或在加强绝缘的情况下分别进行两种保护方式的试验。

NOTE 1 There is no minimum thickness requirement for BASIC INSULATION, nor for insulation operating at WORKING VOLTAGE up to 71 V.

注1：基本绝缘无最小厚度要求，工作电压高达71V的绝缘也无最小厚度要求。

NOTE 2 There is no requirement for all layers of insulation to be of the same material.

注2：不要求所有绝缘层均为同一材料。

Compliance is checked by inspection, by measurement of thickness and by the dielectric strength test of 8.8.3.

通过检查、厚度测量和8.8.3中的介电强度试验来检查合规性。

For wound components, where BASIC INSULATION, SUPPLEMENTARY INSULATION or REINFORCED INSULATION is required between windings, they shall be separated by interleaved insulation complying with a) or b) immediately above, or both, unless one of the following wire constructions is used:

对于绕线部件，如果绕组之间需要基本绝缘、补充绝缘或加强绝缘，则应使用符合a)或b)或上述两种要求的交错绝缘将其分开，除非使用以下其中一种电线结构：

- c) wire that has solid insulation, other than solvent based enamel, complying with a) above;
除溶剂型搪瓷外，具有固体绝缘的电线，符合上述a)的要求；
- d) wire that has multi-layer extruded or spirally wrapped insulation (where the layers can be individually tested for dielectric strength) complying with b) above and passes the tests of Annex L;
具有多层挤压或螺旋缠绕绝缘层（可单独测试各层的介电强度）并通过附录L测试的电线；
- e) wire that has multi-layer extruded or spirally wrapped insulation (where only the finished wire can be tested) and passes the tests of Annex L. The minimum number of constructional layers applied to the conductor shall be as follows:
具有多层挤压或螺旋缠绕绝缘层（仅对成品电线进行试验）并通过附录L试验的电线。施加在导线上的最小结构层数量应如下所示：
- BASIC INSULATION: two wrapped layers or one extruded layer;
基本绝缘：两层包层或一层挤包层；
 - SUPPLEMENTARY INSULATION: two layers, wrapped or extruded;
辅助绝缘：两层，包裹或挤压；
 - REINFORCED INSULATION: three layers, wrapped or extruded.
加强绝缘：三层，包裹或挤压。

In both d) and e), for spirally wrapped insulation where the CREEPAGE DISTANCES between layers, as wrapped, are less than those given in Table 12 or Table 16 (for Pollution Degree 1) depending on the type of insulation in question, the path between layers shall be sealed as for a cemented joint in 8.9.3.3 and the test voltages of the TYPE TESTS in L.3 are increased to 1,6 times their normal values.

在d)和e)中，对于缠绕的绝缘层，层间爬电距离小于表12或表16（污染等级1）中给出的值，具体取决于所讨论的绝缘类型，各层之间的路径应按照8.9.3.3中的水泥接缝密封，L.3中型式试验的试验电压增加至正常值的1.6倍。

NOTE 3 One layer of material wound with more than 50 % overlap is considered to constitute two layers.

注3：重叠超过50%的一层材料被视为两层。

Where two insulated wires or one bare and one insulated wire are in contact inside the wound component, crossing each other at an angle between 45° and 90° and subject to winding tension, protection against mechanical stress shall be provided. This protection can be achieved, for example, by providing physical separation in the form of insulating sleeving or sheet material, or by using double the required number of insulation layers.
如果两条绝缘线或一根裸线和一根绝缘线在绕线部件内部接触，以45°到90°的角度交叉，并受到绕组张力的影响，应提供机械应力保护。这种保护可以实现，例如，通过提供绝缘套管或片材形式的物理隔离，或使用所需数量的两倍的绝缘层。

The finished component shall pass routine tests for dielectric strength using the appropriate test voltages in 8.8.3.
成品部件应通过使用8.8.3中适当试验电压的介电强度常规试验。

Compliance is checked by inspection and measurement and, if applicable, as specified in Annex L. However, the tests of Annex L are not repeated if the material data sheets confirm compliance.
通过检查和测量以及（如适用）附录L中的规定检查是否符合要求。但是，如果材料数据表确认符合性，则不重复附件L的试验。

8.8.3 * Dielectric strength *介电强度

The dielectric strength of solid electrical insulation of ME EQUIPMENT shall be capable of withstanding the test voltages as specified in Table 6. Only insulation with a safety function need be subject to testing (see 8.8.1).
医用电气设备的固体电绝缘的介电强度应能承受表6中规定的试验电压。只有具有安全功能的绝缘才需要进行试验（见8.8.1）。

Compliance is checked by applying the test voltage specified in Table 6 for 1 min:
通过施加表6中规定的试验电压1分钟来检查合规性：

- immediately after the humidity preconditioning treatment (as described in 5.7) with the ME EQUIPMENT de-energized during the test, and
在湿度预处理（如5.7所述）后立即使用
试验期间医用电气设备断电，以及
- after any required sterilization PROCEDURE (see 11.6.7, 7.9.2.12 and the instructions for use) with the ME EQUIPMENT de-energized, and
在任何要求的灭菌程序（见11.6.7、7.9.2.12和使用说明）后，医用电气设备断电，以及
- after reaching a temperature equivalent to the steady state operating temperature reached during the heating test of 11.1.1.
–达到与11.1.1加热试验期间达到的稳态工作温度相等的温度后。

Initially, not more than half the test voltage is applied, and then it is gradually raised over a period of 10 s to the full value, which is maintained for 1 min, after which it is gradually lowered over a period of 10 s to less than half the full value.
最初，施加的试验电压不超过一半，然后在10 s的时间内逐渐升高至全值，保持1 min，然后在10 s内逐渐降低至小于全值的一半。

The test conditions are as follows:
试验条件如下：

- a) * The test voltage has a waveform and frequency such that the dielectric stress on the insulation is at least equal to that occurring in NORMAL USE. The waveform and frequency of the test voltage can differ from the voltage applied in NORMAL USE if it can be demonstrated that the dielectric stress on the insulation tested will not be diminished.
*测试电压的波形和频率应确保绝缘层上的介电应力至少等于正常使用时的介电应力。如果能够证明被测绝缘的介电应力不会减小，则测试电压的波形和频率可以与正常使用时施加

的电压不同。

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz or 60 Hz test voltage. 如果正常使用时相关绝缘所承受的电压为非正弦交流电压，则可使用正弦50 Hz或60 Hz试验电压进行试验。

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

或者，可以使用与交流试验电压峰值相等的直流试验电压。

The test voltage, for the WORKING VOLTAGE to which the insulation is subjected is greater than or equal to the value specified in Table 6.

绝缘所承受的工作电压的试验电压大于或等于表6中规定的值。

- b) During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded as insulation breakdown. 在试验过程中，故障构成故障。当由于施加试验电压而流动的电流以不受控制的方式迅速增加时，即绝缘不限制电流的流动时，认为发生了绝缘击穿。电晕放电或单个瞬间闪络不被视为绝缘击穿。
- c) If it is not possible to test individual solid insulations, it is then necessary to test a large part of the ME EQUIPMENT or even the whole ME EQUIPMENT. In this case, it is important not to overstress different types and levels of insulation and the following must be taken into account. 如果无法测试单个固体绝缘，则有必要测试大部分医用电气设备，甚至整个医用电气设备。在这种情况下，重要的是不要对不同类型和等级的绝缘施加过大的应力，并且必须考虑以下因素。
- Where an ENCLOSURE or part of ENCLOSURE consists of non-conductive surfaces, metal foil is applied. Care is taken that the metal foil is positioned in such a manner that 如果外壳或外壳的一部分由非导电表面组成，则应使用金属箔。注意金属箔的放置方式应确保

flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface.

绝缘衬里边缘不会发生闪络。如适用，移动金属箔以测试表面的所有部分。

- The circuits on either side of the insulation under test should be connected or short circuited such that components within these circuits do not get stressed during the test. For example, the terminals of the MAINS PART, the SIGNAL INPUT/OUTPUT PART and the PATIENT CONNECTION(S) (if applicable) respectively are short circuited during the test.
 应连接或短路被测绝缘层任一侧的电路，以使这些电路中的组件在测试期间不会受到应力。例如，在测试期间，电源部分、信号输入/输出部分和患者连接（如适用）的端子分别短路。
- Where there are capacitors across the insulation under test (e.g. radio-frequency filter capacitors), they may be disconnected during the test, if they are certified to IEC 60384-14.
 如果被测绝缘层上有电容器（如射频滤波电容器），则在试验过程中可断开它们，前提是它们已通过IEC 60384-14的认证。

Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION
 表6——固体绝缘形成保护措施试验电压

PEAK WORKING VOLTAGE 峰值工作电压 {U} V peak V峰值	PEAK WORKING VOLTAGE 峰值工作电压 {U} V d.c. 直流电。	A.C. test voltages in V r.m.s. A、C.试验电压，单位：V r.m.s。							
		MEANS OF OPERATOR PROTECTION 操作员保护方法				MEANS OF PATIENT PROTECTION 保护病人的方法			
		Protection from 保护 MAINS PART 电源部分		Protection from 保护 SECONDARY CIRCUITS 二次回路		Protection from 保护 MAINS PART 电源部分		Protection from 保护 SECONDARY CIRCUITS 二次回路	
		One MOOP 一个 MOOP	Two MOOP 两个月	One MOOP 一个 MOOP	Two MOOP 两个月	One MOPP 一个 MOPP	Two MOPP 两个 MOPP	One MOPP 一个 MOPP	Two MOPP 两个 MOPP
U < 42,4 U<42,4	U < 60 U<60	1 000 1000 个	2 000 2000 个	No test 没有测试	No test 没有测试	1 500 1500 个	3 000 3000 个	500 500	1 000 1000 个
42,4 < U 42.4<U □ 71 □71	60 < U 60<U □ 71 □71	1 000 1000 个	2 000 2000 个	See Table 7 见表7	See Table 7 见表7	1 500 1500 个	3 000 3000 个	750 750	1 500 1500 个
71 < U □ 71 71<U□ 184 184	71 < U □ 71 71<U□ 184 184	1 000 1000 个	2 000 2000 个	See Table 7 见表7	See Table 7 见表7	1 500 1500 个	3 000 3000 个	1 000 1000 个	2 000 2000 个
184 < U 184<美国 □ 212 □212	184 < U 184<U □ 212 212	1 500 1500 个	3 000 3000 个	See Table 7 见表7	See Table 7 见表7	1 500 1500 个	3 000 3000 个	1 000 1000 个	2 000 2000 个
212 < U 212<U	212 < U 212<U	1 500	3 000	See	See	1 500	4 000	1 500	3 000

□ 354 □354	□ 354 □354	1500 个	3000 个	Table 7 见表7	Table 7 见表7	1500 个	4000 个	1500 个	3000 个
354 < U 354<U □ 848 848欧元	354 < U 354<U □ 848 848欧元	See Table 7 见表7	3 000 3000 个	See Table 7 见表7	See Table 7 见表7	□2U □2件 +1 000 +100 0个	2 x (□2U 2 x (□2U) + 1 500) +1500 个)	□2U □2件 +1 000 +100 0个	2 x (□2U 2 x (□2U) + 1 500) +1500 个)
848 < U 848<美国 □ 1 414 □1414	848 < U 848<美国 □ 1 414 □1414	See Table 7 见表7	3 000 3000 个	See Table 7 见表7	See Table 7 见表7	□2U + 1 000 □2U +10 00	2 x (□2U 2 x (□2U) + 1 500) +1500 个)	□2U □2件 +1 000 +100 0个	2 x (□2U 2 x (□2U) + 1 500) +1500 个)
1 414 < U 1414<美国 □ 10 000 10000欧元	1 414 < U 1414<美国 □ 10 000 10000欧元	See Table 7 见表7	See Table 7 见表7	See Table 7 见表7	See Table 7 见表7	U/□2 库存 612/ 件 + 2 000 +200 0个	□2U □2件 + 5 000 +500 0个	U/□2 U/□2 + 2 000 +200 0个	□2U □2件 + 5 000 +500 0个
10 000 < 1万< U 美国 ≤ 14 140 ≤14 140	10 000 < 1万< U 美国 ≤ 14 140 ≤14 140	1,06 x 1.06倍 U/□2 U/□2	1,06 x 1.06倍 U/□2 U/□2	1,06 x 1.06倍 U/□2 U/□2	1,06 x 1.06倍 U/□2 U/□2	U/□2 U/□2 + 2 000 +200 0个	□2U □2件 + 5 000 +500 0个	U/□2 U/□2 + 2 000 +200 0个	□2U □2件 + 5 000 +500 0个
U > U> 14 140 14 140 个	U > U> 14 140 14 140 个	If necessary, to be prescribed by particular standards 必要时，按特定标准规定							

NOTE 1 For a barrier according to:
注1:

- Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.
图J.6，使用“患者保护方法-二次回路保护”一栏MOPP。
拖把。
- 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.
8.5.2.1和图J.7，使用患者保护-电源保护-一个MOPP列。

NOTE 2 See the rationale for 8.8.3.
注2见8.8.3的基本原理。

Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION
表7—操作员保护装置的试验电压

Test voltage in V r.m.s.
试验电压，单位：V r.m.s。

PEAK WORKI NG VOLTA GE 峰值工 作电压 (U) (U) V peak or V d.c. V峰值 或V直 流。	One MOOP 一个 MOOP	Two MOOP 两个月	PEAK WORKI NG VOLTA GE 峰值工 作电压 (U) (U) V peak or V d.c. V峰值 或V直 流。	One MOOP 一个 MOOP	Two MOOP 两个月	PEAK WORKI NG VOLTA GE 峰值工 作电压 (U) (U) V peak or V d.c. V峰值 或V直 流。	One MOOP 一个 MOOP	Two MOOP 两个月
34 34	500 500	800 800	250 250	1 261 126 1年	2 018 201 8年	1 750 1750年	3 257 3257个	3 257 3257个
35 35	507 507	811 811	260 260	1 285 128 5年	2 055 205 5年	1 800 1800个	3 320 3320个	3 320 3320个
36 36	513 513	821 821	270 270	1 307 130 7年	2 092 209 2年	1 900 1900个	3 444 3444个	3 444 3444个
38 38	526 526	842 842	280 280	1 330 133 0个	2 127 127 2个	2 000 2000个	3 566 3566个	3 566 3566个
40 40	539 539	863 863	290 290	1 351 135 1个	2 162 211 6个	2 100 2100个	3 685 3685个	3 685 3685个
42 42	551 551	882 882	300 300	1 373 137 3个	2 196 219 6年	2 200 2200个	3 803 3803个	3 803 3803个
44 44	564 564	902 902	310 310	1 394 139 4年	2 230 223 0个	2 300 2300个	3 920 3920年	3 920 3920年
46 46	575 575	920 920	320 320	1 414 141 4年	2 263 226 3个	2 400 2400个	4 034 4034个	4 034 4034个
48 48	587 587	939 939	330 330	1 435 143 5年	2 296 226 2个	2 500 2500个	4 147 4147个	4 147 4147个
50 50	598 598	957 957	340 340	1 455 145 5年	2 328 228 2个	2 600 2600个	4 259 4259个	4 259 4259个
52 52	609 609	974 974	350 350	1 474 147 4年	2 359 235 9个	2 700 2700个	4 369 4369个	4 369 4369个
54 54	620 620	991 991	360 360	1 494 149 4年	2 390 239 0个	2 800 2800个	4 478 4478个	4 478 4478个
56 56	630 630	1 1	380 380	1 1	2 2	2 900 2 900	4 586 4 586	4 586 4 586

56	630	008 200 8年	380	532 153 2年	451 245 1个	2900个	4586个	4586个
58	641	1 025	400	1 569	2 510	3 000	4 693	4 693
58	641	102 5个	400	156 9年	251 0个	3000个	4693个	4693个
60	651	1 041	420	1 605	2 567	3 100	4 798	4 798
60	651	104 1年	420	160 5年	256 7个	3100个	4798个	4798个
62	661	1 057	440	1 640	2 623	3 200	4 902	4 902
62	661	105 7年	440	164 0个	262 3个	3200个	4902个	4902个
64	670	1 073	460	1 674	2 678	3 300	5 006	5 006
64	670	107 3年	460	674 1 674 2 678 3 300 5 006 5 006 66 680 1 088 480 1 707 2 731 3 400 5 108 5 108 68 690 1 103 500 1 740 2 784 3 500 5 209 5 209 70 699 1 118 520 1 772 2 835 3 600 5 309 5 309 72 708 1 133 540 1 803 2 885 3 800 5 507 5 507 74 717 1 147 560 1 834 2	678 2 678 3 300 5 006 5 006 66 680 1 088 480 1 707 2 731 3 400 5 108 5 108 68 690 1 103 500 1 740 2 784 3 500 5 209 5 209 70 699 1 118 520 1 772 2 835 3 600 5 309 5 309 72 708 1 133 540 1 803 2 885 3 800 5 507 5 507 74 717 1 147 560 1 834 2	3 300 3 300	5 006 5 006	5 006 5 006

934
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744
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190
600
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893
3
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600
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268
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268
85
765
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224
620
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785
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					6 811 100 825 1 319 680 2 006 3 000 5 400 6 987 6 987 105 844 1 350 700 2 034 3 000 5 600 7 162 7 162 110 862 1 379 720 2 060 3 000 5 800 7 334 7 334 115 880 1 408 740 2 087 3 000 6 000 7 504 7 504 120 897				
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108	
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108	
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209	
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209	
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309	
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309	
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507	
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507	
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702	
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702	
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894	
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894	
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082	
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082	
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268	
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268	

		190		893	000				
85	765	1	620	1	3	4 800	6 452	6 452	
		224	620	922	000	4 800	6 452	6 452	
		1		1	3				
90	785	224		922	000				
		1	640	1	3	5 000	6 633	6 633	
90		257	640	951	000	5 000	6 633	6 633	
		1		1	3				
95	805	257		951	000				
95	805	288	660	979	000	5 200	6 811	6 811	
		1		1	3	5 200	6 811	6 811	
		288		979	000				
100	825	1	680	2	3	5 400	6 987	6 987	
100		319	680	006	000	5 400	6 987	6 987	
		1		2	3				
105	844	319		006	000				
105	844	350	700	2	3	5 600	7 162	7 162	
		1		034	000	5 600	7 162	7 162	
		350		2	3				
110	862	379	720	034	000	5 800	7 334	7 334	
110	862	1		2	3	5 800	7 334	7 334	
		379		060	000				
115	880	1	740	2	3	6 000	7 504	7 504	
115	880	408	740	087	000	6 000	7 504	7 504	
		1		2	3				
120	897	408		087	000				
120		436	760	2	3	6 200	7 673	7 673	
		1		113	000	6 200	7 673	7 673	
		436		2	3				
		760		113	000				
		2							
		113							
		3							
		000							
		6							
		200							
		7							
		673							
		7							
		673							
		125							
		915							
		1							
		463							
		780							
		2							
		138							
		3							
		000							
		6							
		400							
		7							
		840							
		7							
		840							
		130							
		931							
		1							
		490							
		800							
		2							
		164							
		3							
		000							
		6							
		600							
		8							
		005							
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		005							
		135							
		948							
		1							
		517							
		850							
		2							
		225							
		3							
		000							
		6							
		800							
		8							
		168							
		8							
		168							
		140							
		964							
		1							
		542							
		900							

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		000							
		1							
		664							
		1							
		200							
		2							
		611							
		3							
		000							
		8							
		200							
		9							
		273							
		9							
		273							
		170							
		1							
		000							
		1							
		688							
		1							
		250							
		2							
		661							
		3							
		000							
		8							
		400							
		9							
		425							
		9							
		425							
		175							
		1							
		000							
		1							
		711							
		1							
		300							
		2							
		710							
		3							
		000							
		8							
		600							
		9							
		577							
		9							
		577							
		180							
		1							
		000							
		1							
		733							
		1							
		350							
		2							
		758							
		3							
		000							
		8							
		800							
		9							
		727							
		9							
		727							
		184							
		1							
		000							
		1							
		751							
		1							
		400							
		2							
		805							
		3							
		000							
		9							
		000							
125	915	1	780	2	3	6 400	7 840	7 840	
125	915	463	780	138	000	6 400	7 840	7 840	
		1		2	3				
		463		138	000				
130	931	1	800	2	3	6 600	8 005	8 005	
130	931	490	800	164	000	6 600	8 005	8 005	
		1		2	3				
		490		164	000				
135	948	1	850	2	3	6 800	8 168	8 168	
135	948	517	850	225	000	6 800	8 168	8 168	
		1		2	3				
		517		225	000				
140	964	1	900	2	3	7 000	8 330	8 330	
140	964	542	900	285	000	7 000	8 330	8 330	
		1		2	3				

145	980	542	950	285	000	7 200	8 491	8 491
145	980	568	950	343	3	7 200	8 491	8 491
		1		2	000			
		568		343	3			
150	995	1	1	2	000	7 400	8 650	8 650
150	995	593	000	399	3	7 400	8 650	8 650
		1	1	2	000			
		593	000	399	3			
152	1 000	1	1	2	000	7 600	8 807	8 807
152	1 000	600	050	454	3	7 600	8 807	8 807
		1	1	2	000			
		600	050	454	3			
155	1 000	1	1	2	000	7 800	8 964	8 964
155	1 000	617	100	508	3	7 800	8 964	8 964
		1	1	2	000			
		617	100	508	3			
160	1 000	1	1	2	000	8 000	9 119	9 119
160	1 000	641	150	560	3	8 000	9 119	9 119
		1	1	2	000			
		641	150	560	3			
165	1 000	1	1	2	000	8 200	9 273	9 273
165	1 000	664	200	611	3	8 200	9 273	9 273
		1	1	2	000			
		664	200	611	3			
170	1 000	1	1	2	000	8 400	9 425	9 425
170	1 000	688	250	661	3	8 400	9 425	9 425
		1	1	2	000			
		688	250	661	3			
175	1 000	1	1	2	000	8 600	9 577	9 577
175	1 000	711	300	710	3	8 600	9 577	9 577
		1	1	2	000			
		711	300	710	3			
180	1 000	1	1	2	000	8 800	9 727	9 727
180	1 000	733	350	758	3	8 800	9 727	9 727
		1	1	2	000			
		733	350	758	3			
184	1 000	1	1	2	000	9 000	9 876	9 876
184	1 000	751	400	805	3	9 000	9876个	9876个
		1	1	2	000			
		751	400	805	3			
185	1 097	1	1	2	000	9 200	10 024	10 024
185	1097年	755	410	814	3	9200个	10024年	10024年
		175	141	281	300			
		5年	0个	4个	0个			
190	1 111	1	1	2	000	9 400	10 171	10 171
190	1111	777	450	868	3	9400个	10171	10171
		177	145	286	300			
		7年	0个	8年	0个			
200	1 137	1	1	2	000	9 600	10 317	10 317
200	1137年	820	500	934	3	9600个	10317年	10317年
		182	150	293	300			
		0年	0个	4年	0个			
210	1 163	1	1	2	000	9 800	10 463	10 463
210	1163个	861	550	000	3	9800个	10463个	10463个
		186	155	300	300			
		1年	0个	0个	0个			
220	1 189	1	1	2	000	10 000	10 607	10 607
220	1189年	902	600	065	3	10 000 1万	10607年	10607年
		190	160	306	306			
		2年	0个	5年	5年			
230	1 214	1	1	2	000			
230	1214年	942	650	130	3			
		194	165	313	313			
		2年	0个	0个	0个			
240	1 238	1	1	2	000			
240	1238年	980	700	194	3			
		198	170	319	319			
		0年	0个	4年	4年			

8.8.4 Insulation other than wire insulation

电线绝缘以外的绝缘

8.8.4.1 * Mechanical strength and resistance to heat

*机械强度和耐热性

The resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

在医用电气设备的预期使用寿命期间，所有类型的绝缘材料（包括绝缘隔墙）应保持耐热性。

Compliance is checked by inspection of the ME EQUIPMENT and the design documentation, and, if necessary, inspection of the RISK MANAGEMENT FILE and, if necessary, in conjunction with the following tests: 通过检查医用电气设备和设计文件，如有必要，检查风险管理文件，如有必要，结合以下测试检查合规性：

- resistance to moisture, etc. (see 11.6);
防潮性等（见11.6）；
- dielectric strength (see 8.8.3);
介电强度（见8.8.3）；
- mechanical strength (see 15.3).
–机械强度（见15.3）。

Resistance to heat is established by the following tests, which need not be performed if satisfactory evidence of compliance is provided.

通过以下试验确定耐热性，如果提供了令人满意的符合性证据，则无需进行这些试验。

- a) For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could result in an unacceptable RISK, by the ball-pressure test:

对于外壳部件和其他外部绝缘部件，其劣化可能导致不可接受的风险，通过球压试验：

ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords and parts of ceramic material, are subjected to a ball-pressure test using the test apparatus shown in Figure 21. The surface of the part to be tested is placed in the horizontal position and a steel ball of 5 mm diameter is pressed against the surface with a force of 20 N. The test is performed in a heating cabinet at a temperature of $75\text{ °C} \pm 2\text{ °C}$ or the ambient temperature indicated in the technical description (see 7.9.3.1) $\pm 2\text{ °C}$ plus the temperature rise of the relevant part of insulating material measured during the test of 11.1, whichever is the higher. 绝缘材料的外壳和其他外部部件（软线绝缘和陶瓷材料部件除外）应使用图21所示的试验装置进行球压试验。将待测零件的表面置于水平位置，用20 N的力将直径为5 mm的钢球压在表面上。在温度为 $75\text{ °C} \pm 2\text{ °C}$ 或技术说明（见7.9.3.1） $\pm 2\text{ °C}$ 的加热箱中进行试验在11.1试验期间测量的绝缘材料相关部分的温升，以较高者为准。

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. An impression greater than 2 mm in diameter constitutes a failure. 1小时后取出钢球，测量钢球压痕的直径。如果压痕直径大于2 mm，则视为不合格。

- b) For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test:

对于支撑电源部件未绝缘部件的绝缘材料部件，其劣化可能影响医用电气设备的安全性，通过球压试验：

A test is performed as described in a) above, but at a temperature of $125\text{ °C} \pm 2\text{ °C}$ or at the ambient temperature indicated in the technical description (see 7.9.3.1) $\pm 2\text{ °C}$

plus the temperature rise that was determined during the test of 11.1 of the relevant part, whichever is the higher.
按照上述A)所述进行试验,但温度为 $125^{\circ}\text{C}\pm 2^{\circ}\text{C}$,或在技术说明(见7.9.3.1) $\pm 2^{\circ}\text{C}$ 的环境温度加上相关零件11.1试验期间确定的温升,以较高者为准。

The test is not performed on parts of ceramic material, insulating parts of commutators, brush-caps and the like, and on coil formers not used as REINFORCED INSULATION.
不在陶瓷材料部件、换向器绝缘部件、刷帽等以及未用作加强绝缘的线圈成型器上进行试验。

NOTE For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also 13.1.2.
注:有关热塑性材料的补充绝缘和加强绝缘,另见13.1.2。

8.8.4.2 Resistance to environmental stress 抗环境压力

The insulating characteristics and mechanical strength of any MEANS OF PROTECTION shall be so designed or protected that it is not likely to be impaired by environmental stresses including deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in 8.9.
任何保护装置的绝缘特性和机械强度的设计或保护应确保其不会受到环境应力(包括灰尘沉积)或医用电气设备内零件磨损产生的灰尘的影响,以致爬电距离和空气间隙降低到8.9中规定的值以下。

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as
未紧密烧结的陶瓷材料等,以及仅使用珠子

SUPPLEMENTARY INSULATION or REINFORCED INSULATION.
附加绝缘或加强绝缘。

Insulating material in which heating conductors are embedded may be considered as one
嵌入加热导体的绝缘材料可视为一种

MEANS OF PROTECTION but shall not be used as two MEANS OF PROTECTION.
但不得用作两种保护手段。

Compliance is checked by inspection, by measurement and for natural latex rubber by the following test:

通过检查、测量和以下试验检查天然乳胶橡胶的合规性：

Parts of natural latex rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least 10 times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97 % pure, to a pressure of 2,1 MPa ± 70 kPa. 天然乳胶橡胶的一部分在压力下在氧气环境中老化。样品自由悬浮在氧气瓶中，氧气瓶的有效容量至少是样品体积的10倍。气瓶内充满纯度不低于97%的市售氧气，压力为2.1 MPa±70 kPa。

The samples are kept in the cylinder at a temperature of 70 °C ± 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined. Cracks visible to the naked eye constitute a failure. 将样品保存在70°C±2°C的钢瓶中96 h。随后，立即将其从钢瓶中取出，并在室温下放置至少16 h。试验结束后，对样品进行检查。肉眼可见的裂纹构成失效。

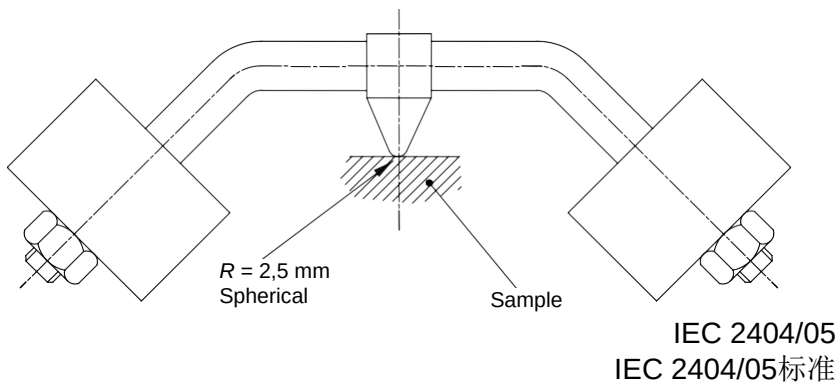


Figure 21 – Ball-pressure test apparatus
图21——球压试验装置
(see 8.8.4.1)
(见8.8.4.1)

8.9 * CREEPAGE DISTANCES and AIR CLEARANCES
*爬电距离和空气间隙

8.9.1 * Values
*价值观

8.9.1.1 General
总则

CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal to or greater than the values of Table 11 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.: 医用电气设备的爬电距离和空气间隙应等于或大于表11至表16（含）的值，8.9.1.2至8.9.1.15中规定的除外。另见8.9.2至8.9.4：

- for insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION in accordance with Table 13, Table 14 and Table 16; and 对于任何电源保险丝或过电流脱扣器电源侧电源部分相反极性部件之间的绝缘，应提供表13、表14和表16中规定的一种操作员保护装置；以及

- for insulation providing at least a MEANS OF PROTECTION, in accordance with Table 12 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.
对于至少提供保护手段的绝缘，应符合表12至表16（包括表12）的要求，但8.9.1.2至8.9.1.15中规定的情况除外。另见8.9.2至8.9.4。

8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1 爬电距离和空气间隙符合IEC 60950-1

The values of Table 11 12 to Table 16 (inclusive) do not apply to CREEPAGE DISTANCES and AIR CLEARANCES forming MEANS OF OPERATOR PROTECTION that comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION and are used in the conditions (e.g. overvoltage category, pollution degree) under which compliance was tested.
表11、表12至表16（含）的值不适用于构成操作员保护装置的爬电距离和空气间隙，这些装置符合IEC 60950-1绝缘协调的要求，并用于进行符合性试验的条件（例如过电压类别、污染程度）。

8.9.1.3 CREEPAGE DISTANCES across glass, mica, ceramic and similar materials 玻璃、云母、陶瓷和类似材料的爬电距离

For CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics, the specified minimum value of AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.
对于穿过具有类似跟踪特性的玻璃、云母、陶瓷和其他无机绝缘材料的爬电距离，应采用规定的最小空气间隙值作为最小爬电距离。

8.9.1.4 Minimum CREEPAGE DISTANCE 最小爬电距离

If the minimum CREEPAGE DISTANCE derived from Table 11 12 to Table 16 (inclusive) is less than the applicable minimum AIR CLEARANCE, that value of minimum AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.
如果表11-12至表16（含）得出的最小爬电距离小于适用的最小空气间隙，则最小空气间隙值应作为最小爬电距离。

8.9.1.5

ME EQUIPMENT RATED for high altitudes

高海拔医用电气设备

Unless otherwise declared by the MANUFACTURER, ME EQUIPMENT is RATED to operate at an altitude □ 2 000 m. Where ME EQUIPMENT is intended to be operated in a pressurized environment, e.g. aircraft, the operating altitude corresponding to the air pressure concerned shall be used in determining multiplication factor from Table 8. The AIR CLEARANCE is then multiplied by this factor. CREEPAGE DISTANCES are not subject to the multiplication factors but shall always be at least as large as the resulting value for AIR CLEARANCE.

除非制造商另有声明，医用电气设备的额定运行高度为□2 000 m。如果医用电气设备拟在加压环境（如飞机）中运行，则应使用与相关气压相对应的工作高度来确定表8中的倍增系数。然后将空气间隙乘以该系数。爬电距离不受倍增系数的影响，但应始终至少与空气间隙的结果值一样大。

Table 8 – Multiplication factors for AIR CLEARANCES

表8——空气间隙的倍增系数

for altitudes up to 5 000 m

海拔不超过5000米

RATED operating altitude (a) m	Normal barometric pressure kPa	Multiplication factor for MOOP	Multiplication factor for MOPP
a ≤ 2 000	80,0	1,00	1,00
2 000 < a ≤ 3 000	70,0	1,14	1,00
3 000 < a ≤ 4 000	62,0	1,29	1,14
4 000 < a ≤ 5 000	54,0	1,48	1,29
NOTE 1 The multiplication factors for MEANS OF OPERATOR PROTECTION relate to IEC 60950-1, which specifies AIR CLEARNACES for altitudes up to 2 000 m.			
NOTE 2 The multiplication factors for MEANS OF PATIENT PROTECTION relate to the second edition of IEC 60601-1, which specified spacing AIR CLEARANCES for altitudes up to 3 000 m.			
NOTE 3 The multiplication factors for MOOPS (column 3) are derived from IEC 60664- 1: ~~2007~~ ~~1992 as-~~ amended.			

8.9.1.6

* Interpolation

*插值

If the WORKING VOLTAGE has a value between those given in Table 11 12 to Table 16 (inclusive):

如果工作电压值介于表11、12至表16（含）之间：

- for determining CREEPAGE DISTANCES, linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;
为了确定爬电距离，允许在最近的两个值之间进行线性插值，计算的间距四舍五入到下一个较高的0.1mm增量；
- for determining AIR CLEARANCES for PEAK WORKING VOLTAGES above 2 800 V peak or d.c., linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;
为确定峰值工作电压高于2800V峰值或直流电时的空气间隙，允许在最近的两个值之间进行线性插值，计算的间距四舍五入到下一个较高的0.1mm增量；
- for determining AIR CLEARANCES for PEAK WORKING VOLTAGE up to 2 800 V peak or d.c., the higher of the two values shall be applied.
为确定峰值工作电压高达2800V峰值或直流电的空气间隙，应采用两个值中较高的一个。

8.9.1.7

Material groups classification

物料组分类

Material groups are classified as shown in Table 9.

材料组分类如表9所示。

Table 9 – Material group classification
表9——材料组分类

Material group 材料组	Comparative tracking index (CTI) 比较跟踪指数 (CTI)
I Ⅰ	600 □ CTI 600□CTI公司
II Ⅱ	400 □ CTI < 600 400□CTI<600
IIIa Ⅲa公司	175 □ CTI < 400 175□CTI<400
IIIb Ⅲb公司	100 □ CTI < 175 100□CTI<175

The material group is verified by evaluation of the test data for the material according to IEC 60112 using 50 drops of solution A.

根据IEC 60112，使用50滴溶液A，通过评估材料的试验数据来验证材料组。

If the material group is not known, material group IIIb shall be assumed.

如果材料组未知，应假设材料组Ⅲb。

8.9.1.8 Pollution degree classification 污染程度分类

Pollution degrees are classified as follows:
污染程度划分如下：

- Pollution degree 1 is used to describe a micro-environment that is sealed so as to exclude dust and moisture.

污染度1用于描述封闭的微环境，以排除灰尘和湿气。

NOTE 1 An example of such a micro-environment is a sealed or potted component or assembly.
注1：这种微环境的一个例子是密封或密封的部件或组件。

- Pollution degree 2 is used to describe a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.

污染度2用于描述仅发生非导电性污染的微环境，偶尔会出现由冷凝引起的暂时导电性。

- Pollution degree 3 is used to describe a micro-environment that is subject to conductive pollution, or to dry non-conductive pollution that could become conductive due to expected condensation.

污染度3用于描述受到导电污染或干燥非导电污染的微环境，该污染可能由于预期的冷凝而变得导电。

- Pollution degree 4 is used to describe a micro-environment where continuous conductivity occurs due to conductive dust, rain or other wet conditions.

污染度4用于描述由于导电性粉尘、雨水或其他潮湿条件而产生连续导电性的微环境。

NOTE 2 This type of environment can occur inside commutating motors which generate carbon dust from the brushes.

注2：这种环境可能发生在换向电机内部，这些电机从电刷中产生碳粉。

Pollution degree 4 is not acceptable for insulation providing a MEANS OF PROTECTION. However, in the case where insulation between the MAINS PART and earth might be compromised, it is necessary to provide measures, such as planned maintenance, to ensure that the micro-environment is mitigated to a lower pollution degree.
对于提供保护措施的绝缘，4级污染是不可接受的。但是，如果电源部分和地面之间的绝缘可能受损，则有必要提供措施，如计划维护，以确保微环境减轻到较低的污染程度。

Annex M specifies measures that may be used to reduce the pollution degree.
附录M规定了可用于降低污染程度的措施。

8.9.1.9 Overvoltage category classification 过电压分类

The applicable value of the MAINS TRANSIENT VOLTAGE shall be determined from the overvoltage category according to IEC 60664-1 and the NOMINAL a.c. MAINS VOLTAGE using Table 10.
电源瞬态电压的适用值应根据IEC 60664-1的过电压类别和表10中的标称交流电源电压确定。

8.9.1.10 AIR CLEARANCE for MAINS PARTS 主要部件的空气间隙

For MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V, the required AIR CLEARANCE shall be the value in Table 13 for the r.m.s. or d.c. RATED MAINS VOLTAGE plus the additional AIR CLEARANCE in Table 14 for the PEAK WORKING VOLTAGE.

对于在300 V以下额定电源电压下运行的电源部件，所需的空气间隙应为表13中r.m.s.或d.c.额定电源电压加上表14中峰值工作电压的额外空气间隙。

8.9.1.11 SUPPLY MAINS overvoltage

电源过压

This standard relates to overvoltage category II according to IEC 60664-1. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is overvoltage category III, the values specified in Table 13 to Table 15 (inclusive) will be inadequate for clearance. Therefore the values given in the next MAINS TRANSIENT VOLTAGE column upwards shall be used. Whilst it is not envisaged that PATIENT protection (Table 12) will be required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, should this be necessary, guidance is given on the values required in the rationale for Subclause 8.9.

根据IEC 60664-1，本标准涉及II类过电压。如果医用电气设备拟用于供电干线为III类过电压的位置，则表13至表15（含）中规定的值不足以满足间隙要求。因此，应使用下一个向上的电源瞬态电压列中给出的值。虽然没有设想在三类过电压供电干线上使用医用电气设备需要患者保护（表12），但如果有必要，则在第8.9款基本原理中给出了所需值的指导。

Table 10 – MAINS TRANSIENT VOLTAGE
 表10-电源瞬态电压

NOMINAL a.c. SUPPLY MAINS voltage line-to- neutral 标称交流电源线至中性点 up to and including V r.m.s. 小于等于V r.m.s。	MAINS TRANSIENT VOLTAGE 电源瞬态电压 V peak V峰值			
	Overvoltage Category 过压范围			
	I 我	II 二	III 三	IV 四
50 50	330 330	500 500	800 800	1 500 150 0个
100 100	500 500	800 800	1 500 150 0个	2 500 250 0个
150 a 150安	800 800	1 500 150 0个	2 500 250 0个	4 000 400 0个
300 b 300磅	1 500 150 0个	2 500 250 0个	4 000 400 0个	6 000 600 0个
600 c 600摄氏度	2 500 250 0个	4 000 400 0个	6 000 600 0个	8 000 800 0个
NOTE 1 In Norway, due to the IT power distribution system used, the a.c SUPPLY MAINS voltage is considered to be equal to the line-to-line voltage, and will remain 230 V in case of a single earth fault. 注1：在挪威，由于采用IT配电系统，交流电源电压被视为等于线对线电压，并且在发生单一接地故障时将保持230 V。				
NOTE 2 In Japan, the value of the MAINS TRANSIENT VOLTAGES for the NOMINAL a.c. 注2：在日本，标称交流电源瞬态电压值。 SUPPLY MAINS voltage of 100 V is determined from columns applicable to the NOMINAL 根据适用于标称值的列确定100 V的电源电压 a.c. SUPPLY MAINS voltage of 150 V. a、c.电源电压为150V。				
a Including 120/208 or 120/240 V. a包括120/208或120/240伏。 b Including 230/400 or 277/480 V. b包括230/400或277/480 V。 c Including 400/690 V. c包括400/690伏。				

8.9.1.12 SECONDARY CIRCUITS

二次回路

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I according to IEC 60664-1 if the MAINS PART is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 15.

根据IEC 60664-1, 如果电源部分为II类过电压, 则从电源干线引出的二次电路通常为I类过电压; 表15的列标题中显示了I类过电压中各种电源电压的最大瞬态。

Where the SECONDARY CIRCUIT is earthed or the ME EQUIPMENT is INTERNALLY POWERED, Table 15 applies.

如果二次电路接地或医用电气设备内部供电, 则表15适用。

Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14.

如果二次电路未接地, 且来自电源干线, 则该电路应符合表13和表14中一次电路的要求。

If the SECONDARY CIRCUIT is separated from the MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in the SECONDARY CIRCUIT are below the levels expected for overvoltage category I, (for example due to being attenuated by connecting a component, such as a capacitor, between the SECONDARY CIRCUIT and earth), the values in Table 15 apply.

如果二次电路通过功能接地或保护性接地金属屏蔽与电源部分分离, 或二次电路中的瞬态低于I类过电压的预期水平(例如, 由于在二次电路和接地之间连接一个电容器等元件而衰减), 表15中的值适用。

The column for circuits not subject to transient overvoltages applies to:

不受瞬态过电压影响的电路一栏适用于:

- d.c. SECONDARY CIRCUITS that are reliably connected to earth and have capacitive filtering which limits the peak-to-peak ripple to 10 % of the d.c. voltage; and
d、c.可靠接地并具有电容滤波的二次电路, 其将峰间纹波限制为直流电压的10%
- circuits in INTERNALLY POWERED ME EQUIPMENT.
医用电气设备内部供电。

8.9.1.13 PEAK WORKING VOLTAGES above 1 400 V peak or d.c.

峰值工作电压高于1400V峰值或直流。

The values in Table 15 for PEAK WORKING VOLTAGES above 1 400 V peak or d.c. do not apply if all the following conditions are satisfied:

如果满足以下所有条件, 则表15中峰值工作电压高于1400 V峰值或直流电的值不适用:

- the AIR CLEARANCE is at least 5 mm;
空气间隙至少为5 mm;
- the insulation involved passes a dielectric strength test according to 8.8.3 using:
 - an a.c. test voltage whose r.m.s. value is equal to 1,06 times the PEAK WORKING VOLTAGE or
交流试验电压, 其r.m.s.值等于峰值工作电压的1.06倍或
 - a d.c. test voltage equal to the peak value of the a.c. test voltage prescribed above;
直流试验电压等于上述交流试验电压的峰值;

- and
和
- the AIR CLEARANCE path is partly or entirely through air or along the surface of an insulating material of material group I.

空气间隙路径部分或全部通过空气或沿着材料组I的绝缘材料的表面。

If the AIR CLEARANCE path is also partly along the surface of a material that is not material group I, the dielectric strength test is conducted only across the part(s) of the path that are through air.
如果空气间隙路径部分沿着非I类材料的表面进行，则介电强度试验仅在穿过空气的路径部分进行。

8.9.1.14 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION
两种操作员保护装置的最小爬电距离

Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values shown in Table 16 for one MEANS OF OPERATOR PROTECTION.

两种操作员保护方式的最小爬电距离是通过将表16中所示的一种操作员保护方式的值加倍得到的。

8.9.1.15 * CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-
PROOF APPLIED PARTS
*除颤应用部件的爬电距离和空气间隙

CREEPAGE DISTANCES and AIR CLEARANCES needed to satisfy 8.5.5.1 for DEFIBRILLATION-
PROOF

满足8.5.5.1除颤要求的爬电距离和空气间隙
APPLIED PARTS shall not be less than 4 mm.
应用部件不得小于4 mm。

NOTE In Table 11 and Table 12, which detail the spacing for PATIENT protection, the CREEPAGE DISTANCE and AIR CLEARANCE are both related to r.m.s. or d.c. WORKING VOLTAGES. In Table 13, Table 14 and Table 15, which detail the spacing for OPERATOR protection, the clearance AIR CLEARANCE is related to peak or d.c. WORKING VOLTAGE and the CREEPAGE DISTANCE is related to r.m.s. or d.c. WORKING VOLTAGE.

注：表11和表12详细说明了保护病人的间距，爬电距离和空气间隙都与r.m.s.或d.c.工作电压有关。在表13、表14和表15中，详细说明了操作员保护的间距，间隙空气间隙与峰值或直流工作电压有关，爬电距离与r.m.s.或直流工作电压有关。

Table 11 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts
of opposite polarity of the MAINS PART Not used
表11-未使用的电源部件极性相反部件之间的最小爬电距离和
空气间隙

WORKI NG VOLTA GE 工作电 压 V d.c. 直流 电。 up to and	WORKIN G VOLTAG E 工作电压 V r.m.s. V r.m.s.公 司。 up to and including 包括	CREEPAGE DISTANCE 爬电距离 mm 毫米	AIR CLEARAN CE 空气间隙 mm 毫米

including 包括			
17 17	12 12	0,8 0,8个	0,4 0,4个
43 43	30 30	1 1	0,5 0,5个
85 85	60 60	1,3 1, 3	0,7 0,7个
177 177	125 125	2 2	1 1
354 354	250 250	3 三	1,6 1,6个
566 566	400 400	4 4	2,4 2,4个
707 707	500 500	5,5 5,5个	3 三
934 934	660 660	7 7	4 4
1 061 1061年	750 750	8 8	4,5 4,5个
1 414 1414年	1 000 100 0个	11 11	6 6

Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing

表12——最小爬电距离和空气间隙

MEANS OF PATIENT PROTECTION

保护病人的方法

WORKING VOLTAGE 工作电压 V d.c. 直流电。 up to and including 包括	WORKING VOLTAGE 工作电压 V r.m.s. V r.m.s.公司。 up to and including 包括	Spacing providing 间距提供 one MEANS OF PATIENT PROTECTION 一种保护病人的方法		Spacing providing 间距提供 two MEANS OF PATIENT PROTECTION 两种保护病人的方法	
		CREEPAGE DISTANCE 爬电距离 mm 毫米	AIR CLEARANCE 空气间隙 mm 毫米	CREEPAGE DISTANCE 爬电距离 mm 毫米	AIR CLEARANCE 空气间隙 mm 毫米
17 17	12 12	1,7 1,7个	0,8 0,8个	3,4 3,4个	1,6 1,6个
43 43	30 30	2 2	1 1	4 4	2 2
85 85	60 60	2,3 2, 3	1,2 1, 2	4,6 4,6个	2,4 2,4个
177 177	125 125	3 三	1,6 1,6个	6 6	3,2 3, 2
354 354	250 250	4 4	2,5 2,5个	8 8	5 5
566 566	400 400	6 6	3,5 3,5个	12 12	7 7
707 707	500 500	8 8	4,5 4,5个	16 16	9 9
934 934	660 660	10,5 10,5个	6 6	21 21	12 12
1 061 1061年	750 750	12 12	6,5 6,5个	24 24	13 13
1 414 1414年	1 000 1000个	16 16	9 9	32 32	18 18
1 768 1768年	1 250 1250个	20 20	11,4 11,4号	40 40	22,8 22,8个
2 263 2263个	1 600 1600个	25 25	14,3 14,3号	50 50	28,6 28,6岁
2 828 2828个	2 000 2000个	32 32	18,3 18,3号	64 64	36,6 36,6个
3 535 3535个	2 500 2500个	40 40	22,9 22,9岁	80 80	45,8 45,8个
4 525 4525个	3 200 3200个	50 50	28,6 28,6岁	100 100	57,2 57.2万
5 656	4 000	63	36,0	126	72,0

5656个	4000个	63	36,0分	126	72.0万
7 070 7070	5 000 5000个	80 80	45,7 45,7岁	160 160	91,4 91,4个
8 909 8909年	6 300 6300个	100 100	57,1 57,1号	200 200	114,2 114,2号
11 312 11 312	8 000 8000个	125 125	71,4 71,4个	250 250	142,8 142,8个
14 140 14 140个	10 000 1万	160 160	91,4 91,4个	320 320	182,8 182,8个

Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the

表13–最小空气间隙为操作员提供保护，使其免受

MAINS PART

电源部分

AIR CLEARANCE in mm

空气间隙（mm）

WORKING VOLTAGE 工作电压 up to and including 包括		NOMINAL MAINS VOLTAGE 标称电源电压 < 150 V <150伏 (MAINS TRANSIENT VOLTAGE 1 500 V) (电源瞬态电压1500 V)		150 V < 150伏< NOMINAL MAINS VOLTAGE 标称电源电压 < 300 V <300伏 (MAINS TRANSIENT VOLTAGE 2 500 V) (电源瞬态电压2500 V)		300 V < 300伏< NOMINAL MAINS VOLTAGE 标称电源电压 < 600 V <600伏 (MAINS TRANSIENT VOLTAGE 4 000V) (电源瞬态电压4000V)	
Voltage peak or d.c. 电压峰值或直流。	Voltage r.m.s (sinusoidal) 电压有效值(正弦曲线)	Pollution degrees 1 and 2 污染程度1度和2度		Pollution degree 3 污染程度3		Pollution degrees 1, 2 and 3 污染程度1、2和3度	
		One MOOP 一 穆普	Two MOOP 二 穆普	One MOOP 一 穆普	Two MOOP 二 穆普	One MOOP 一 穆普	Two MOOP 二 穆普
210 210	150 150	1, 0 1, 0 个	2, 0 2, 0 个	1, 3 1, 3 个	2, 6 2, 6 个	2, 0 2, 0 个	4, 0 4, 0 个
420 420	300 300	1 MOOP 2, 0 2 MOOP 4, 0 1摩尔2, 0 2摩尔4, 0				3, 2 3, 2	6, 4 6, 4 个
840 840	600 600	1 MOOP 3, 2 2 MOOP 6, 4 1个月3, 2个月6, 4					
1 400	1 000	1 MOOP 4, 2 2 MOOP 6, 4					

140 0个	100 0个	1个月4,2个月 6,4
2 800 280 0个	2 000 200 0个	1 or 2 MOOP 8,4 1或2 MOOP 8,4
7 000 700 0个	5 000 500 0个	1 or 2 MOOP 17,5 1或2 MOOP 17,5
9 800 980 0个	7 000 700 0个	1 or 2 MOOP 25 1或2 MOOP 25
14 000 140 00个	10 000 1万	1 or 2 MOOP 37 1或2 MOOP 37
28 000 280 00个	20 000 200 00个	1 or 2 MOOP 80 1或2 MOOP 80
AIR CLEARANCES for WORKING VOLTAGES above 20 kV r.m.s. or 28 kV d.c. can be prescribed by particular standards if necessary. 如有必要，工作电压高于20kV r.m.s.或28kV d.c.的空气间隙可由特殊标准规定。		
NOTE AIR CLEARNACES are a function of peak voltage in the circuit. The r.m.s. voltage column is provided for the special case where the voltage has a sinusoidal waveform. 注：空气净化器是电路中峰值电压的函数。r.m.s.电压列用于电压具有正弦波形的特殊情况。		

Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE a

表14—峰值工作电压超过标称电源电压a峰值的电源部件绝缘的附加空气间隙
(see 8.9.1.10)
(见8.9.1.10)

NOMINAL MAINS VOLTAGE 标称电源电压 □ 150 V r.m.s. or 210 V d.c. □150 V r.m.s.或210 V d.c。		150 V r.m.s. or 210 V dc < NOMINAL MAINS VOLTAGE 150 V r.m.s.或210 V dc<标称电源电压 □ 300 V r.m.s. or 420 V d.c. □300 V r.m.s.或420 V d.c。	Additional AIR CLEARANCE 附加空气间隙 mm 毫米	
Pollution degrees 1 and 2 污染等级1和2	Pollution degree 3 污染程度3	Pollution degrees 1, 2 and 3 污染等级1、2和3	One MOOP 一个穆普	TWO MOOP 二穆普
PEAK WORKING VOLTAGE 峰值工作电压 V 五	PEAK WORKING VOLTAGE 峰值工作电压 V 五	PEAK WORKING VOLTAGE 峰值工作电压 V 五		
210 210 298 298	210 210 294 294	420 420 493 493	0 0 0,1 0,1	0 0 0,2 0,2个
386 386	379 379	567 567	0,2 0,2个	0,4 0,4个
474 474	463 463	640 640	0,3 0,3个	0,6 0,6
562 562	547 547	713 713	0,4 0,4个	0,8 0,8个
650 650	632 632	787 787	0,5 0,5个	1,0 1,0个
738	715	860	0,	1,2

738	715	860	6 0, 6	1, 2
826	800	933	0, 7	1,4
826	800	933	0, 7 个	1,4个
914		1 006	0, 8	1,6
914		2006年	0, 8 个	1,6个
1 002		1 080	0, 9	1,8
100		1080个	0, 9	1,8个
2年				
1 090		1 153	1, 0	2,0
109		1153年	1, 0 个	2,0个
0年				
		1 226	1, 1	2,2
		1226年	1, 1 , 1	2, 2
		1 300	1, 2	2,4
		1300个	1, 2 1 , 2	2,4个

a When using this table, select the appropriate column for the RATED MAINS VOLTAGE and pollution degree and choose the row in that column which covers the actual PEAK WORKING VOLTAGE. Read the additional AIR CLEARANCE required from the relevant right hand column (for one or two MEANS OF OPERATOR PROTECTION and add this to the minimum AIR CLEARANCE from Table 13 to give the total minimum AIR CLEARANCE.

a在使用本表时，应为额定电源电压和污染程度选择适当的列，并在该列中选择涵盖实际峰值工作电压的行。从相关右侧栏中读取所需的额外空气间隙（用于一种或两种操作员保护措施），并将其添加到表13中的最小空气间隙中，以得出总最小空气间隙。

NOTE For voltage values above the PEAK WORKING VOLTAGE values given in the table, linear extrapolation is permitted.

注：对于高于表中给出的峰值工作电压值的电压值，允许线性外推。

Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR
PROTECTION in SECONDARY CIRCUITS

表15-二次电路中操作员保护装置的最小空气间隙
(see 8.9.1.12)
(见8.9.1.12)

AIR CLEARANCES in mm
空气间隙（mm）

WORKING VOLTAGE 工作电压 up to and including 包括		Transient value for 瞬态值 SECONDARY CIRCUIT 二次回路 □ 800 V □800伏 (NOMINAL MAINS VOLTAGE (标称电源电压 □ 150 V) □150伏)				Transient value for 瞬态值 SECONDARY CIRCUIT 二次回路 □ 1 500 V □1500伏 (150 V < (150伏< NOMINAL MAINS VOLTAGE 标称电源电压 □ 300 V) □300伏)				Transient value for 瞬态值 SECONDARY CIRCUIT 二次回路 □ 2 500 V □2500伏 (300 V < NOMINAL MAINS VOLTAGE (300 V<标称电源电压 □600 V) □600伏)		Circuit not subject to transient overvoltages 不受瞬态影响的电路过电压	
Voltag e V peak or 电压V 峰值 或 V d.c. 直流电。	Voltag e V r.m.s. (sinu- 电压V r.m.s. (sinu- soidal) 索 达 尔)	Pollutio n degree s 1 and 2 污 染 等 级1和2		Pollution degree 3 污染程度 3		Pollutio n degree s 1 and 2 污 染 等 级1和2		Pollution degree 3 污染程度 3		Pollution degrees 污染程度 1, 2 and 3 1、2和3		Pollution degrees 污染程度 1 and 2 only 仅1和2	
		One MO OP 一个 MO OP	Two MO OP 两个月	One MO OP 一个 MO OP	Two MO OP 两个月	One MO OP 一个 MO OP	Two MO OP 两个月	One MO OP 一个 MO OP	Two MO OP 两个月	One MO OP 一个 MO OP	Two MO OP 两个月	One MO OP 一个 MO OP	Two MO OP 两个月
71 71	50 50	0,7 0,7	1,4 1,4	1,3 1,	2,6 2,6	1,0 1,0	2,0 2,0	1,3 1,	2,6 2,6	2,0 2,0	4,0 4,0	0, 4	0,8 0,8

[illegible]

个		
NOTE AIR CLEARANCES are a function of peak voltage in the circuit. The r.m.s voltage column is provided for the special case where the voltage has a sinusoidal waveform. 注：空气净化器是电路中峰值电压的函数。r.m.s电压列用于电压具有正弦波形的特殊情况。		

Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION a
表16–提供操作员保护手段的最小爬电距离a

CREEPAGE DISTANCE in mm
爬电距离（mm）

WORKING VOLTAGE 工作电压 V 五 r.m.s or d.c. r、m.s或 d.c。	Spacing for one MEANS OF OPERATOR PROTECTION 一种操作员保护装置的间距						
	Pollution degree 1 污染程度1	Pollution degree 2 污染程度2			Pollution degree 3 污染程度3		
	Material group 材料组	Material group 材料组			Material group 材料组		
	I, II, IIIa, IIIb 一、二、 三、三、三	I 我	II 二	IIIa or IIIb IIIa或IIIb	I 我	II 二	IIIa or IIIb IIIa或IIIb
50	Use the 使用 AIR CLEARANC E 空气间隙 from the appropriate 从适当的 table 桌子	0,	0,	1,2	1,5	1,7	1,9
50		6	9	1,	1,5	1,7	1,9
100		0,	0,	2	个	个	个
100		6	9	1,4	1,8	2,0	2,2
125		0,	1,	1,4	1,8	2,0	2,
125		7	0	个	个	个	2
150		0,	1,	1,5	1,9	2,1	2,4
150		7	0	1,5	1,9	2,	2,4
200		个	个	个	个	1	个
200		0,	1,	1,6	2,0	2,2	2,5
250		8	1	1,6	2,0	2,	2,5
250		0,	,	个	个	2	个
300		8	1	2,0	2,5	2,8	3,2
300		个	1,	2,0	2,5	2,8	3,
400		0,	1	个	个	个	2
400		8	1	2,5	3,2	3,6	4,0
600		0,	,	2,5	3,	3,6	4,0
600		个	1	个	2	个	个
800		1,	1,	3,2	4,0	4,5	5,0
800		0	4	3,	4,0	4,5	5,0
1000		1,	1,	2	个	个	分
1000		0	4	4,0	5,0	5,6	6,3
1000		个	个	4,0	5,0	5,6	6,3
1000		1,	1,	个	分	个	个
1000		3	8	6,3	8,0	9,6	10,
1000		1	1,	6,3	8,0	9,6	0
1000		,	8	个	分	个	10,
1000		3	个	个	分	个	0分
1000		1,	2,	8,0	10,	11,	12,
1000		6	2	8,0	0	0	5
1000		1,	2	分	10,	11,	12,
1000		6	,	10,	0分	0号	12,

		个 2, 0 2, 0 个 3, 2 3 , 2 4. 0 4 5, 0 5, 0 分	2 2, 8 2, 8 个 4, 5 4, 5 个 5, 6 5, 6 个 7, 1 7, 1 号	0 10, 0分	12, 5 12, 5个	14, 0 14. 0万	5个 16, 0 16, 0分

NOTE Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

注：两种操作员保护装置的最小爬电距离是通过将该表中的值加倍得到的。

a CREEPAGE DISTANCES within this table apply to all situations.

表中的爬电距离适用于所有情况。

WORKING VOLTAGE 工作电压 V 五 r.m.s or d.c. r、 m.s或 d.c。	Spacing for one MEANS OF OPERATOR PROTECTION 一种操作员保护装置的间距						
	Pollution degree 1 污染程度1	Pollution degree 2 污染程度2			Pollution degree 3 污染程度3		
	Material group 材料组	Material group 材料组			Material group 材料组		
	I, II, IIIa, IIIb 一、二, 三, 三, 三	I 我	II 二	IIIa or IIIb IIIa或IIIb	I 我	II 二	IIIa or IIIb IIIa或IIIb
25 25 50 50 100 100 125 125 150 150 200 200 250	Use the 使用 AIR CLEARANC E 空气间隙 from the appropriate 从适当的 table 桌子	0, 5 0, 5 个 0, 6 0, 6 0, 7 0, 7 个	0. 5 0. 5 0, 9 0, 9 1, 0 1, 0 个 1,	0,5 0,5 个 1,2 1, 2 1,4 1,4 个 1,5 1,5 个 1,6 1,6	1,3 1, 3 1,5 1,5 个 1,8 1,8 个 1,9 1,9 个 2,0 2,0 个 2,1 2, 1 2,2	1,3 1, 3 1,7 1,7 个 2,0 2,0 个 2,1 2, 1 2,2	1,3 1, 3 1,9 1,9 个 2,2 2, 2 2,4 2,4 个 2,5 2,5

250		0,	1	个	个	2,	个
300		8	1	2,0	2,5	2	3,2
300		0,	,	2,0	2,5	2,8	3,
400		8	1	个	个	2,8	2
400		个	1,			个	
600		0,	1	2,5	3,2		4,0
600		8	1	2,5	3,	3,6	4,0
800		0,	,	个	2	3,6	个
800		8	1	3,2	4,0	个	5,0
1		个	1,	3,	4,0	4,5	5,0
000		1,	4	2	个	4,5	分
100		0	1,	4,0	5,0	个	6,3
0个		1,	4	4,0	5,0	5,6	6,3
		0	个	个	分	5,6	个
		个	1,	6,3	8,0	个	10,
		1,	8	6,3	8,0	9,6	0
		3	1,	个	分	9,6	10,
		1	8	8,0	10,	个	0分
		,	个	8,0	0	11,	12,
		3	2,	分	10,	0	5
		1,	2	10,	0分	11,	12,
		6	2	0	12,	0号	5个
		1,	,	10,	5	14,	16,
		6	2	0分	12,	0	0
		个	2,		5个	14.	16,
		2,	8			0万	0分
		0	2,				
		2,	8				
		0	个				
		3,	4,				
		2	5				
		3	4,				
		,	5				
		2	个				
		4.	5,				
		0	6				
		4	5,				
			6				
		5,	个				
		0	7,				
		5,	1				
		0	7,				
		分	1				
			号				

NOTE 1 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

注1：两种操作员保护装置的最小爬电距离通过将该表中的值加倍获得。

NOTE 2 A CREEPAGE DISTANCE cannot be less than the required air clearance. See 8.9.1.4. NOTE 3 For WORKING VOLTAGE values greater than 1 000 V, refer to Table A.2.

注2爬电距离不能小于要求的空气间隙。见8.9.1.4。注3：对于大于1000 V的工作电压值，参考表A.2。

a CREEPAGE DISTANCES within this table apply to all situations.

表中的爬电距离适用于所有情况。

For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested. The sample is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4, followed by humidity preconditioning according to 5.7

except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1.6. The tests are followed by inspection, including sectioning, and measurement. Cracks or voids in the insulating compound such as would affect the homogeneity of the material constitute a failure. 对于绝缘化合物在导电部件之间形成固体绝缘的情况，测试单个成品样品。按照8.9.3.4的规定，对样品进行热循环程序，然后根据5.7进行湿度预处理（仅48小时除外），然后根据8.8.3进行介电强度试验，但试验电压乘以1.6。测试之后是检查，包括切片和测量。绝缘化合物中可能影响材料均匀性的裂纹或空隙构成失效。

8.9.3.3 Insulating compound forming a cemented joint with other insulating parts 与其他绝缘部件形成胶合接头的绝缘化合物

For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples. If a winding of solvent-based enamelled wire is used, it is replaced for the test by a metal foil or by a few turns of bare wire, placed close to the cemented joint. The three samples are then tested as follows. 对于绝缘化合物与其他绝缘部件形成胶结接头的情况，通过测试三个样品来检查接头的可靠性。如果使用溶剂型漆包线绕组，则在试验中用金属箔或几圈裸线代替，放在水泥接头附近。然后对三个样品进行如下测试。

- One of the samples is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4. Immediately after the last period at highest temperature during thermal cycling it is subjected to a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1.6; 对其中一个样品进行8.9.3.4中规定的热循环程序。在热循环过程中的最高温度下的最后一段时间后，应立即按照8.8.3进行介电强度试验，但试验电压乘以1.6;
- The other two samples are subjected to humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1.6. 其他两个样品按照5.7进行湿度预处理（仅48小时除外），然后根据8.8.3进行介电强度试验，但试验电压乘以1.6。

8.9.3.4 Thermal cycling 热循环

The sample is subjected 10 times to the following sequence of temperature

cycles: 68 h at $T1 \pm 2\text{ }^{\circ}\text{C}$;

将样品按以下顺序进行10次温度循环：温度为 $T1\pm2^{\circ}\text{C}$ 时为

68小时；

1 h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$;

$25^{\circ}\text{C}\pm2^{\circ}\text{C}$ 下1h；

2 h at $0\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$;

$0^{\circ}\text{C}\pm2^{\circ}\text{C}$ 下2h；

not less than 1 h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$,

where $T1$ is the higher of

在 $25^{\circ}\text{C}\pm2^{\circ}\text{C}$ 下不少于1h，其中 $T1$ 为

- $10\text{ }^{\circ}\text{C}$ above the maximum temperature of the relevant part as determined according to 11.1.1; or

高于根据11.1.1确定的相关部件最高温度 10°C ；或

- $85\text{ }^{\circ}\text{C}$.

–85摄氏度。

However, the $10\text{ }^{\circ}\text{C}$ margin is not added if the temperature is measured by an embedded thermocouple.

但是，如果使用嵌入式热电偶测量温度，则不会增加 10°C 的裕度。

The period of time taken for the transition from one temperature to another is not specified, but the transition is permitted to be gradual.

没有规定从一种温度过渡到另一种温度所需的时间，但允许逐渐过渡。

8.9.4 * Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

8.9.4*爬电距离和空气间隙的测量

Compliance is checked by measurement taking into account the rules in Figure 22 to Figure 31 (inclusive). In each figure, the dashed line () represents AIR CLEARANCE and the shaded bar () represents CREEPAGE DISTANCE.

根据图22至图中的规则，通过测量检查合规性
31 (inclusive). In each figure, the dashed line () represents AIR CLEARANCE and the shaded bar () represents CREEPAGE DISTANCE.

31（含）。在每个图中，虚线（）表示空气间隙，阴影条（）表示爬电距离。

The minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE in Figure 23 to Figure 25 and Figure 27 to Figure 31 (inclusive) that are considered a MEANS OF OPERATOR PROTECTION may be adjusted based on pollution degree if the minimum AIR CLEARANCE is 3 mm or more. The minimum width of the groove is:
图23至图25和图27至图31（含）中与爬电距离横向的槽的最小间距（X）可根据污染程度进行调整，前提是最小空气间隙为3mm或更大。凹槽的最小宽度为：

- 0,25 mm for pollution degree 1
污染等级1为0.25 mm
- 1,0 mm for pollution degree 2
污染等级2为1.0 mm
- 1,5 mm for pollution degree 3
污染等级3为1.5 mm

If the specified minimum AIR CLEARANCE is less than 3 mm, the minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE is the lesser of:

如果规定的最小空气间隙小于3 mm，则垂直于爬电距离的凹槽的最小间距（X）为以下较小值：

- the relevant value specified in the previous paragraph, or
前款规定的相关价值，或
- one third of the specified minimum AIR CLEARANCE.
规定最小空气间隙的三分之一。

The minimum spacing (X) for a groove transverse to a CREEPAGE DISTANCE that is considered a MEANS OF PATIENT PROTECTION is 1 mm for pollution degree 1 and pollution degree 2, and 1,5 mm for pollution degree 3.
横向于爬电距离的沟槽的最小间距（X）被认为是一种患者保护手段，对于污染等级1和污染等级2，最小间距（X）为1 mm，对于污染等级3，最小间距为1.5 mm。

Any corner with included angle less than 80° is assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 25).

任何夹角小于80°的角落都被假定用1 mm的绝缘链环桥接在最不利的位置（见图25）。

Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 24).

如果穿过沟槽顶部的距离为1 mm或更大，则整个空气空间中不存在爬电距离（见图24）。

CREEPAGE DISTANCES and AIR CLEARANCES between parts moving relative to each other are measured with the parts in their least favourable positions.

在零件处于最不利位置时，测量相对运动部件之间的爬电距离和空气间隙。

Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.

计算的爬电距离绝不小于测量的空气间隙。

Coatings of varnish, enamel or oxide are ignored. Coverings of any insulating material, however, are considered as insulation, if the covering is equivalent to a sheet of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.
清漆、搪瓷或氧化物涂层被忽略。但是，任何绝缘材料的覆盖层，如果其电气、热和机械性能相当于一层厚度相等的绝缘材料，则视为绝缘。

If CREEPAGE DISTANCES or AIR CLEARANCES for one or two MEANS OF PROTECTION are interrupted by one or more floating conductive parts, the minimum values specified in Table 11 12 to Table 16 (inclusive) apply to the sum of the sections, except that distances less than 1 mm are not taken into consideration.
如果一个或两个保护装置的爬电距离或空气间隙被一个或多个浮动导电部件中断，则表11、表12至表16（包括表16）中规定的最小值适用于截面总和，但小于1 mm的距离不被考虑在内。

If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 24). In all other cases the groove is neglected.
如果有横向爬电距离的沟槽，只有当槽的宽度大于1 mm时，槽壁才算作爬电距离（见图24）。在所有其他情况下，凹槽都被忽略了。

In the case of a barrier placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCES are measured over the barrier only if the latter is so affixed that dust and moisture cannot penetrate into the joint or recess.
如果绝缘层表面或凹陷处设置了屏障，则只有当屏障的附着方式使灰尘和水分无法渗透到接头或凹槽中时，才测量绝缘层上的爬电距离。

For ME EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other ME EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified by the MANUFACTURER and also without conductors.
对于配有器具插座的医用电气设备，测量时应插入适当的连接器。对于包含电源线的其他医用电气设备，它们由制造商规定的最大横截面积的电源导线制成，也不包括导线。

Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.
将活动部件放在最不利的位置；将带有非圆头的螺母和螺钉拧紧到最不利的位置。

CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts are measured to the standard test finger of Figure 6. If necessary, a force is applied to any point on bare conductors and to the outside of metal ENCLOSURES in an endeavour to reduce the CREEPAGE DISTANCES and AIR CLEARANCES while taking the measurements.

根据图6中的标准试验指，通过外部零件的槽或开口测量爬电距离和空气间隙。如有必要，对裸导线上的任何一点和金属外壳的外部施加力，以减小爬电距离和空气间隙，同时进行测量。

The force is applied by means of a standard test finger having a tip as shown in Figure 6 and has a value of:
通过具有图6所示尖端的标准试验指施加力，其值为：

2 N for bare conductors;

30 N for ENCLOSURES.

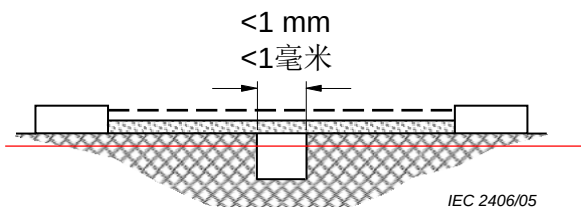
裸导线为2N；外壳为30N。

CREEPAGE DISTANCE and AIR CLEARANCES are measured after use of the test hook according to 5.9.2.2, if relevant.
根据5.9.2.2的规定，使用试验钩后测量爬电距离和空气间隙（如相关）。

Condition: Path under consideration is a flat surface.
条件：正在考虑的路径是平面。

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the surface.
规则：爬电距离和空气间隙直接通过表面测量。

Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1
图22-爬电距离和空气间隙-示例1

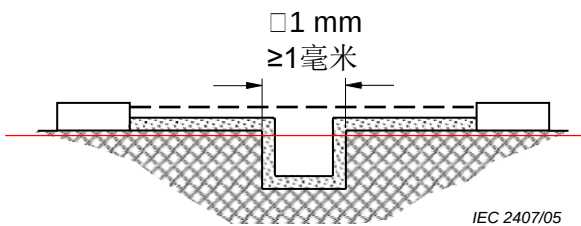


<X mm
<X毫米

Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1 mm.
条件：考虑中的路径包括并行-或收敛-边槽。

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.
规则：爬电距离和空气间隙直接穿过凹槽，如图所示。

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2
图23-爬电距离和空气间隙-示例2



□X mm
≥X毫米

Condition: 条件:

Path under consideration includes a parallel-sided
所考虑的路径

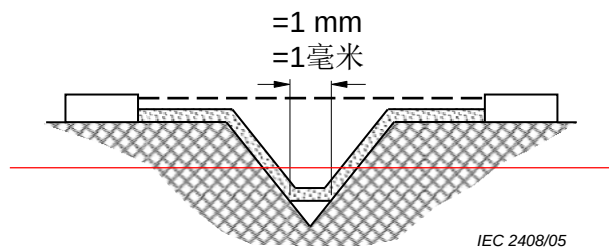
Rule:
规则:

包括平行边
groove of any
depth and equal
to or more than
1 X mm.
任何深度且等于
或大于1 X mm的
凹槽。

AIR
CLEARANCE

is the “line of sight”
distance. CREEPAGE
空气间隙是“视线”距离。
爬电
DISTANCE path
follows the contour of
the groove.
距离路径沿着凹槽的
轮廓。

Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3
图24-爬电距离和空气间隙-示例3



>X mm
>X 毫米

Condition: Path under consideration
条件：正在考虑的路径

Rule: includes a V-shaped
规则：包括宽度大于1 X mm
且内角小于80°的V形
槽。

AIR CLEARANCE is
the “line of sight”
distance. CREEPAGE
空气间隙是“视线”距离。
爬电

DISTANCE path
follows the contour of
the groove but “short
circuits” the bottom of
距离路径遵循凹槽轮
廓，但“短路”底部
the groove by a 1 X mm link.
通过1 X mm连杆的凹槽。

Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4
图25—爬电距离和空气间隙—示例4

Condition: Path under consideration
条件：正在考虑的路径
includes a rib.
包括肋骨。

Rule: AIR CLEARANCE is the shortest
规则：空气间隙最短
direct air path over the
top of the rib.
CREEPAGE
DISTANCE
肋骨顶部的直接空气通
道。爬电距离
path follows the
contour of the rib.
沿着肋骨的轮廓走。

Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5

图26-爬电距离和空气间隙-示例5

<1 mm <1毫米<1毫米	<1 mm		
IEC 2410/05 IEC 2410/05标准			
<X mm mm <X毫米<X毫米	<X	Path under consideration 正在考虑的路径 includes an uncemented joint (see 8.9.3) with	grooves less than 1 X mm wide on each side. 包括一个无粘结接缝 (见8.9.3)，每侧有小于1 X mm宽的凹槽。
Condition: 条件:			CREEPAGE DISTANCE and AIR 爬电距离和空气
Rule: 规则:			CLEARANCE path are the “line of sight” distance shown. 间隙路径是所示的“视线” 距离。

Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6
图27-爬电距离和空气间隙-示例6

□1 mm □1 mm
≥1毫米≥1毫米

IEC 1418/12
IEC 1418/12标准

Condi
on:
条件:

Rule:
规则:

Path under consideration
正在考虑的路径
includes an
uncemented joint (see
8.9.3) with grooves
equal to or more that 1
X mm wide
包括无粘结接缝（见
8.9.3），凹槽宽度等于
或大于1 X mm
on each side.
在每一边。

AIR CLEARANCE is
the “line of sight”
distance. CREEPAGE
空气间隙是“视线”距离。
爬电
DISTANCE path
follows the contour of
the groove.
距离路径沿着凹槽的
轮廓。

Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7
图28-爬电距离和空气间隙-示例7

□1 mm <1 mm
≥1毫米<1毫米

Condition:
条件:

Rule:
规则:

Path under consideration

正在考虑的路径

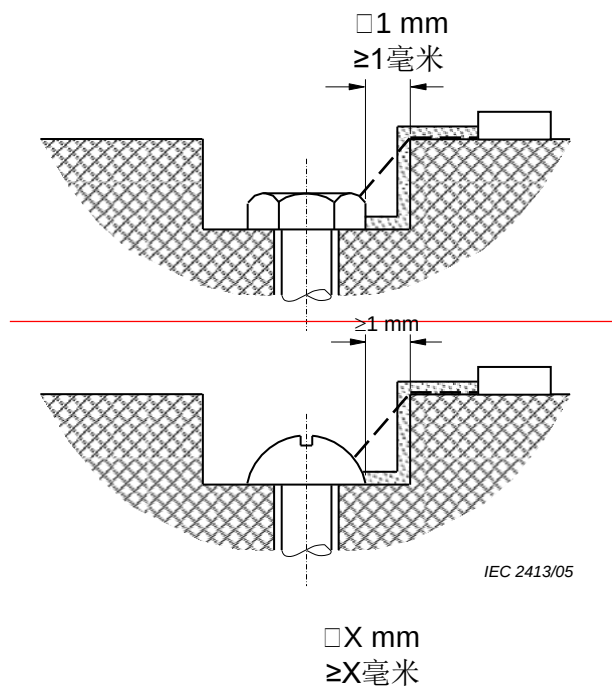
includes an uncemented joint (see 8.9.3) with a groove on one side less than 1 X mm wide and the groove on the other side equal to or more than 1 X mm wide.

包括一个非胶接接头（见8.9.3），其一侧的凹槽宽度小于1 X mm，且

另一侧宽度等于或大于1 X mm。

AIR CLEARANCE and CREEPAGE DISTANCE are as shown.
空气间隙和爬电距离如图所示。

Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8
图29-爬电距离和空气间隙-示例8

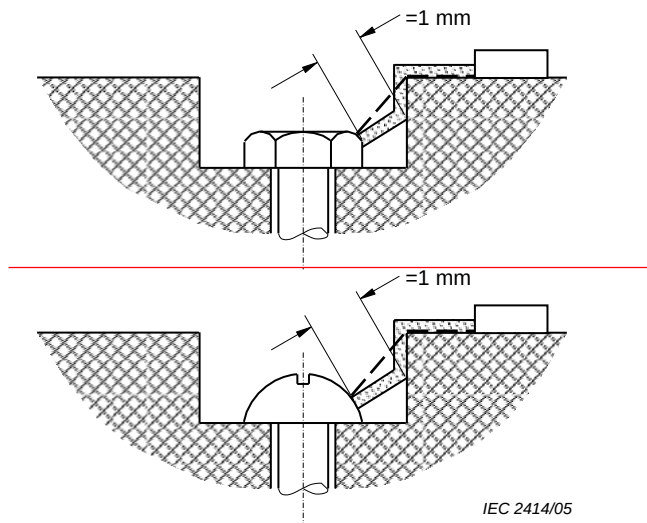


Condition: Gap between head of screw and wall of recess wide
条件：

Rule: enough to be taken into account.
规则：足够被考虑在内。

The AIR CLEARANCE is the shortest distance to any point on the head of the screw.
空气净化器是到螺钉头上任何点的最短距离。
CREEPAGE DISTANCE path follows the surface.
爬电距离路径跟随表面。

Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9
图30-爬电距离和空气间隙-示例9



Gap between head of screw and wall of recess too narrow to be taken into account.
 螺钉头和凹槽壁之间的间隙太窄，无法考虑。

Measurement of CREEPAGE
 爬电测量

Condition: DISTANCE is from screw to wall at any point where the
 条件：距离是指在
 Rule: distance is equal to 1 mm.
 规则：距离等于1毫米。
 The AIR CLEARANCE is the
 空气净化器是
 shortest distance to any point on the head of the screw.
 到螺钉头上任何点的最短距离。

Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10
 图31-爬电距离和空气间隙-示例10

8.10 Components and wiring 部件和接线

8.10.1 * Fixing of components *部件的固定

Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.
 医用电气设备的不必要移动可能导致不可接受的风险，应牢固安装，以防止此类移动。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
 通过检查医用电气设备和风险管理文件检查合规性。

8.10.2 * Fixing of wiring *接线固定

Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a HAZARDOUS SITUATION. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching circuit points parts resulting in a HAZARDOUS SITUATION described in 13.1. 医用电气设备的导线和连接器应固定或绝缘，以防意外分离而导致危险情况。如果在其接头处断裂并在其支撑点周围移动时能够接触到电路点部件，则认为它们没有充分固定，从而导致13.1中所述的危险情况。

Breaking free of one means of mechanical restraint shall be considered a SINGLE FAULT CONDITION.

脱离一种机械约束应视为单一故障状态。

Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a HAZARDOUS SITUATION described in 13.1.

如果绞合导线通过任何夹紧方式固定，则不应涂上焊料，接触不良可能导致13.1中所述的危险情况。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
通过检查医用电气设备和风险管理文件检查合规性。

8.10.3 Connections between different parts of ME EQUIPMENT 医用电气设备不同部件之间的连接

Flexible cords detachable without the use of a TOOL that are used for interconnection of different parts of ME EQUIPMENT shall be provided with means for connection such that compliance of metal ACCESSIBLE PARTS with 8.4 is not compromised when a connection is loosened or broken due to the disengagement of one of the connecting means.
医用电气设备不同部件互连时, 无需使用工具可拆卸的软线应配备连接装置, 以确保金属可触及部件符合第8.4节的要求, 当其中一个连接装置断开或松脱时, 不会影响金属可触及部件的合规性。

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to 5.9.2.1.

根据5.9.2.1, 通过检查和测量以及(如有必要)用标准试验指进行试验来检查合规性。

8.10.4 * Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (see also 15.4.7) *绳索连接的手持部件和绳索连接的脚踏控制装置(另见15.4.7)

8.10.4.1 Limitation of operating voltages 工作电压限制

Cord-connected HAND-HELD and foot-operated control devices of ME EQUIPMENT and their associated connection cords shall contain only conductors and components operating at voltages not exceeding 42,4 V peak a.c. or 60 V d.c. in circuits isolated from the MAINS PART by two MEANS OF PROTECTION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies.
医用电气设备的线连接手持式和脚踏式控制装置及其相关连接线应仅包含在电压不超过42.4V交流峰值或60V直流电压下运行的导体和部件, 这些电路通过两种保护措施与电源部分隔离。60 V的直流限制适用于峰值纹波不超过10%的直流电。如果纹波超过该值, 则42.4 V峰值限制适用。

Compliance is checked by inspection and, if necessary, voltage measurements.
通过检查和电压测量(如有必要)检查合规性。

8.10.4.2 Connection cords 连接线

The connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, shall comply with the requirements specified for POWER SUPPLY CORDS in 8.11.3, if breaking free or shorting between the conductors could result in a HAZARDOUS SITUATION described in 13.1. This requirement also applies to other HAND-HELD parts if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION described in 13.1.
软线两端与医用电气设备手持式或脚踏式控制装置的连接和锚固, 以及控制装置电缆两端的连接和锚固, 应符合8.11.3中对电源线的规定要求, 如果导线之间的自由断开或短路可能导致13.1中所述的危险情况。如果一个或多个连接的干扰或断裂可能导致13.1中所述的危险情况, 本要求也适用于其他手持部件。

Compliance is checked by performance of the tests of 8.11.3.
通过执行8.11.3中的试验来检查是否符合要求。

8.10.5 * Mechanical protection of wiring *接线机械保护

- a) Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1.
内部电缆和接线应充分保护, 以防与活动部件接触, 或在尖角和边缘摩擦, 因为绝缘损坏

可能导致13.1中所述的危险情况。

- b) ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1. 医用电气设备的设计应确保在组装或打开或关闭检修盖的过程中，接线、电线形式或组件不可能受损，此类损坏可能导致13.1中所述的危险情况。

Compliance is checked by inspection and, where appropriate, by manual test or reference to the RISK MANAGEMENT FILE.

合规性通过检查进行检查，并在适当情况下通过手动测试或参考风险管理文件进行检查。

8.10.6 Guiding rollers for insulated conductors **绝缘导线用导辊**

Guiding rollers of insulated conductors of ME EQUIPMENT shall be constructed in such a manner that movable insulated conductors in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned. 医用电气设备绝缘导线的导辊的构造应确保在正常使用中可移动绝缘导线的弯曲半径不小于相关导线外径的五倍。

Compliance is checked by inspection and measurement of the relevant dimensions. 通过检查和测量相关尺寸来检查是否符合要求。

8.10.7 * Insulation of internal wiring***内部接线绝缘**

a) If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured. Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.
如果医用电气设备的内部接线需要绝缘套管, 则应充分固定。为了满足这一要求, 可使用只能通过断裂或切割或两端固定的套管。

b) Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as a MEANS OF PROTECTION if it is subject to mechanical or thermal stresses outside its RATED characteristics.

在医用电气设备内部, 如果软线的护套受到超出其额定特性的机械或热应力, 则不得将其用作保护手段。

c) Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.
医用电气设备的绝缘导线, 在正常使用时, 其温度超过70°C, 如果符合本标准的要求很可能因绝缘性能恶化而受损, 则应采用耐热材料绝缘。

Compliance is checked by inspection and, if necessary, by special tests. Temperatures are determined as indicated in 11.1.

通过检查和特殊试验 (如有必要) 检查合规性。根据11.1中的指示确定温度。

8.11 MAINS PARTS, components and layout**电源部件、组件和布局****8.11.1 Isolation from the SUPPLY MAINS****与电源隔离**

a) * ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS

*医用电气设备应具有将其电路与供电干线电气隔离的装置

on

all

poles

simultaneously.

同时所有电极上。

PERMANENTLY INSTALLED ME EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 c).
与多相供电干线相连的永久安装医用电气设备可配备一个不会中断中性导线的装置, 前提是当地安装条件应确保在正常情况下中性导线上的电压不会超过8.4.2 c) 中规定的限值。

For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if:

对于永久性安装的医用电气设备, 在下列情况下, 将其电路与供电干线进行电气隔离的装置应能够锁定在关闭位置:

– reconnection would result in a HAZARDOUS SITUATION; or

重新连接会导致危险情况; 或

– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position.

任何操作员 (包括维修人员) 都无法查看与预期位置隔离的方式。

The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION.

锁定机构可以在责任机构提供的电源开关中。

The requirements for the isolation device shall be specified in the ACCOMPANYING DOCUMENTS.

隔离装置的要求应在随附文件中规定。

- b) Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.9.3.1). 隔离装置应包括在医用电气设备中，或者，如果是外部的，应在技术说明中说明（见 7.9.3.1）。

- c) * A SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV.

*符合8.11.1 A) 要求的电源开关应符合IEC 61058-1规定的4 kV电源瞬态电压下的爬电距离和空气间隙。

NOTE Table 22 in IEC 61058-1:2000 specifies different values for contact separation depending on the MAINS TRANSIENT VOLTAGE , which is referred to in that table as the “rated impulse withstand voltage.”

注：IEC 61058-1:2000中的表22根据电源瞬态电压规定了不同的触点分离值，在该表中被称为“额定冲击耐受电压”

- d) A SUPPLY MAINS switch shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead. 电源开关不得安装在电源线或任何其他外部软导线中。

- e) The direction of movement of the actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447. 符合8.11.1 a) 要求的电源开关执行器的运动方向应符合IEC 60447。

f) In non-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.
在没有电源开关的非永久性安装医用电气设备中，用于将医用电气设备与电源隔离的合适插头装置应被视为符合8.11.1 a) 的要求。可使用带电源插头的电器耦合器或软线。

g) A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.
熔丝或半导体器件不得用作本款意义上的隔离装置。

h) * ME EQUIPMENT shall not include a device that causes disconnection of the ME EQUIPMENT from the SUPPLY MAINS by producing a short circuit that results in operation of an over-current protection device.
*医用电气设备不应包括通过产生短路导致过电流保护装置运行而导致医用电气设备与电源断开的装置。

i) * Any part within the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 42,4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device that is accessible at all times shall be protected against being touched even after opening of the ENCLOSURE by an additional covering or, in the case of a spatially separated arrangement, shall be marked clearly as exceeding the permitted voltage for parts that can be touched. The use of the symbol ISO 7000-0434 (see Table D.1, symbol

*医用电气设备外壳内电路电压超过交流峰值42.4 V或直流60 V的任何部分，如果不能通过外部开关或随时可接近的插头装置断开其电源，则即使在打开外壳后，也应通过额外的覆盖物或，如果是空间分离布置，则应清楚地标记为超过可接触部件的允许电压。符号ISO 7000-0434的使用（见表D.1，符号

10) is not sufficient. A warning notice on the outside of the ME EQUIPMENT may be used.

10) 还不够。可使用医用电气设备外部的警告通知。

Compliance is checked by inspection.
通过检查检查合规性。

For a part that cannot be disconnected from the supply by an external switch or a plug device that is accessible at all times, compliance is checked by inspection of the required cover or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 6.

对于不能通过外部开关或随时可接近的插头装置断开电源的零件，通过检查所需的盖子或警告通知（如有）以及（如有必要）使用图6中的标准测试指检查合规性。

8.11.2 * MULTIPLE SOCKET-OUTLETS

*多个插座

MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT shall comply with the requirements of 16.2 d), second dash, and 16.9.2.1.
与医用电气设备集成的多个插座应符合16.2 d)、第二个破折号和第16.9.2.1条的要求。

Compliance is checked by inspection.
通过检查检查合规性。

8.11.3 POWER SUPPLY CORDS
电源线

8.11.3.1 Application

应用

The MAINS PLUG of ME EQUIPMENT shall not be fitted with more than one POWER SUPPLY CORD.
医用电气设备的电源插头不得配备一根以上的电源线。

Compliance is checked by inspection.
通过检查检查合规性。

8.11.3.2 Types
类型

Any POWER SUPPLY CORD of ME EQUIPMENT shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53).
医用电气设备的任何电源线的坚固性不得低于普通硬橡胶护套软线（IEC 60245-1:2003，附录A，名称53）或普通聚氯乙烯护套软线（IEC 60227-1:1993，附录A，名称53）。

A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for ME EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which can be touched in NORMAL USE by the cord, unless it is RATED for that temperature. See also Table 22.
聚氯乙烯绝缘电源线不得用于具有外部金属部件的医用电气设备，其外部金属部件的温度超过75℃，并且在正常使用过程中可以被电源线接触，除非其额定温度为该温度。另见表22。

Compliance is checked by inspection and measurement.
通过检查和测量来检查符合性。

8.11.3.3 Cross-sectional area of POWER SUPPLY CORD conductors
电源线导体的横截面积

The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than that shown in Table 17.
医用电气设备任何电源线导体的标称横截面积应不小于表17所示值。

Compliance is checked by inspection.
通过检查检查合规性。

Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD
 表17-电源线导线的标称横截面积

RATED current (I) of ME EQUIPMENT 医用电气设备额定电流 (I) A A	NOMINAL cross- sectional area 标称截面积 mm ² Cu 平方毫米铜
I □ 6 6号州际公路	0,75 0,75
6 < I □ 10 6<10	1 1
10< I □ 16 10<16	1,5 1,5个
16< I □ 25 16<25	2,5 2,5个
25< I □ 32 25<I□32	4 4
32< I □ 40 32<40	6 6
40< I □ 63 40<I□63	10 10

8.11.3.4 * APPLIANCE COUPLERS

*电器耦合器

APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.

符合IEC 60320-1的电器耦合器应符合8.11.3.5和8.11.3.6的要求。

Compliance is checked by inspection of the documentation demonstrating that the APPLIANCE COUPLER conforms to the requirements of IEC 60320-1.

通过检查证明电器耦合器符合IEC 60320-1要求的文件来检查符合性。

8.11.3.5 * Cord anchorage

*绳索锚固

a) The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.
 电源线的导线应消除应力，包括扭曲，导线的绝缘应在医用电气设备或电源连接器的入口点通过电源线固定点进行保护，以防磨损。

b) If a total insulation failure of the POWER SUPPLY CORD could cause conductive ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED to exceed the limits specified in 8.4, the cord anchorage of a POWER SUPPLY CORD shall be made:
 如果电源线的完全绝缘故障可能导致未进行保护接地的导电可触及部件超过8.4中规定的限值，则电源线的软线锚固应：

- of insulating material, or
绝缘材料，或
- of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by a

金属制，与可接触导电部件绝缘
MEANS OF PROTECTION, or
保护手段，或

- of metal provided with an insulating lining, which shall be affixed to the cord anchorage, unless it is a flexible bushing that forms part of the cord guard specified in 8.11.3.6, and which shall comply with the requirements for one MEANS OF PROTECTION.

带有绝缘衬里的金属制成，应将其固定在软线固定点上，除非它是构成8.11.3.6中规定的软线防护装置一部分的软套管，并且应符合一种保护方法的要求。

- c) The cord anchorage of a POWER SUPPLY CORD shall be so designed that the cord is not clamped by a screw that bears directly on the cord insulation.
电源线的电源线固定点的设计应确保电源线不会被直接承受电源线绝缘层的螺钉夹住。
- d) Screws, if any, that have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.
更换电源线时必须操作的螺钉（如有）不得用于固定除电源线固定点以外的任何部件。
- e) Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.
电源线导线的布置应确保，如果电源线固定装置发生故障，只要相导线与其端子接触，保护接地导线就不会受到应变。
- f) The cord anchorage shall prevent the POWER SUPPLY CORD from being pushed into the
电源线固定点应防止电源线被推入
ME EQUIPMENT or MAINS CONNECTOR.
医用电气设备或电源连接器。

Compliance is checked by inspection and by the following tests:
通过检查和以下试验检查合规性：

ME EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the
医用电气设备，如果设计为电源线，则使用
MANUFACTURER.
制造商。

The POWER SUPPLY CORD conductors are, if possible, disconnected from the terminals or from the MAINS CONNECTOR.
如果可能，电源线导线应与端子或电源连接器断开。

The cord is subjected 25 times to a pull on the sheath of the value shown in Table 18. The pulls are applied in the most unfavourable direction without jerks, each time for 1 s.
电缆在护套上受到表18所示值的拉力25次。在最不利的方向上施加拉力，每次持续1s。

Immediately afterwards, the cord is subjected for 1 min to a torque of the value shown in Table 18.
紧接着，将绳索施加表18所示扭矩1分钟。

Table 18 – Testing of cord anchorages
表18-脐带固定点的试验

Mass (m) of ME EQUIPMENT 医用电气设备质量 (m) kg 公斤	Pull 拉 N N	Torqu e 扭矩 Nm 海里
m □ 1 1月1日	30 30	0,1 0,1
1 < m □ 4 1<m□4	60 60	0,25 0,25
m > 4 m>4个	100 100	0,35 0,35 岁

A cord anchorage that allows the cord sheath to be longitudinally displaced by more than 2 mm or the conductor ends to move over a distance of more than 1 mm from their normally connected position is considered to fail.
允许电线护套纵向位移超过2 mm或导线端部从其正常连接位置移动超过1 mm的电线固定点被视为失效。

CREEPAGE DISTANCES and AIR CLEARANCES that are reduced below the values specified in 8.9 constitutes a failure.
爬电距离和空气间隙减小到8.9中规定的值以下即构成故障。

Attempt to push the cord into the ME EQUIPMENT or the MAINS CONNECTOR. If the cord can be pushed into the ME EQUIPMENT or the MAINS CONNECTOR to such an extent that the cord or internal parts are damaged, the cord anchorage is considered to fail.
尝试将电源线插入医用电气设备或电源连接器。如果电源线被推入医用电气设备或电源连接器，以致电线或内部部件损坏，则认为电源线固定装置失效。

8.11.3.6 *

Cord

guards

*绳索防护装置

POWER SUPPLY CORDS of other than STATIONARY ME EQUIPMENT shall be protected against excessive bending at the inlet opening of the equipment or of the MAINS CONNECTOR by means of a cord guard of insulating material or by means of an appropriately shaped opening in the ME EQUIPMENT.
固定式医用电气设备以外的电源线应通过绝缘材料的电源线防护罩或医用电气设备中适当形状的开口防止其过度弯曲。

Compliance is checked by inspection and by either the test described in IEC 60335-1:2001, subclause 25.14 or the following test. An arrangement that passes either test is considered to comply with the requirement.
通过检验和IEC 60335-1:2001第25.14款中所述的试验或以下试验来检查是否符合要求。通过任一试验的布置视为符合要求。

ME EQUIPMENT having a cord guard or opening is so placed that the axis of the cord guard, where the cord leaves it, projects at an angle of 45° when the cord is free from stress. A mass equal to $10 \times D^2$ gram is then attached to the free end of the cord, where D is the overall diameter of, or for flat cords, the minor overall dimension of the POWER SUPPLY CORD in millimetres.
医用电气设备带有护线罩或开口，当电源线不受应力时，其轴线（电源线离开时）以 45° 角突出。然后将一个等于 $10 \times D^2$ 克的质量连接到电源线的自由端，其中D是电源线的总直径，或者对于扁平线，电源线的次要外形尺寸为毫米。

If the cord guard is of temperature-sensitive material, the test is made at $23 \pm 2^\circ\text{C}$.

Flat cords are bent in the plane of least resistance.

如果软线护套是温度敏感材料，则在 $23^\circ\text{C} \pm 2^\circ\text{C}$ 下进行试验。在电阻最小的平面上

弯曲软线。

If the radius of curvature of the cord, immediately after the mass has been attached, is anywhere less than $1.5 \times D$, the cord guard is considered to fail.
如果在连接质量物后，绳索的弯曲半径小于 $1.5 \times D$ ，则认为绳索防护装置失效。

8.11.4 MAINS TERMINAL DEVICES 电源终端设备

8.11.4.1 * General requirements for MAINS TERMINAL DEVICES *电源终端设备的一般要求

PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT having a non-DETACHABLE POWER

永久安装的医用电气设备和具有不可拆卸电源的医用电气设备

SUPPLY CORD that is replaceable by SERVICE PERSONNEL shall be provided with MAINS TERMINAL DEVICES that ensure reliable connection.

维修人员可更换的电源线应配备电源终端装置，以确保可靠连接。

Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES that serve as a MEANS OF PROTECTION cannot be reduced to less than the values specified in 8.9, if any conductor breaks away. See also 8.10.2.
不得仅依靠端子来维持导线的位置，除非提供了屏障，以便在任何导线断开的情况下，作为保护手段的爬电距离和空气间隙不能减小到小于8.9中规定的值。另见8.10.2。

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this subclause and are properly marked according to 7.3.7.
除接线板外的部件端子可作为用于外部导体的端子使用，前提是它们符合本款的要求，并根据7.3.7进行了适当标记。

Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.
夹紧外部导线的螺钉和螺母不得用于固定任何其他部件，除非它们也可以夹紧内部导线，前提是它们的布置使它们在安装电源导线时不可能移位。

Compliance is checked by inspection.
通过检查检查合规性。

8.11.4.2 Arrangement of MAINS TERMINAL DEVICES 电源终端设备的布置

- a) * For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.
*对于带有可拆线电线的医用电气设备，其端子用于连接外部电源线或电源线，这些端子应与任何保护接地端子紧密地组合在一起，以便提供方便的连接方式。

Compliance is checked by inspection.
通过检查检查合规性。

- b) For details of PROTECTIVE EARTH CONDUCTOR connections, see 8.6.
有关保护接地导体连接的详细信息，请参阅8.6。

- c) For marking of MAINS TERMINAL DEVICES, see 7.3.
有关电源终端设备的标记，见7.3。

- d) MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL.
不使用工具不得接近电源终端设备。

Compliance is checked by inspection.
通过检查检查合规性。

- e) MAINS TERMINAL DEVICES shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short circuiting a MEANS OF PROTECTION is unlikely.
电源终端设备的位置或屏蔽应确保，如果在安装导线时，绞合导线的电线逸出，则不可能出现短路保护措施。

Compliance is checked by inspection and, if necessary, by the following test:
通过检查和（如有必要）以下试验检查合规性：

The end of a flexible conductor having the NOMINAL cross-sectional area specified in

Table 17 is stripped of its insulation for a length of 8 mm.
具有表17中规定的标称横截面积的软导线的端部剥去了8 mm长的绝缘层。

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.
绞合导线的一根导线保持自由，其余导线固定在端子上。

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.
在不拉回绝缘护套的情况下，自由导线向每个可能的方向弯曲，也不会隔板周围形成急弯。

Contact between the free wire and any other part such that a MEANS OF PROTECTION is short circuited constitutes a failure.
自由线与其他任何部件之间的接触导致保护装置短路，即构成故障。

8.11.4.3

Fixing

of

mains

terminals

电源端子的固定

Terminals shall be FIXED such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in 8.9.
端子的固定方式应确保，当夹紧导线的方法被拧紧或松开时，内部接线不受应力影响，爬电距离和空气间隙不会降低到8.9中规定的值以下。

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.
在紧固和松开规定的最大横截面积导线10次后，通过检查和测量来检查合规性。

8.11.4.4 * Connections to mains terminals

***与电源端子的连接**

Terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed that the conductors are not damaged and cannot slip out when the clamping means are tightened. See also 8.10.2.

带有可拆线软线夹紧装置的端子不需要对导线进行特殊准备, 以实现正确连接, 并且其设计或放置方式应确保导线不会损坏, 并且在夹紧装置拧紧时不会滑出。另见8.10.2。

Compliance is checked by inspection of the terminals and of the conductors after the test of 8.11.3.4.

在8.11.3.4的试验后, 通过检查端子和导线来检查合规性。

8.11.4.5 Accessibility of the connection

连接的可访问性

The space inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the ACCESS COVER is fitted. See also 8.10.5.

医用电气设备内设计用于固定布线或可拆线电源线的空间应足以使导线易于引入和连接, 并在不损坏导线或其绝缘层的情况下安装盖子(如有)。在安装检修盖之前, 应能够检查导线是否正确连接和定位。另见8.10.5。

Compliance is checked by inspection and by an installation test.

通过检查和安装测试检查是否符合要求。

8.11.5 * Mains fuses and OVER-CURRENT RELEASES

***电源保险丝和过电流脱扣器**

A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT and for CLASS II ME EQUIPMENT having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT, except that:

根据8.6.9, 一级医用电气设备和具有功能性接地连接的二级医用电气设备的每条电源线应配备保险丝或过电流脱扣器, 其他单相二级医用电气设备的至少一根电源线应配备保险丝或过电流脱扣器, 但以下情况除外:

- for PERMANENTLY INSTALLED ME EQUIPMENT, the neutral conductor shall not be fused;
对于永久性安装的医用电气设备, 中性导线不得熔断;
- if examination shows that two MEANS OF PROTECTION are present between all parts of opposite polarity within the MAINS PART, and between all parts of the MAINS PART and earth, then the fuses or OVER-CURRENT RELEASES may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short-circuit fault conditions in other circuits shall be considered VERIFIED before eliminating fuses or OVER-CURRENT RELEASES.
如果检查表明, 在电源部件内极性相反的所有部件之间以及电源部件的所有部件和接地之间存在两种保护方法, 则可以省略保险丝或过电流释放装置。这些绝缘要求应持续到任何部件。在消除保险丝或过电流脱扣器之前, 应考虑验证其他电路中短路故障条件的影响。

A PROTECTIVE EARTH CONDUCTOR shall not incorporate a fuse or OVER-CURRENT RELEASE.

保护接地导线不得包含保险丝或过电流脱扣器。

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.

保护装置应具有足够的断开能力, 以中断可能流动的最大故障电流(包括短路电流)。

NOTE If fuses complying with IEC 60127) are used and the prospective short-circuit current exceeds 35

A or

注：如果使用符合IEC 60127) 的保险丝，且预期短路电流超过35 A或10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).

熔断器额定电流的10倍，以较大者为准，熔断器应具有较高的分断能力（1500 A）。

Justification for omission of fuses or OVER-CURRENT RELEASES shall be included in the RISK MANAGEMENT FILE documented.

遗漏保险丝或过电流释放的理由应包含在记录的风险管理文件中。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE MANUFACTURER'S documentation.

通过检查医用电气设备和制造商的风险管理文件来检查合规性。

8.11.6 Internal wiring of the MAINS PART

电源部分的内部接线

- a) Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE or the APPLIANCE INLET and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3. 电源终端设备或电器插座与保护装置之间的电源部分内部接线的横截面积不得小于8.11.3.3中规定的电源线所需的最小截面积。

Compliance is checked by inspection.

通过检查检查合规性。

- b) The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits of ME EQUIPMENT shall be sufficient to prevent fire in case of possible fault currents. 主电源部分其他布线的横截面积和医用电气设备印刷线路上的轨道尺寸应足以在可能的故障电流情况下防止火灾。

20) IEC 60127 series, Miniature fuses

20) IEC 60127系列，微型熔断器

When necessary, compliance is checked by connecting the ME EQUIPMENT to a specified SUPPLY MAINS from which the most unfavourable short-circuit current expected can be drawn in the event of a fault in the MAINS PART. Subsequently, a fault in a single insulation in the MAINS PART is simulated so that the fault current is the least favourable. The occurrence of any HAZARDOUS SITUATIONS listed in 13.1.2 constitutes a failure.

必要时，通过将医用电气设备连接到规定的电源干线上，在电源部件发生故障时，可从该电源中提取最不利的短路电流，以检查是否符合要求。随后，模拟电源部分中的单个绝缘中的故障，以使故障电流最不利。13.1.2中所列的任何危险情况的发生均构成故障。

9

* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS
*医用电气设备和医用电气系统的机械危害防护

9.1

MECHANICAL HAZARDS of ME EQUIPMENT
医用电气设备的机械危害

For general requirements on design and manufacture of ME EQUIPMENT, see Clause 4 and 15.3. 医用电气设备设计和制造的一般要求见第4条和第15.3条。

Table 19 identifies the subclauses that address the MECHANICAL HAZARDS. 表19列出了处理机械危害的子条款。

Table 19 – MECHANICAL HAZARDS covered by this clause

表19——本条款所涵盖的机械危害

MECHANICAL HAZARD 机械危险	Covered by subclause 包含在子条款中
Crushing HAZARD 压碎危险	9.2, 9.4 and 9.8 9.2、9.4和9.8
Shearing HAZARD 剪切危险	9.2 and 9.8 9.2和9.8
Cutting or severing HAZARD 切割或切断危险	9.2, 9.3 and 9.8 9.2、9.3和9.8
Entanglement HAZARD 纠缠危险	9.2 9.2
Trapping HAZARD 诱捕危险	9.2 9.2
Stabbing or puncturing HAZARD 刺伤或刺穿危险	9.2, 9.3 and 9.8 9.2、9.3和9.8
Friction or abrasion HAZARD 摩擦或磨损危险	9.2 and 9.3 9.2和9.3
Expelled parts HAZARD 排出部件危险	9.5 9.5
High pressure fluid ejection HAZARD 高压液体喷射危险	9.7 9.7
Falling HAZARD 坠落危险	9.8 9.8
Instability HAZARD 不稳定危险	9.4 9.4

Impact HAZARD 撞击危险	9.2 and 9.8 9.2和9.8
Moving and positioning of PATIENT 病人的移动和定位	9.2 and 9.4 9.2和9.4
Vibration and noise 振动和噪声	9.6 9.6

9.2 * MECHANICAL HAZARDS associated with moving parts
*与运动部件相关的机械危险

9.2.1 * General
*总则

ME EQUIPMENT with moving parts shall be designed, built and laid out so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENTS or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level.
带有活动部件的医用电气设备的设计、制造和布局应确保，当按照随附文件中的说明正确安装和使用，或在合理可预见的误用情况下，将与这些活动部件相关的风险降低到可接受的水平。

The RISK from contact with the moving parts shall be reduced to an acceptable level by use of protective RISK CONTROL measures, bearing in mind the ease of access, the ME EQUIPMENT'S function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT.
应采用保护性风险控制措施，将接触运动部件的风险降低到可接受的水平，同时考虑到易于接近、医用电气设备的功能、部件的形状、运动的能量和速度以及对患者的益处。

The RESIDUAL RISK associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended function. If after all reasonable protective measures have been implemented HAZARDS persist, warnings shall be marked on the ME EQUIPMENT or given in the instructions for use., and RISK CONTROL measures have been implemented (e.g. warnings).
如果医用电气设备需要暴露以实现其预期功能，则与移动部件相关的残余风险被认为是可接受的。在合理的危险控制措施后，应在设备上标明警告和控制措施。

NOTE 1 Requirements for parts subject to wear are found in 15.2.
注1：磨损零件的要求见15.2。

NOTE 2 See ISO 14971:2007, subclauses 6.2 and 6.5.
注2见ISO 14971:2007第6.2和6.5款。

9.2.2 TRAPPING ZONE 陷波区

9.2.2.1 General 总则

Where feasible, ME EQUIPMENT with a TRAPPING ZONE shall comply with the requirements of one or more of the following:

在可行的情况下, 带有隔离区的医用电气设备应符合以下一项或多项要求:

- gaps as specified in 9.2.2.2; or
9.2.2.2中规定的间隙; 或
- safe distances as specified in 9.2.2.3; or
9.2.2.3中规定的安全距离; 或
- GUARDS and protective other RISK CONTROL measures as specified in 9.2.2.4; or
9.2.2.4中规定的防护和其他风险控制措施; 或
- continuous activation as specified in 9.2.2.5.
9.2.2.5中规定的连续激活。

If implementation of the above protective RISK CONTROL measures would be inconsistent with the INTENDED USE of the ME EQUIPMENT or the ME SYSTEM, control of the relevant motion shall comply with 9.2.2.6.

如果上述保护性风险控制措施的实施与医用电气设备或医用电气系统的预期用途不一致, 相关动作的控制应符合9.2.2.6的规定。

9.2.2.2 Gaps 差距

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the gaps of the 如果

TRAPPING ZONE comply with the dimensions specified in Table 20.

陷波区符合表20规定的尺寸。

NOTE In general the values for adults should be used. However, in the case of devices specifically designed for use with children, the dimensions given for children should be applied.

注: 通常应使用成人值。但是, 如果是专门为儿童设计的设备, 则应采用为儿童提供的尺寸。

9.2.2.3 Safe distances 安全距离

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the distances separating the OPERATOR, PATIENT and other persons from the TRAPPING ZONES exceed the values specified in ISO 13852 ISO:13857:2008. The distances are measured from the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE or under reasonably foreseeable misuse.

如果操作员、患者和其他人员与隔离区之间的距离超过ISO 13852中规定的值, 则认为诱捕区不存在机械危险国际标准化组织: 13857: 2008年。在正常使用或合理可预见的误用情况下, 从医用电气设备附近的操作员、病人和其他人员的预期位置测量距离。

9.2.2.4 * GUARDS and protective other RISK CONTROL measures *防护和防护性其他风险控制措施

9.2.2.4.1 Access to TRAPPING ZONES 进入诱捕区

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if GUARDS and protective or other RISK CONTROL measures (e.g. electro-mechanical):

如果防护装置和防护措施或其他风险控制措施（如机电式），则认为诱捕区不存在机械危害：

- are of robust construction;
结构坚固；
- are not easy to bypass or render non-operational;
不易绕过或不可操作；
- do not introduce any additional unacceptable RISK.
不要引入任何额外的不可接受的风险。

NOTE RISK CONTROL measures (e.g. electro-mechanical) addressed by this subclause are intended to include collision detection or collision avoidance systems, such as those employing light barrier(s) and similar feedback control(s).
注：本款所述的风险控制措施（例如机电）旨在包括碰撞检测或防撞系统，例如采用光障和类似反馈控制的系统。

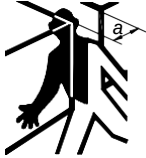
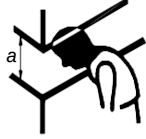
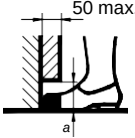
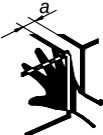
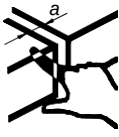
Compliance is checked by the applicable tests of 15.3 for ENCLOSURES.
通过15.3中适用于外壳的试验检查合规性。

9.2.2.4.2 FIXED GUARDS 固定防护装置

FIXED GUARDS shall be securely held in place by systems that cannot be dismantled without the use of a TOOL.
固定防护装置应通过不使用工具就无法拆卸的系统牢牢固定到位。

Compliance is checked by inspection.
通过检查检查合规性。

Table 20 – Acceptable gaps a
表20——可接受间隙a

Part of body	Adult gap a mm	Children gap a mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	
^a The values in this table are taken from ~~ISO 13852:1996~~ ISO13857:2008.			

9.2.2.4.3 Movable GUARDS 活动防护装置

Movable GUARDS that can be opened without the use of a TOOL:
无需使用工具即可打开的活动防护装置：

- shall remain attached to the ME EQUIPMENT when the GUARD is open;
当防护装置打开时，应与医用电气设备保持连接；
- shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the TRAPPING ZONE is accessible and stops movement when the GUARD is opened;
当与移动部件相关联的防护装置打开时，应防止启动装置停止移动；
- shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.
其设计应确保其中一个部件的缺失或故障可防止启动和停止移动部件。

Compliance is checked by inspection of the ME EQUIPMENT and by conducting any applicable tests and inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
通过检查医用电气设备、进行任何适用的医用电气设备测试和检查以及风险管理文件来检查合规性。

9.2.2.4.4 Protective Other RISK CONTROL measures 保护性其他风险控制措施

Protective measures shall be designed and incorporated into the control system so that:
应设计保护措施并将其纳入控制系统，以便：

- moving parts cannot start to move while they are in the reach of persons;
活动部件在人够得着的地方不能开始移动；
- once the ME EQUIPMENT has started to move, the TRAPPING ZONE cannot be reached, or, if the TRAPPING ZONE is reached, system movement must stop. In the later case, no HAZARD or damage shall result;
一旦医用电气设备开始移动，就无法到达捕捉区域，或者，如果到达捕捉区域，则必须停止系统移动。在后一种情况下，不会造成危害或损害；
- if in a SINGLE FAULT CONDITION of the protective measure, an unacceptable RISK could arise, one or more emergency stopping device(s) in the ME EQUIPMENT shall be provided (see 9.2.4).
如果在保护措施的单一故障条件下，可能产生不可接受的风险，则应在医用电气设备中提供一个或多个紧急停止装置（见9.2.4）。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
通过检查医用电气设备和风险管理文件检查合规性。

Other RISK CONTROL measures (e.g. electro-mechanical) shall be designed and incorporated into the control system so that:

其他风险控制措施（如机电）应设计并纳入控制系统，以便：

- once the ME EQUIPMENT has started to move, if the TRAPPING ZONE is reached, system movement shall stop; and
一旦医用电气设备开始移动，如果达到陷波区，系统移动应停止；并且
- if the RISK CONTROL measure is defeated in a SINGLE FAULT CONDITION, a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).
如果风险控制措施在单一故障条件下失败，则应提供第二种风险控制措施，例如一个或多个

个紧急停止装置（见9.2.4），否则医用电气设备应为单一故障安全设备（见4.7）。

Compliance is checked by the following as necessary:

必要时，通过以下方式检查合规性：

- inspection of the ME EQUIPMENT;
医用电气设备的检查；
- examination of the construction and circuits;
结构和电路检查；
- conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.
进行任何适用的试验，如有必要，包括单一故障条件下的试验。

9.2.2.5 * Continuous activation

***连续激活**

Where it is impractical to make the TRAPPING ZONE inaccessible, continuous activation may be used as a RISK CONTROL measure.

如果无法进入诱捕区，可使用连续激活作为风险控制措施。

A TRAPPING ZONE is not considered to present a MECHANICAL HAZARD if:

如果出现以下情况，则不认为诱捕区存在机械危险：

- a) the movement is in the OPERATOR'S field of view;
动作在操作员的视野内；

Compliance is checked by inspection.

通过检查检查合规性。

- b) movement of the ME EQUIPMENT or its parts is possible only by the continuous activation of the control by the OPERATOR as long as the response of the OPERATOR to deactivate the device can be relied on to prevent HARM;
医用电气设备或其部件的移动只能通过操作员持续启动控制装置来实现，前提是可以依靠操作员停用装置的响应来防止伤害；

NOTE Manually operated movements are also considered to comply with this clause, as long as mass and velocity allow adequate control of positioning without causing an unacceptable RISK.

注：只要质量和速度允许在不造成不可接受风险的情况下对定位进行充分控制，则手动操作的移动也被视为符合本条规定。

Compliance is checked by inspection.
通过检查检查合规性。

- c) in a SINGLE FAULT CONDITION of the continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) are provided in the ME EQUIPMENT (see 9.2.4).
在连续激活系统的单一故障条件下，可能会产生不可接受的风险，医用电气设备中提供一个或多个紧急停止装置（见9.2.4）。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
通过检查医用电气设备和风险管理文件检查合规性。

- c) the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).
连续激活系统在单一故障条件下失效，则应提供第二种风险控制措施，例如一个或多个紧急停止装置（见9.2.4），否则医用电气设备应为单一故障安全设备（见4.7）。

Compliance is checked by the following as necessary:
必要时，通过以下方式检查合规性：

- inspection of the ME EQUIPMENT;
医用电气设备的检查；
- examination of the construction and circuits;
结构和电路检查；
- conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.
进行任何适用的试验，如有必要，包括单一故障条件下的试验。

9.2.2.6 * Speed of movement(s) *移动速度（s）

The speed of movement(s) that position parts of the ME EQUIPMENT or PATIENT, where contact with the ME EQUIPMENT could result in a HAZARDOUS SITUATION an unacceptable RISK, shall be limited so that the OPERATOR will have adequate control of positioning without resulting in an unacceptable RISK the movement.
当与医用电气设备接触可能导致危险情况和不可接受的风险时，应限制医用电气设备部件或患者的移动速度，以便操作员能够充分控制定位，而不会导致不可接受的移动风险。

The overtravel (stopping distance) of such movement, occurring after operation of a control to stop the movement, shall not result in an unacceptable RISK.
在控制装置停止运行后，此类运动的超程（停止距离）不得导致不可接受的风险。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
通过检查医用电气设备和风险管理文件检查合规性。

Compliance is checked by the following as necessary:
必要时，通过以下方式检查合规性：

- inspection of the overtravel (stopping distance) calculations and evaluation;
检查超程（停车距离）计算和评估；
- any functional tests.
任何功能测试。

NOTE The overtravel (stopping distance) calculations and evaluation are part of the RISK MANAGEMENT FILE.

注：超程（停车距离）计算和评估是风险管理文件的一部分。

9.2.3 * Other MECHANICAL HAZARDS associated with moving parts *与活动部件相关的其他机械危险

9.2.3.1 Unintended movement 意外移动

Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated, resulting in unacceptable RISK, unless ergonomic considerations for the intended PATIENT dictate otherwise (e.g. PATIENT with special needs) unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs) or activation does not result in an unacceptable RISK. 除非预期患者的人体工程学考虑另有规定（如有特殊需求的患者），否则控制装置的位置、凹陷或其他方式的保护应确保其不会意外启动，从而导致不可接受的风险，除非针对预期患者，可用性工程过程以其他方式得出结论（例如，有特殊需求的患者）或激活不会导致不可接受的风险。

Compliance is checked by inspection of ME EQUIPMENT, and, if the control is part of the 通过检查医用电气设备来检查合规性，如果控制是
PRIMARY OPERATING FUNCTIONS, inspection of the USABILITY ENGINEERING FILE.
主要操作功能，可用性工程文件的检查。

9.2.3.2 Overtravel end stops 超程终点挡块

The RISK due to overtravel (past range limits) of ME EQUIPMENT parts shall be reduced to an acceptable level. Overtravel past range limits of ME EQUIPMENT parts shall be prevented. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure in both NORMAL CONDITION and SINGLE FAULT CONDITION. 医用电气设备部件超程（超过量程限制）的风险应降低至可接受水平。应防止超程超过医用电气设备部件的量程限制。应提供端部止动装置或其他停止装置，作为正常条件和单一故障条件下的最终行程限制措施。

Such means shall have the mechanical strength to withstand the intended loading in NORMAL USE and reasonably foreseeable misuse. 此类装置应具有机械强度，以承受正常使用和合理可预见的误用情况下的预期荷载。

Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, specifications of materials used and the processing specifications for these materials. and the following test:
通过检查医用电气设备、风险管理文件、所用材料的规格和这些材料的加工规范来检查合规性。以及以下测试：

- The ME EQUIPMENT is
医用电气设备
- loaded with the SAFE WORKING LOAD,
装载安全工作负载，
 - unloaded,
卸载，或
 - loaded to any intermediate level that is likely to provide the most severe test result.
加载到可能提供最严重测试结果的任何中间水平。

The moving part is to be driven against each end stop or other mechanical means for the number of cycles, operating speed and test conditions as specified in Table 33. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the test.
根据表33中规定的循环次数、运行速度和试验条件，移动部件应顶着每个止动块或其他机械装置进行驱动。试验完成后，所需的端部止动装置或其他机械装置应能够执行其预期功能。

Table 33 – Test conditions for overtravel end stop test
表33-超程终点止动试验的试验条件

Constructi on 结构	Number of cycles 循环次数	Test condition 试验条件
1. Motor driven: No range limit system provided a 1电机驱动：未提供范围限制系统	6 000 600 0个	Run at maximum speed 以最高速度运行
2. Motor driven: Non-independent range limit system or systems provided a, b 2电机驱动：非独立量程限制系统或提供a、b系统	50 50	Defeat all switches simultaneously, and run at maximum speed 同时关闭所有开关，以最大速度运行
3. Motor driven: Two or more independent range limit systems a, b 三。电机驱动：两个或多个独立的量程限制系统a、b	1 1	Defeat all switches simultaneously, and run at maximum speed 同时关闭所有开关，以最大速度运行
4. Manually driven or manually driven, power assisted 4手动或手动驱动，动力辅助	50 50	Run at any speed, including reasonably foreseeable misuse 以任何速度运行，包括合理可预见的误用
a A range limit system consists of all components required to stop motion, for example, it may consist of (1) a limit switch, (2) sensing circuits, and (3) related mechanical actuating mechanism. 行程限制系统由停止运动所需的所有部件组成，例如，它可以由（1）个限位开关，（2）传感电路，和（3）相关的机械执行机构组成。		
b To qualify as an independent range limit system, each system shall, in addition to the		

criteria in footnote a,

b 为符合独立量程限制系统的要求，除脚注a中的标准外，每个系统还应：，
comply with both of the following:
遵守以下两项：

1. the system is capable of de-energizing the motor(s) directly; that is, the switch or motor controller circuit interrupts the motor's rotor or stator current, or both, and
该系统能够直接断开电机的电源；也就是说，开关或电机控制器电路会中断电机的转子或定子电流，或两者兼而有之，以及
2. the system provides a means by which a malfunction of one range limit system is made obvious to the
该系统提供了一种使一个量程限制系统的故障变得明显的方法
OPERATOR. This may be an audible, visual or otherwise discernible indicator.
操作员。这可能是一个听觉、视觉或其他可辨别的指示器。

9.2.4 * Emergency stopping devices

*紧急停车装置

Where it is considered necessary to have one or more emergency stopping device(s), the emergency stopping device shall comply with all the following requirements.

如果认为有必要配备一个或多个紧急停止装置，紧急停止装置应符合以下所有要求。

- a) The emergency stopping device shall reduce the RISK to an acceptable level.
紧急停止装置应将风险降低到可接受的水平。
- b) The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM.
可依靠操作员的接近性和对启动紧急停止装置的响应来防止伤害。
- c) The emergency stopping device actuator shall be readily accessible to the OPERATOR.
紧急停止装置致动器应易于操作。
- d) Emergency stopping device(s) shall not be part of the normal operation of the
紧急停止装置不应是
ME EQUIPMENT.
医用电气设备。
- e) Operation of an emergency switching or stopping means shall neither introduce a further MECHANICAL HAZARD nor interfere with the complete operation necessary to remove the original HAZARD.
紧急开关或停止装置的操作不得引入进一步的机械危险，也不得干扰消除原有危险所需的完整操作。
- f) Emergency stopping device(s) shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like.
紧急停止装置应能够断开相关电路的满载，并考虑到可能的失速电机电流等。

g) Means for stopping of movements shall operate as a result of one single action.
停止运动的装置应在一次动作的结果下运行。

h) The emergency stopping device shall have an actuator coloured red designed to be distinctive and easily identifiable from that of other controls.
紧急停止装置应具有一个红色的执行机构，其设计应与其他控制装置的执行机构不同且易于识别。

i) An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 (DB:2002-中断/开启机械运动的致动器应在致动器表面或紧挨致动器表面标记符号IEC 60417-5638 (DB:2002-10) (see Table D.1, symbol 18) or the word “STOP”.
10)（见表D.1，符号18）或“停止”一词。

NOTE If the actuator is a switch that interrupts all power, compliance with the above marking requirement is not required.

注：如果致动器是切断所有电源的开关，则不要求符合上述标记要求。

j) The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the disabled condition until a deliberate action, different from that used to actuate it, is performed.

一旦启动紧急停止装置，应将医用电气设备保持在禁用状态，直到执行了不同于用于驱动的操作。

k) The emergency stopping device shall be shown to be suitable for its application.
应证明紧急停止装置适合其应用。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

通过检查医用电气设备和风险管理文件，以及功能测试来检查合规性。

9.2.5 * Release of PATIENT

*释放病人

Means shall be provided to permit the release of the PATIENT quickly and safely in the event of breakdown of the ME EQUIPMENT or failure of the power supply (see 11.8), activation of a protective RISK CONTROL measure or emergency stopping. Special attention shall be given to the following.
应提供装置，以便在医用电气设备故障或电源故障（见11.8）、启动保护性风险控制措施或紧急停止时，快速安全地释放患者。应特别注意以下事项。

- Uncontrolled or unintended movement of the ME EQUIPMENT that could result in an unacceptable RISK shall be prevented.
应防止医用电气设备不受控制或意外移动，从而导致不可接受的风险。
- Situations where the PATIENT is subjected to unacceptable RISKS due to the proximity of moving parts, removal of normal exit routes, or other HAZARDS, shall be prevented.
应防止患者因靠近活动部件、移除正常出口路线或其他危险而遭受不可接受的风险。
- When, after removal of counterbalanced parts, other parts of the ME EQUIPMENT can move in a hazardous way, measures shall be provided to reduce the RISK to an acceptable level.
当拆除平衡部件后，医用电气设备的其他部件可能以危险方式移动时，应采取措施将风险降低到可接受的水平。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

通过检查医用电气设备和风险管理文件，以及功能测试来检查合规性。

9.3 * MECHANICAL HAZARD associated with surfaces, corners and edges

***与表面、角落和边缘相关的机械危险**

Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK cause injury or damage shall be avoided or covered.

应避免或覆盖医用电气设备的粗糙表面、锐角和边缘，以免造成不可接受的风险，造成伤害或损坏。

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

尤其要注意法兰或框架边缘，并清除毛刺。

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

通过检查医用电气设备和风险管理文件检查合规性。

NOTE 1 If inspection is insufficient to determine sharpness of edges or burrs, the rationale for 9.3 provides a reference to an optional functional test.

注1：如果检验不足以确定边缘或毛刺的锐度，则第9.3条的基本原理为可选功能试验提供参考。

NOTE 2 A sharp edge MECHANICAL HAZARD could cut wire insulation which could lead to an electrical HAZARD. This requirement is intended to cover all these HAZARDS.

注2：锐边机械危险可能割断电线绝缘，从而导致电气危险。本要求旨在涵盖所有这些危险。

9.4 * Instability HAZARDS

***不稳定危害**

9.4.1 General

总则

ME EQUIPMENT and its parts, other than FIXED ME EQUIPMENT and HAND-HELD ME EQUIPMENT, intended to be placed on a surface such as a floor or a table in NORMAL USE shall not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to the PATIENT, OPERATOR or other person.

医用电气设备及其部件（固定医用电气设备和手持医用电气设备除外），在正常使用中，如地板或桌子上，不应失去平衡（倾翻）或意外移动，以免对患者、操作员或其他人造成不可接受的风险。

NOTE The meaning of transport in this subclause is moving ME EQUIPMENT from room to room during NORMAL USE. HAND-HELD parts of FIXED ME EQUIPMENT are intended to be tested.

注: 本款中运输的含义是在正常使用期间将医用电气设备从一个房间移动到另一个房间。固定医用电气设备的手持部件应进行测试。

Compliance is checked by the tests in 9.4.2 to 9.4.4 (inclusive). Each test is performed separately.

通过9.4.2至9.4.4 (包括9.4.4) 中的试验检查合规性。每项试验单独进行。

9.4.2 * Instability – overbalance

***不稳定性-失衡**

9.4.2.1 Instability in transport position

运输位置不稳定

ME EQUIPMENT or its parts shall not overbalance when placed in any transport position of 医用电气设备或其部件在放置在

NORMAL USE on a plane inclined at an angle of 10° from the horizontal plane.

在与水平面成10°角的平面上正常使用。

NOTE The meaning of transport in this subclause is moving ME EQUIPMENT from room to room during NORMAL USE.

注: 本款中运输的含义是在正常使用期间将医用电气设备从一个房间移动到另一个房间。

Compliance is checked by the following test:

通过以下试验检查合规性:

Prior to the test the ME EQUIPMENT is prepared as indicated in the ACCOMPANYING DOCUMENTS (or, if not specified, as in 9.4.2.2). The ME EQUIPMENT or its parts is placed on a plane inclined at an angle 10° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

试验前, 医用电气设备按照随附文件中的说明进行准备 (如果没有规定, 则按照9.4.2.2的规定)。医用电气设备或其部件放置在与水平面成10°角的平面上。如果医用电气设备或其部件失去平衡, 则构成故障。

9.4.2.2 Instability excluding transport position

不包括运输位置的不稳定性

ME EQUIPMENT or its parts shall not overbalance when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane. 医用电气设备或其部件放置在与水平面成5°角的平面上时, 其正常使用位置 (不包括任何运输位置) 不得失去平衡。

If the ME EQUIPMENT or its parts overbalances when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 10° from the horizontal plane, it shall carry a warning notice stating that transport should only be undertaken in a certain condition that shall be clearly described in the instructions for use or marked on the ME EQUIPMENT with an indication of the RESIDUAL RISK if the ME EQUIPMENT or its parts overbalances. 如果医用电气设备或其部件在任何正常使用位置 (不包括任何运输位置) 时, 在与水平面成10°角的平面上放置时出现失衡, 其应附有警告通知, 说明运输只能在特定条件下进行, 该条件应在使用说明书中明确说明, 或在医用电气设备或其部件失去平衡时, 在医用电气设备上标明剩余风险。

NOTE For warning notice requirements, see 7.9.2.2.

注: 警告通知要求见7.9.2.2。

Compliance is checked by the following test:

通过以下试验检查合规性:

Prior to conducting the test, the ME EQUIPMENT is prepared as follows:

在进行试验之前，医用电气设备准备如下：

- a) ME EQUIPMENT is provided with all specified connection leads, the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts, ACCESSORIES and load as specified in NORMAL USE.
医用电气设备配备所有指定的连接导线、电源线和任何互连电线。在正常使用中，它配备了可能的可拆卸部件、附件和负载的最不利组合。
- b) ME EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.
设备配有可拆卸电源线。
- c) The connection leads are laid down on the inclined plane in the position most unfavourable for stability.
连接导线敷设在最不利于稳定的斜面上。
- d) If castors/wheels are present, they are temporarily immobilized, if necessary by blocking, in their most disadvantageous position.
如果存在脚轮/车轮，则在最不利的位置临时固定（如有必要，通过阻挡）。
- e) Doors, drawers, shelves and the like are placed in the most disadvantageous position and fully loaded or unloaded whichever represents “worst case” as specified in NORMAL USE according to the ACCOMPANYING DOCUMENTS.
根据随附文件，门、抽屉、架子等应放置在最不利的位置，并满载或空载，以正常使用中规定的“最坏情况”为准。
- f) ME EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.
对装有液体容器的医用电气设备进行试验，容器完全或部分充满或空，以最不利者为准。
- g) The ME EQUIPMENT is not connected to the SUPPLY MAINS.
医用电气设备未连接到电源。

The test floor surface is to be hard and flat (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material).
试验地板表面应坚硬平整（例如，混凝土地板覆盖2 mm至4 mm厚的乙烯基地板材料）。

The ME EQUIPMENT or the ME EQUIPMENT parts is placed on a plane inclined at an angle of 10° from the horizontal plane, or, if a warning notice is present, compliance is checked by inspection of the warning notice and the ME EQUIPMENT or its parts is placed on a plane inclined at an angle of 5° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.
将医用电气设备或医用电气设备部件放置在与水平面成10°角的平面上，或者，如果有警告通知，则通过检查警告通知来检查是否符合要求，并且将医用电气设备或其部件放置在与水平面成5°角的平面上。如果医用电气设备或其部件失去平衡，则构成故障。

9.4.2.3 Instability from horizontal and vertical forces 水平和垂直力引起的不稳定性

- a) ME EQUIPMENT having a mass of 25 kg or more, other than FIXED ME EQUIPMENT that is intended to be used on the floor, shall not overbalance due to pushing, leaning, resting etc.

质量为25 kg或以上的医用电气设备（用于地板上的固定医用电气设备除外）不得因推压、倾斜、休息等而失去平衡。

Surfaces of the ME EQUIPMENT where a RISK of overbalancing the ME EQUIPMENT exists from pushing, leaning, resting etc., shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table D.2, safety sign 5).
医用电气设备的表面，如果医用电气设备存在因推挤、倾斜、休息等而失去平衡的风险，则应在其表面永久性地标记清楚易读的警告，例如使用安全标志ISO 7010-P017（见表D.2，安全标志5）。

* ME EQUIPMENT or its parts having a mass of 25 kg or more other than FIXED ME EQUIPMENT that is intended to be used on the floor shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table D.2, safety sign 5), or it shall not overbalance due to being pushed, leaned, rested upon etc.
*质量大于等于25 kg的医用电气设备或其部件（非拟用于地板上的固定医用电气设备）应永久性地标记有该风险的清晰易读警告，例如使用安全标志ISO 7010-P017（见表D.2，安全标志5），不得因被推、靠、靠等而失去平衡。

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during NORMAL USE, but not on surfaces for which pushing is associated with NORMAL USE (e.g. surfaces with handles).
如果由于医用电气设备失去平衡而提供标记，则标记应在正常使用期间可见，但不能出现在与正常使用相关的推压表面（例如带把手的表面）。

Compliance is checked by inspection and of the marking provided or the following test:
通过检查和提供的标记或进行以下试验来检查是否符合要求：

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane and a force equal to 25 ± 15 % of its weight, but not more than 220 ± 150 N, is applied in any direction, except a direction having an upward component. Unless otherwise marked, the force is applied at any point of the ME EQUIPMENT but not exceeding 1,5 m from the floor. The ME EQUIPMENT is prevented from sliding on the floor by a horizontal obstruction, not exceeding 20 mm height, which is fastened flat on the floor. If the application of the test force results in lateral movement of the ME EQUIPMENT, increase the height of the obstruction to the minimum extent necessary to prevent lateral movement. If the ME EQUIPMENT overbalances, it constitutes a failure. ME EQUIPMENT without marking shall not overbalance.

试验前，医用电气设备按9.4.2.2所述进行准备。医用电气设备放置在水平面上，向任何方向施加等于其重量的25.15%，但不超过220.150 N的力，具有向上分量的方向除外。除非

另有标记，否则应在医用电气设备的任何点施加力，但不得超过离地板1.5 m的距离。医用电气设备通过一个高度不超过20 mm的水平障碍物防止在地板上滑动，该障碍物平稳地固定在地板上。如果施加试验力导致医用电气设备发生横向移动，应将障碍物的高度增加至防止横向移动所需的最小程度。如果医用电气设备失去平衡，则构成故障。无标记的医用电气设备不得失衡。

- b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table, shall not overbalance due to sitting or stepping unless a legible warning of this RISK is provided on the ME EQUIPMENT, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7). 除固定式医用电气设备外，拟用于地板或桌子上的医用电气设备不得因坐着或踩踏而失去平衡，除非医用电气设备上有明确的危险警告，例如使用安全标志ISO 7010-P018或ISO 7010-P019（见表D.2，安全标志6和7）。

ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon. 除固定式医用电气设备外，拟在地板或桌子上使用的医用电气设备或其部件应永久性地标记有该风险的清晰易读警告，例如使用安全标志ISO 7010-P018或ISO 7010-P019（见表D.2，安全标志6和7），不得因坐或踩而失去平衡。

NOTE Requirements for PATIENT support surfaces are found in 9.8.3.

注：9.8.3中给出了患者支撑面要求。

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during potential stepping or sitting misuse.

如果由于医用电气设备失去平衡而提供标记，则标记应在潜在的踩踏或坐姿误用期间可见。

Compliance is checked by inspection and of the marking provided or by the following test:

Prior to the test the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT

通过检查和提供的标记或通过以下试验检查是否符合要求：在试验之前，应按照9.4.2.2的

要求准备医用电气设备。医用电气设备

is placed on a horizontal plane and a constant downward force of 800 N is applied at the 放置在水平面上，并在

point of maximum moment to any working surface, excluding PATIENT support surfaces, 任何工作面（不包括患者支撑面）的最大力矩点，

offering an obvious foothold or sitting surface of a minimum 20 cm by 20 cm area, and at a height not exceeding 1 m from the floor. Overbalancing constitutes a failure. ME EQUIPMENT without marking shall not overbalance.
提供一个明显的立足点或坐面，面积至少为20 cm×20 cm，且离地面不超过1 m。失去平衡即为失败。无标记的医用电气设备不得失衡。

9.4.2.4 * Castors and wheels
***脚轮和车轮**

9.4.2.4.1 General
总则

The means used for transportation of MOBILE ME EQUIPMENT, e.g. castors or wheels, shall not result in an unacceptable RISK when the MOBILE ME EQUIPMENT is moved or parked in NORMAL USE.
当移动式医用电气设备在正常使用中移动或停放时，移动式医用电气设备（如脚轮或车轮）的运输方式不得导致不可接受的风险。

9.4.2.4.2 Force for propulsion
推进力

The force required for moving MOBILE ME EQUIPMENT along a hard and flat horizontal surface shall not exceed 200 N unless the instructions for use state that more than one person is needed.
移动医用电气设备在坚硬平坦的水平面上移动所需的力不应超过200 N，除非使用说明中规定需要一人以上。

Compliance is checked by placing the ME EQUIPMENT on a hard flat horizontal floor (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material) and measuring the force needed to propel the ME EQUIPMENT at a speed of 0,4 m/s □ 0,1 m/s. The force is applied at a height of 1 m above the floor or at the highest point on the ME EQUIPMENT if its height is less than 1 m.
通过将医用电气设备放置在坚硬平坦的水平地板上（例如，覆盖有2 mm至4 mm厚乙烯基地板材料的混凝土地板）并测量以0.4 m/s±0.1 m/s的速度推进医用电气设备所需的力。该力施加在离地板1 m的高度或医用电气设备，如果其高度小于1米。

9.4.2.4.3 * Movement over a threshold
***超过门槛的运动**

MOBILE ME EQUIPMENT exceeding 45 kg shall be able to pass over a 20 10 mm threshold. Passing over a 20 10 mm threshold shall not result in an unacceptable RISK overbalancing.
超过45 kg的移动式医用电气设备应能通过20 mm的阈值。超过20-10 mm阈值不得导致不可接受的失衡风险。

Compliance is checked by the following test:
通过以下试验检查合规性：

The ME EQUIPMENT is configured in transport position with any SAFE WORKING LOAD in place as indicated in the ACCOMPANYING DOCUMENTS. The ME EQUIPMENT is moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction with a rectangular cross-section, 20 mm high and 80 mm wide that is affixed flat on the floor. The obstruction shall have a rectangular cross section of 10 mm □ 0,5 mm high and at least 80 mm wide with a radius of 2 mm □ 0,1 mm at the top edges. The method of passing over the obstruction has to be applied in accordance with the instructions in the ACCOMPANYING DOCUMENTS, or if no instructions are given, by the following test.
医用电气设备配置在运输位置，并按照随附文件中的指示，在适当的位置安装任何安全工作负载。医用电气设备在（上下）实心垂直平面障碍物上（上下）向前移动10次，障碍物的横截面为矩形，高20 mm，宽80 mm，平贴在地板上。障碍物的矩形横截面高度应为10 mm±0.5 mm，宽度至少为80 mm，上边缘的半径为2 mm±0.1 mm。必须按照随附文件中的说明使用越过障

障碍物的方法，如果没有给出说明，则通过以下试验。

All wheels and castors are to impact the obstruction at a speed of 0,4 0,8 m/s $\square$ 0,1 m/s for manual MOBILE ME EQUIPMENT, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained. Manual MOBILE ME EQUIPMENT is propelled by a force acting at its handle.
对于手动移动式医用电气设备，所有车轮和脚轮应以 0.4 ± 0.8 m/s ± 0.1 m/s的速度撞击障碍物，或者对于电动移动式医用电气设备，应以能够保持的最大速度撞击障碍物。手动移动医用电气设备由手柄上的力推动。

It is unacceptable for ME EQUIPMENT to be unable to go over (up) the obstruction (due to small wheel diameter, for example). Overbalancing or any unacceptable RISK constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.
医用电气设备不能越过（向上）障碍物是不可接受的（例如，由于车轮直径小）。失衡或任何不可接受的风险均构成故障。应保持基本安全和基本性能。

Unacceptable RISK is determined by inspection of the ME EQUIPMENT, its parts, and the RISK MANAGEMENT FILE.
通过检查医用电气设备及其部件和风险管理文件，确定不可接受的风险。

NOTE Examples of damage that can result in unacceptable RISK affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.
注：可能导致影响基本安全的不可接受风险的损坏示例包括爬电距离和空气间隙降低到8.9中规定的值以下，接近超出8.4中限制的部件，或接近可能造成危害的活动部件。

Assessment criteria that can be useful in determining if this test has resulted in an unacceptable RISK a loss of

评估标准，可用于确定该测试是否导致不可接受的风险

BASIC SAFETY include:
基本安全包括:

- those in Clause 9 8 and 11.6;
第9.8条和第11.6条的规定;
- the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid SUPPLEMENTARY or REINFORCED INSULATION insulation providing a MEANS OF PROTECTION; and
8.8.3中规定的介电强度试验，以评估提供保护手段的固体补充或增强绝缘的完整性；以及
- measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.
测量爬电距离或空气间隙，以将数值与8.9中规定的最小距离进行比较。通常可以忽略不会对电击或湿气保护产生不利影响的小芯片。

9.4.3 * Instability from unwanted lateral movement (including sliding)

*不必要的横向运动（包括滑动）引起的不稳定性

9.4.3.1 Instability in transport position

运输位置不稳定

- a) Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally activated and can only be released by continuous actuation of a control. 电动移动式医用电气设备的制动器的设计应确保其正常启动，并且只能通过控制装置的连续驱动来释放。

Compliance is checked by inspection.

通过检查检查合规性。

- b) MOBILE ME EQUIPMENT shall be fitted with means (such as locking devices) intended to prevent any unwanted movement of the ME EQUIPMENT or its parts in the transport position.

移动式医用电气设备应配备防止医用电气设备或其部件在运输位置发生任何不必要的移动的装置（如锁定装置）。

Compliance is checked by inspection.

通过检查检查合规性。

- c) MOBILE ME EQUIPMENT that is intended to be used on the floor shall not result in an unacceptable RISK due to unwanted lateral movement. * MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position. 拟在地板上使用的移动医用电气设备不得因不必要的横向移动而导致不可接受的风险。*移动式医用电气设备应配备车轮锁或制动系统，以防止在运输位置时在10°的斜坡上发生不必要的移动。

Compliance is checked by the following test:

通过以下试验检查合规性：

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT is placed in its transport position (or in the worst case NORMAL USE position) with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a hard flat surface inclined at 10° from the horizontal plane. If castors are incorporated, they are positioned in their worst-case position. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the MOBILE ME EQUIPMENT greater than 50 mm (in relation to the inclined plane) constitutes a failure. The RISK due to any initial movement is assessed, taking into account the NORMAL USE of the ME EQUIPMENT. 试验前，医用电气设备按9.4.2.2所述进行准备。将移动式医用电气设备放置在其运输位置（或在最坏情况下的正常使用位置），安全工作负载到位，锁紧装置（如制动器）激活，放置在与水平面倾斜10°的坚硬平坦表面上。如果安装了脚轮，则将其置于最坏的位置。在脚轮的初始弹性运动、初始蠕变和初始旋转之后，移动式医用电气设备的任何进一步移动超过50 mm（相对于斜面）即构成故障。考虑到医用电气设备的正常使用，对任何初始移动造成的风险进行评估。

9.4.3.2 Instability excluding transport position

不包括运输位置的不稳定性

- a) MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system appropriate to the intended modes of use and sufficient to ensure that unintended movement is prevented on an incline of 5° to prevent unwanted movement on an incline

of 5° when in any position excluding transport position. 移动式医用电气设备应配备轮锁或适用于预期使用模式的制动系统，并足以确保在5°的斜坡上防止意外移动，以防止在不包括运输位置的任何位置时在5°的斜坡上发生不必要的移动。

Compliance is checked by the following test:

通过以下试验检查合规性：

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT with the SAFE WORKING LOAD in place is positioned on a hard flat surface inclined at an angle of 5° from the horizontal plane with wheels locks on or braking system activated. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the inclined surface) constitutes a failure. The RISK due to any initial movement is assessed taking into account the NORMAL USE of the ME EQUIPMENT. 试验前，医用电气设备按9.4.2.2所述进行准备。安全工作负载就位的移动式医用电气设备放置在坚硬平坦的表面上，与水平面成5度角，车轮锁紧或制动系统激活。在脚轮的初始弹性运动、初始蠕变和初始旋转之后，医用电气设备的任何进一步移动超过50 mm（相对于斜面）即构成故障。考虑到医用电气设备的正常使用，对任何初始移动造成的风险进行评估。

- b) TRANSPORTABLE or STATIONARY ME EQUIPMENT that is intended to be used on the floor shall not result in an unacceptable RISK due to unwanted lateral movement. MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement from lateral forces. 拟在地板上使用的移动式或固定式医用电气设备不得因不必要的横向移动而导致不可接受的风险。移动式医用电气设备应配备车轮锁或制动系统，以防止横向力产生不必要的移动。

Compliance is checked by the following test:

通过以下试验检查合规性：

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated. If castors are incorporated, they are positioned in their worst-case position. A force equal to 25 15 % of the weight of the unit, but not more than 220 150 N, is applied in any direction, except a direction having an upwards component, at the highest point of the ME EQUIPMENT that does not lead to overbalancing but not exceeding 1,5 m from the floor. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the horizontal plane) constitutes a failure. The RISK due to any initial movement is assessed, taking into account the NORMAL USE of the ME EQUIPMENT.

试验前, 医用电气设备按9.4.2.2所述进行准备。医用电气设备放置在水平面上, 且安全工作负载到位, 且锁定装置(如制动器)启动。如果安装了脚轮, 则将其置于最坏的位置。在医用电气设备的最高点处, 向任何方向施加等于装置重量25-15%, 但不超过220-150 N的力, 除了有向上分量的方向外, 该最高点不会导致失衡, 但离地面不超过1.5米。在脚轮的初始弹性运动、初始蠕变和初始旋转之后, 医用电气设备的任何进一步移动超过50 mm (相对于水平面) 即构成故障。考虑到医用电气设备的正常使用, 对任何初始移动造成的风险进行评估。

9.4.4 Grips and other handling devices

9.4.4 夹具和其他搬运装置

- a) ME EQUIPMENT other than PORTABLE ME EQUIPMENT or its part with a mass of more than 20 kg that needs to be lifted in NORMAL USE or transport shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where it can be lifted safely, unless the method of handling is obvious and no HAZARDS unacceptable RISK can develop when this is done. If the means for lifting are handles, they shall be suitably placed to enable the ME EQUIPMENT or its part to be carried by two or more persons.
- 除便携式医用电气设备或其在正常使用或运输过程中需要提升的部件外, 医用电气设备或其部件应配备适当的搬运装置(例如手柄、吊耳等), 或随附文件应说明其可安全提升的位置, 除非处理方法明显且没有危害, 否则在处理过程中不会产生不可接受的风险。如果起重工具是手柄, 则应适当放置, 使医用电气设备或其部件能够由两人或两人以上搬运。

Compliance is checked by weighing (if necessary) and by inspection of the ME EQUIPMENT or its part or the ACCOMPANYING DOCUMENTS.

通过称重(如有必要)和检查医用电气设备来检查合规性
或其部分或随附文件。

- b) ME EQUIPMENT specified by the MANUFACTURER as PORTABLE ME EQUIPMENT with a mass of more than 20 kg shall have one or more carrying-handles suitably placed to enable the ME EQUIPMENT to be carried by two or more persons.
- 制造商指定为便携式医用电气设备(质量大于20 kg)的医用电气设备应具有一个或多个适当放置的搬运把手, 以使医用电气设备能够由两个或多个人员搬运。

Compliance is checked by carrying.

通过携带检查合规性。

- c) Carrying handles or grips furnished on PORTABLE ME EQUIPMENT shall withstand loading as described in the following test:
- 便携式医用电气设备上提供的搬运把手或把手应能承受以下试验中所述的荷载:

The handles and their means of attachment are subjected to a force equal to four times the weight of the ME EQUIPMENT in any direction of NORMAL USE and transport.

在正常使用和运输的任何方向上, 手柄及其连接装置受到的力等于医用电气设备重量的四

倍。

If more than one handle is furnished on PORTABLE ME EQUIPMENT, the force is distributed between the handles. The distribution of forces is determined by measuring the percentage of the ME EQUIPMENT weight sustained by each handle with the ME EQUIPMENT in the normal carrying position. If the ME EQUIPMENT is furnished with more than one handle but is so designed that it can readily be carried by only one handle, then each handle is to be capable of sustaining the total force. 如果在便携式医用电气设备上安装了多个手柄，则力分布在两个手柄之间。通过测量医用电气设备处于正常承载位置时每个手柄承受的医用电气设备重量百分比来确定力的分布。如果医用电气设备配备有一个以上的手柄，但其设计应使其仅能由一个手柄携带，则每个手柄应能承受全部力。

The force is applied uniformly over a 7 cm length of the handle at the centre, starting at zero and gradually increasing so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min. 将力均匀施加在把手中心7 cm长的范围内，从零开始逐渐增加，以便在5 s到10 s内达到试验值，并保持1 min。

Handles that break loose from the ME EQUIPMENT or exhibit any permanent distortion, cracking or other evidence of breakdown constitutes a failure. 把手从医用电气设备上脱落或显示出任何永久变形、开裂或其他故障迹象，即构成故障。

9.5 * Expelled parts HAZARD *排出部件危险

9.5.1 Protective means 保护手段

Where expelled parts could result in an unacceptable RISK, the ME EQUIPMENT shall be provided with a means for protecting against such RISK. 如果排出的部件可能导致不可接受的风险，医用电气设备应配备防止此类风险的措施。

Compliance is checked by assessment of the suitability of the protective means and by inspection of the RISK MANAGEMENT FILE. 通过评估防护措施适用性和检查风险管理文件来检查合规性。

9.5.2 Cathode ray tubes 阴极射线管

Any cathode ray tube shall comply with the applicable requirements of IEC 60065:2001, Clause 18; or IEC 61965.

任何阴极射线管应符合IEC 60065:2001第18条或IEC 61965的适用要求。

Compliance is checked by inspection of a certificate of compliance or by the relevant tests of IEC 60065:2001, Clause 18.

通过检查合格证书或通过IEC 60065:2001第18条的相关试验来检查是否合格。

9.6 Acoustic energy (including infra- and ultrasound) and vibration 声能（包括红外线和超声波）和振动

9.6.1 * General *总则

ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK.

医用电气设备的设计应确保人体接触声能和振动不会导致不可接受的风险。

Compliance is checked by the tests in 9.6.2 and 9.6.3, and, if necessary, by inspection of the RISK MANAGEMENT FILE (taking into account the audibility of auditory alarm signals and PATIENT sensitivity) and the tests indicated in 9.6.2 and 9.6.3.
通过9.6.2和9.6.3中的测试检查合规性，如有必要，通过检查风险管理文件（考虑听觉警报信号的可听性和患者的敏感性）以及9.6.2和9.6.3中所述的测试来检查合规性。

9.6.2 * Acoustic energy *声能

9.6.2.1 Audible acoustic energy 可听声能

In NORMAL USE, the PATIENT, OPERATOR and other persons shall not be exposed to acoustic energy from ME EQUIPMENT, except sound from auditory ALARM SIGNALS, exceeding the levels specified below.
在正常使用中，患者、操作员和其他人员不得接触医用电气设备的声能，但听觉报警信号发出的声音除外，超过以下规定水平。

- 80 dBA for a cumulative exposure of 24 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 83 dBA for 12 h over a 24 h period);
对于24小时内24小时的累积暴露，为80 dBA；当将24小时内的累积暴露时间减半时，应将3 dBA的偏移量加到该值上（例如，24小时内12小时内83 dBA）；
- 140 dB un-weighted dBC (peak) sound pressure level for impulsive or impact acoustic energy (noise).
冲击或冲击声能（噪声）的140 dB未加权dBC（峰值）声压级。

NOTE 1 Interpolation or extrapolation is allowed for exposure times in accordance with the following formula, $80 - 10 \cdot \log_{10}(h/24)$, in dBA, where h is cumulative exposure time over a 24 h period.
注1：根据以下公式， $80 - 10 \cdot \log_{10}(h/24)$ ，以dBA为单位，允许对暴露时间进行内插或外推，其中h是24小时内的累积暴露时间。

NOTE 2 Since PATIENTS might have a higher sensitivity to acoustic energy (noise), a lower level could be more appropriate. Consideration should also be given to perception of auditory ALARM SIGNALS. The World Health Organization has recommended a maximum impulse or impact acoustic energy (noise) level for children of 120 dB.
注2：由于患者对声能（噪声）的敏感性较高，因此较低的声能水平可能更为合适。还应考虑听觉报警信号的感知。世界卫生组织建议儿童的最大冲击声能量（噪声）水平为120分贝。

NOTE 3 If the A-weighted sound pressure level exceeds 80 dB(A) dBA, noise protection measure should be considered.

注3: 如果A计权声压级超过80 dB (A) dBA, 应考虑采取噪声防护措施。

Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of PATIENT, OPERATOR and other persons from the source of acoustic energy (noise) in NORMAL USE, and if necessary, calculating the A-weighted sound pressure level produced by the ME EQUIPMENT in accordance with ISO 3746, ISO 9614-1 or IEC 61672-1. The following conditions apply. 通过测量患者、操作员和其他人员在正常使用时远离声能（噪声）源的最小距离处的最大A计权声压级来检查合规性，如有必要，根据ISO 3746计算医用电气设备产生的A计权声压级，ISO 9614-1或IEC 61672-1。以下条件适用。

- a) The ME EQUIPMENT is operated under worst-case NORMAL CONDITION.
医用电气设备在最坏情况下正常运行。
- b) Any protective means provided or called for in ACCOMPANYING DOCUMENTS are to be in place during sound measurement.
在声音测量期间，应准备好随附文件中提供或要求的任何保护措施。
- c) Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2.
测量中使用的声级计符合IEC 61672-1和IEC 61672-2。
- d) The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the ME EQUIPMENT is not less than 3 m.
试验室是半混响的，地板是硬反射的。任何墙壁或其他物体与医用电气设备表面之间的距离不小于3 m。
- e) When sound measurements in a test room are not feasible (e.g. for a large PERMANENTLY INSTALLED ME EQUIPMENT), measurements may be done in situ.
当无法在试验室进行声音测量时（例如，对于大型永久性安装的医用电气设备），可在现场进行测量。

9.6.2.2 **Infrasound and ultrasound energy** **次声和超声波能量**

When applicable, the MANUFACTURER shall address the RISKS associated with infrasound or ultrasound in the RISK MANAGEMENT PROCESS.

适用时, 制造商应在风险管理过程中解决次声或超声波相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

9.6.3 *** Hand-transmitted vibration** ***手传振动**

Except for vibrations directly required to carry out the INTENDED USE of the ME EQUIPMENT, means shall be provided to protect the PATIENT, OPERATOR and other persons if in NORMAL USE the hand-transmitted frequency-weighted r.m.s. acceleration generated by the ME EQUIPMENT exceeds the value below:
除了执行医用电气设备预期用途所需的振动外, 如果医用电气设备产生的手动传输频率加权均方根加速度超过以下值, 则应提供保护患者、操作员和其他人员的装置:

- 2,5 m/s² for a cumulative time of 8 h during a 24 h period.
2.5 m/s², 24小时内累计8小时。
- Allowable accelerations for different times are inversely proportional to the square root of the time (e.g. the allowable acceleration for 2 h would be 5,0 m/s²).
不同时间的容许加速度与时间的平方根成反比 (例如, 2小时的容许加速度为5,0 m/s²)。

NOTE Interpolation or extrapolation is allowed for allowable acceleration in accordance with the following formula, $2,5 \times \sqrt{8 / t}$, in m/s², where t is the cumulative time over a 24 h period.

注: 允许根据以下公式 $2,5 \times \sqrt{8 / t}$ 进行内插或外推, 单位为m/s², 其中t是24小时内的累计时间。

Compliance is checked by measurements at points of equipment in hand contact with PATIENT, OPERATOR or other persons. Measurements are made in accordance with ISO 5349-1.

通过在与患者、操作员或其他人员接触的设备点进行测量来检查合规性。根据ISO 5349-1进行测量。

9.7 *** Pressure vessels and parts subject to pneumatic and hydraulic pressure** ***承受气压和液压压力的压力容器和零件**

9.7.1 **General** **总则**

The requirements of this subclause apply to vessels and parts of ME EQUIPMENT subject to pressure, the rupture of which could result in an unacceptable RISK.

本子条款的要求适用于承受压力的医用电气设备的容器和部件, 其破裂可能导致不可接受的风险。

The parts of a pneumatic or hydraulic system that are used as a support system shall additionally comply with the requirements in 9.8.

用作支撑系统的气动或液压系统部件还应符合9.8的要求。

9.7.2 **Pneumatic and hydraulic parts** **气动和液压部件**

Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES shall be so designed that:
医用电气设备或附件的气动和液压部件的设计应确保:

- no unacceptable RISK results from loss of pressure or loss of vacuum;
无因压力损失或真空损失而导致的不可接受风险;

- no unacceptable RISK results from a fluid jet caused by leakage or a component failure;
泄漏或部件故障导致的流体喷射不会产生不可接受的风险；
- elements of the ME EQUIPMENT or an ACCESSORY, and especially pipes and hoses, that can lead to an unacceptable RISK shall be protected against harmful external effects;
医用电气设备或附件的元件，尤其是管道和软管，可能导致不可接受的风险，应防止有害的外部影响；
- reservoirs and similar vessels (e.g. hydro-pneumatic accumulators) that can lead to an unacceptable RISK are automatically depressurized when the ME EQUIPMENT is isolated from its power supply (e.g. pulling out the pneumatic plug at the connector mounted on the facility wall). If this is not possible, means shall be provided for the isolation (e.g. cutting off from the peripheral circuit), or local depressurizing of reservoirs and similar vessels, and pressure indication;
当医用电气设备与其电源隔离时（例如，拔出安装在设施墙上的连接器处的气动插头），可能导致不可接受风险的储液罐和类似容器（如油气储能器）将自动减压。如果无法做到这一点，应提供隔离措施（例如切断与外围电路的连接），或对储气罐和类似容器进行局部减压，并指示压力；
- all elements that can remain under pressure after isolation of the ME EQUIPMENT or an ACCESSORY from its power supply and that could result in an unacceptable RISK shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the ME EQUIPMENT or ACCESSORIES.
医用电气设备或附件与电源隔离后，所有可能仍处于压力下且可能导致不可接受风险的元件应配备明确标识的排气装置，以及一个警告标签，提醒注意在对医用电气设备或附件进行任何设置或维护活动之前，对这些元件进行减压的必要性。

Compliance is checked by inspection and examination of RISK MANAGEMENT FILE.

通过对风险管理文件的检查和审查来检查合规性。

9.7.3 Maximum pressure 最大压力

The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall be considered to be whichever is the highest of the following:
医用电气设备的一部分在正常条件和单一故障条件下所能承受的最大压力应视为以下两者中的最高值：

- a) the **RATED** maximum supply pressure from an external source;
来自外部源的额定最大供给压力；
- b) the pressure setting of a pressure-relief device provided as part of the assembly;
作为总成一部分提供的泄压装置的压力设定值；
- c) the maximum pressure that can be developed by a source of pressure that is part of the assembly, unless the pressure is limited by a pressure-relief device.
作为总成一部分的压力源可以产生的最大压力，除非压力受到泄压装置的限制。

9.7.4 Pressure rating of ME EQUIPMENT parts 医用电气设备部件的压力额定值

The maximum pressure to which a part of ME EQUIPMENT can be subjected in **NORMAL CONDITION** and **SINGLE FAULT CONDITION** shall not exceed the **MAXIMUM PERMISSIBLE WORKING PRESSURE**
医用电气设备部件在正常条件和单一故障条件下所承受的最大压力不得超过最大允许工作压力
PRESSURE for the part, except as allowed for pressure relief devices in 9.7.7.
零件压力，9.7.7中允许的泄压装置除外。

Compliance is checked by inspection of the **MANUFACTURER'S** data for the component, inspection of the **ME EQUIPMENT**, inspection of the **RISK MANAGEMENT FILE**, and where necessary, by functional test.
通过检查制造商的部件数据、检查医用电气设备、检查风险管理文件以及必要时通过功能测试来检查合规性。

9.7.5 * Pressure vessels *压力容器

A pressure vessel shall withstand a **HYDRAULIC TEST PRESSURE** if both the following conditions are met:
如果满足以下两个条件，压力容器应能承受水压试验压力：

- the pressure is greater than 50 kPa; and
压力大于50 kPa；以及
- the product of pressure and volume is greater than 200 kPa·l.
压力与容积之积大于200kPa·l。

Compliance is checked by the following tests:
通过以下试验检查合规性：

The **HYDRAULIC TEST PRESSURE** is the **MAXIMUM PERMISSIBLE WORKING PRESSURE** multiplied by a factor obtained from Figure 32.
液压试验压力是最大允许工作压力乘以从图32中获得的系数。

The pressure is raised gradually to the specified test value and is held at that value for 1 min. A sample that bursts or suffers from permanent (plastic) deformation or leaks constitutes a failure. Leakage at a gasket during this test is not considered to constitute failure unless it occurs at a pressure below 40 % of the required test value, or below the **MAXIMUM PERMISSIBLE WORKING PRESSURE**, whichever is greater.
压力逐渐升高至规定的试验值，并在该值下保持1分钟。破裂或永久（塑性）变形或泄漏的样品构成失效。除非在低于所需试验值40%的压力下或低于最大允许工作压力（以较大者为准），否则在试验过程中垫圈处的泄漏不被视为失效。

No leakage is allowed for pressure vessels intended for toxic, flammable or otherwise hazardous substances. For other pressure vessels, no leakage is allowed that will otherwise result in an unacceptable RISK (e.g. high pressure fluid jet). 用于储存有毒、易燃或其他有害物质的压力容器不允许泄漏。对于其他压力容器，不允许出现泄漏，否则会导致不可接受的风险（例如高压流体射流）。

Where unmarked pressure vessels and pipes (e.g. those with no national certification) cannot be hydraulically tested, integrity is verified by other suitable tests, e.g. pneumatic using suitable media, at the same test pressure as for the hydraulic test. 如果无法对未标记的压力容器和管道（例如没有国家认证的压力容器和管道）进行液压试验，则应通过其他合适的试验（例如使用合适介质的气动试验）在与水压试验相同的试验压力下验证完整性。

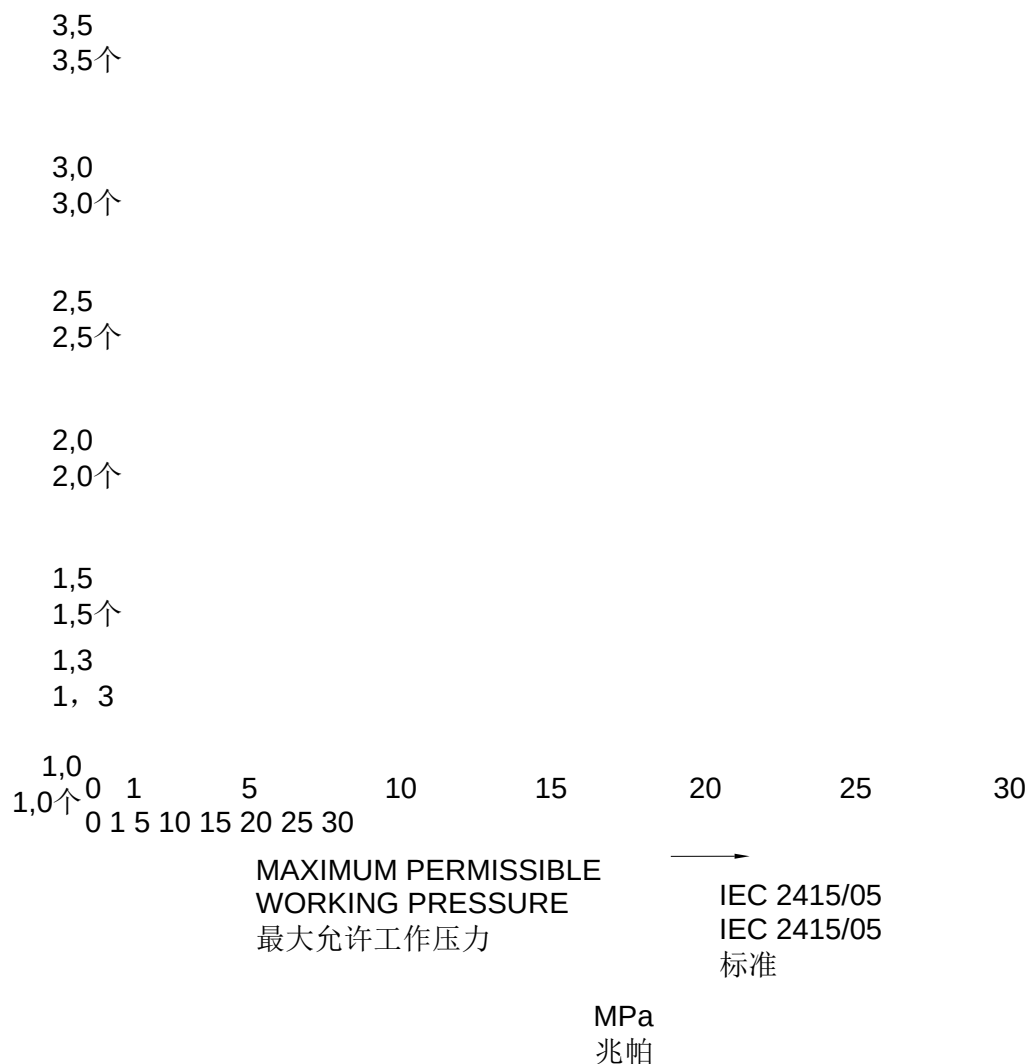


Figure 32 – Ratio between HYDRAULIC TEST PRESSURE
图32-水压试验压力比
and MAXIMUM PERMISSIBLE WORKING PRESSURE
最大允许工作压力
(see 9.7.5)
(见9.7.5)

9.7.6 Pressure-control device 压力控制装置

In ME EQUIPMENT for which 9.7.7 requires a pressure-relief device, any pressure-control device responsible for regulating the pressure shall be capable of performing under RATED load for 100 000 cycles of operation and shall prevent the pressure from exceeding 90 % of the setting of the pressure-relief device under any condition of NORMAL USE.
在9.7.7要求使用泄压装置的医用电气设备中，负责调节压力的任何压力控制装置应能够在额定负载下运行100000次循环，并应防止压力在任何正常使用条件下超过泄压装置设定值的90%。

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and where necessary, by functional test.
通过检查制造商的部件数据、检查医用电气设备、检查风险管理文件以及必要时通过功能测试来检查合规性。

9.7.7 Pressure-relief device

泄压装置

ME EQUIPMENT shall incorporate pressure-relief device(s) where the MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded.

医用电气设备应包括泄压装置，否则可能超过最大允许工作压力。

A pressure-relief device shall comply with all of the following requirements:

泄压装置应符合以下所有要求：

- a) it shall be connected as close as reasonably practical to the pressure vessel or parts of the system that it is intended to protect;
其应尽可能靠近其拟保护的压力容器或系统部件；
- b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;
其安装应便于检查、维护和修理；
- c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;
在不使用工具的情况下，不得对其进行调整或使其不起作用；
- d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;
其排放口的位置和方向应确保释放的材料不会朝向任何人；
- e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK;
其排放口的位置和方向应确保装置的操作不会在可能导致不可接受风险的零件上沉积材料；
- f) it shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply pressure;
其应具有足够的排放能力，以确保在供应压力控制失效的情况下，压力不会超过其所连接系统的最大允许工作压力的10%；

- g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect;
泄压装置和其拟保护的部件之间不得有截止阀；
- h) the minimum number of cycles of operation shall be 100 000, except for one-time use devices such as bursting disks.
除爆破片等一次性使用装置外，最小操作循环次数应为100000次。

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and where necessary, by functional test.
通过检查制造商的部件数据、检查医用电气设备、检查风险管理文件以及必要时通过功能测试来检查合规性。

9.7.8 RATED maximum supply pressure
额定最大供气压力

See 7.2.18.

9.8 * MECHANICAL HAZARDS associated with support systems
*与支撑系统相关的机械危险

9.8.1 General
总则

Where ME EQUIPMENT parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK.
如果医用电气设备部件设计用于支撑负载或提供驱动力，如果机械故障可能构成不可接受的风险，则应采用以下要求。

- The construction of the support, suspension or actuation system shall be designed based upon Table 21 and the TOTAL LOAD.
支撑、悬挂或驱动系统的结构应根据表21和总荷载进行设计。
- Means of attachment of ACCESSORIES shall be designed such that any possibility of incorrect attachment that could result in an unacceptable RISK is avoided.
附件连接方式的设计应避免任何可能导致不可接受风险的错误连接。
- The RISK ANALYSIS of support systems shall consider MECHANICAL HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions.
支撑系统的风险分析应考虑由静态、动态、振动、冲击和压力载荷、基础和其他运动、温度、环境、制造和使用条件所引起的机械危害。
- All likely failure effects shall be considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration and residual stresses resulting from the manufacturing PROCESSES, e.g. machining, assembling, welding, heat treatment or surface coating.
风险分析中应考虑所有可能的失效影响。这些因素包括过度偏转、塑性变形、延性或脆性断裂、疲劳断裂、不稳定性（屈曲）、应力辅助腐蚀开裂、磨损、材料蠕变、材料劣化和制造过程（如机加工、装配、焊接、热处理或表面涂层）产生的残余应力。
- The ACCOMPANYING DOCUMENTS shall contain instructions on attachment of structures to a floor, wall, ceiling, etc. making adequate allowances for quality of the materials used to make the connection and shall list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which the parts will be attached.
随附文件应包含关于将结构连接到地板、墙壁、天花板等的说明，充分考虑到用于连接的

材料的质量，并应列出所需的材料。此外，还应提供检查部件所附结构表面是否充分的建议。

9.8.2 * TENSILE SAFETY FACTOR

*拉伸安全系数

Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. TENSILE SAFETY FACTORS shall not be less than those shown in Table 21 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the ME EQUIPMENT, or the support is a foot rest. The requirements for foot rests are in
在医用电气设备的预期使用寿命期间，支撑系统应保持结构完整性。拉伸安全系数不得低于表21所示值，除非有替代方法证明医用电气设备在整个预期使用寿命内的结构完整性，或者支架是脚踏板。对搁脚板的要求见

9.8.3.2

9.8.3.2 a) 段) 。

a).

Table 21 – Determination of TENSILE SAFETY FACTOR

表21——拉伸安全系数的测定

Situati on 形势			Minimum TENSILE SAFETY FACTOR a 最小拉伸安全系 数a	
No · 不 。	System Part 系统部分	Elongati on 延伸率	A b 甲b	B c 卑诗 省
1 1	Support system parts not impaired by wear 支撑系统零件不会因 磨损而受损	Metallic material d having a specific elongation at break equal to or greater than 5 % 比断裂伸长率等于或大 于5%的金属材料d	2,5 2,5个	4 4
2 2	Support system parts not impaired by wear 支撑系统零件不会因 磨损而受损	Metallic material d having a 金属材料d具有 specific elongation at break of less than 5 % 断裂伸长率小于5%	4 4	6 6
3 三	Support system parts 支撑系统部件 impaired by wear e and no 因磨损e和no而受损 MECHANICAL PROTECTIVE DEVICE 机械保护装置	Metallic material d having a specific elongation at break equal to or greater than 5 % 比断裂伸长率等于或大 于5%的金属材料d	5 5	8 8
4 4	Support system parts 支撑系统部件 impaired by wear e and no 因磨损e和no而受损 MECHANICAL PROTECTIVE DEVICE 机械保护装置	Metallic material d having a 金属材料d具有 specific elongation at break of less than 5 % 断裂伸长率小于5%	8 8	12 12
5 5	Support system parts 支撑系统部件 impaired by wear e and with 因磨损而受损 MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems) 设备（或多个支持系统 的主要系统）	Metallic material d having a specific elongation at break equal to or greater than 5 % 比断裂伸长率等于或大 于5%的金属材料d	2,5 2,5个	4 4

6 6	Support system parts 支撑系统部件 impaired by wear e and 因磨损而受损 MECHANICAL PROTECTIVE 机械防护 DEVICE (or primary system of multiple support systems) 设备（或多个支持系统 的主要系统）	Metallic material d having a 金属材料d具有 specific elongation at break of less than 5 % 断裂伸长率小于5%	4 4	6 6
7 7	MECHANICAL PROTECTIVE 机械防护 DEVICE (or back-up system of multiple support system) 装置（或多重支援系统 的后备系统）		2,5 2,5个	4 4
a The TENSILE SAFETY FACTORS are intended to take account of conditions defined in 15.3.7 (i.e. environmental effects, impairing effects of wear, corrosion, material fatigue or ageing). a拉伸安全系数旨在考虑15.3.7中规定的条件（即环境影响、磨损、腐蚀、材料疲劳或老化的损害效应）。 b Case A = The material TENSILE STRENGTH and all external forces to be expected are quantifiable and known accurately. b情况A=材料抗拉强度和预期的所有外力都是可量化且准确已知的。 c Case B = Other than case A; specifically, the material TENSILE STRENGTH and all external forces to be expected are known approximately, but not with sufficient accuracy to justify the TENSILE SAFETY FACTOR for case A. c情况B=情况A以外的情况；具体而言，材料抗拉强度和预期的所有外力大致已知，但不足以证明拉伸是正确的 案例A的安全系数。 d For non-metallic materials, particular standards can prescribe adequate TENSILE SAFETY FACTORS d对于非金属材料，特殊标准可规定足够的拉伸安全系数 (see rationale in Annex A, Subclause 9.8). （见附录A第9.8款的基本原理）。 e Components considered impaired by wear include: chains, cables (wire rope), belts, jack screw nuts, springs, pneumatic or hydraulic hoses, gaskets or rings of pneumatic or hydraulic pistons. e因磨损而受损的部件包括：链条、电缆（钢丝绳）、皮带、千斤顶螺丝螺母、弹簧、气动或液压软管、气动或液压活塞的垫圈或环。				

Compliance with 9.8.1 and 9.8.2 is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.
通过检查医用电气设备、风险管理文件、所用材料的规格和这些材料的加工规范来检查是否符合9.8.1和9.8.2。

When test results are part of relevant information, testing consists of gradually applying a test load to the support assembly under test equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR. If testing is needed to demonstrate compliance with 9.8.1 or 9.8.2, a test load equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR

is gradually applied to the support assembly under test. The support assembly under test is to be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK. 当试验结果为相关信息的一部分时，试验包括逐渐向试验中的支撑组件施加试验荷载，试验荷载等于总荷载乘以所需的拉伸安全系数。如果需要进行试验以证明符合9.8.1或9.8.2的要求，则应逐渐将等于总荷载乘以所需拉伸安全系数的试验荷载施加于受试支撑组件上。试验中的支撑组件应在1分钟后达到平衡，否则不会导致不可接受的风险。

NOTE 1 It might be necessary to support assemblies that are connected to the assembly under test but do not require such a high safety factor, e.g. assembly under test requires TENSILE SAFETY FACTOR = 8 and assembly supporting it is designed with a TENSILE SAFETY FACTOR = 4. Use of additional support should be explained in the test report. 注1：可能有必要支撑与被测组件连接但不需要如此高安全系数的组件，例如，被测组件要求拉伸安全系数=8，支撑其组件的设计拉伸安全系数=4。应在试验报告中说明使用附加支撑。

NOTE 2 The 1 min time period might need to be longer for materials which might have creep type problems, such as plastics or other non-metallic materials. 注2：对于可能存在蠕变类型问题的材料，如塑料或其他非金属材料，1分钟的时间可能需要更长。

9.8.3 * Strength of PATIENT or OPERATOR support or suspension systems *患者或操作员支撑或悬挂系统的强度

9.8.3.1 General 总则

ME EQUIPMENT parts serving for support or immobilization of PATIENTS shall be designed and manufactured so as to minimize the there is no unacceptable RISK of physical injuries and or of accidental loosening of fixings.
用于支持或固定患者的医用电气设备部件的设计和制造应尽量减少不可接受的人身伤害和/或固定件意外松动的风险。

The SAFE WORKING LOAD of ME EQUIPMENT or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by MANUFACTURERS to be supported or suspended by the ME EQUIPMENT or ME EQUIPMENT parts.

医用电气设备或其用于支撑或悬挂患者或操作员的部件的安全工作负载应为患者或操作员的质量加上制造商拟由医用电气设备或医用电气设备部件支撑或悬挂的附件的质量之和。

Unless otherwise stated by the MANUFACTURER, supporting and suspending parts for adult human PATIENTS or OPERATORS shall be designed for a PATIENT or OPERATOR having a minimum mass of 135 kg and ACCESSORIES having a minimum mass of 15 kg. 除非制造商另有说明，成人患者或操作员的支撑和悬挂部件应设计为最小质量为135 kg的患者或操作员，以及最小质量为15 kg的附件。

Where a MANUFACTURER specifies particular applications (e.g. paediatric use), the maximum mass of the PATIENT included in the SAFE WORKING LOAD of the ME EQUIPMENT or its parts serving for support or suspension of PATIENTS may be adapted. When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the ME EQUIPMENT and described in ACCOMPANYING DOCUMENTS. When the maximum allowable value of the mass of the PATIENT is more than 135 kg, that value shall be described in ACCOMPANYING DOCUMENTS. 如果制造商规定了特殊应用（例如儿科应用），医用电气设备或其用于支撑或悬吊患者的部件的安全工作负载中包含的患者最大质量可以进行调整。当病人质量的最大允许值小于135 kg时，该值应标记在医用电气设备上，并在随附文件中说明。当病人质量的最大允许值大于135 kg时，应在随附文件中说明该值。

Compliance is checked by inspection of markings, ACCOMPANYING DOCUMENTS, and the RISK MANAGEMENT FILE.
通过检查标记、随附文件和风险管理文件检查合规性。

Compliance is checked by inspection of the ME EQUIPMENT (including markings), the ACCOMPANYING DOCUMENTS, the MANUFACTURER'S data for the component, the RISK MANAGEMENT FILE, and, where necessary, functional test. 通过检查医用电气设备（包括标记）、随附文件、部件的制造商数据、风险管理文件以及必要时功能测试来检查合规性。

9.8.3.2 * Static forces due to loading from persons *由人员荷载引起的静力

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of the PATIENTS or OPERATORS is distributed on the support/suspension surface in a manner representing the human body (see the example in Figure A.19).

在分析支撑组件上的荷载力和扭矩时，代表患者或操作员质量的安全工作荷载部分以代表人体的方式分布在支撑/悬挂表面上（见图a.19中的示例）。

NOTE 1 The position of the human body varies depending on the configuration of the

support/suspension system and therefore the load acting on different sections will vary and should be taken into account.

注1：人体的位置取决于支撑/悬挂系统的配置，因此作用在不同部位的荷载也会有所不同，应予以考虑。

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of ACCESSORIES shall be deployed as in NORMAL USE or, if not defined, at the worst case position permitted by the configuration or ACCESSORIES attachment on the support/suspension parts.

在分析支撑组件上的荷载力和扭矩时，代表附件质量的安全工作荷载部分应在正常使用时进行部署，或者，如果没有规定，则应在支架/悬挂部件上的配置或附件附件允许的最坏情况位置进行部署。

a) For a foot rest that is intended to temporarily support a standing PATIENT or OPERATOR, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0,1 m².

对于用于临时支撑站立患者或操作员的脚踏板，患者或操作员的整个质量分布在0.1 m²的面积上。

Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials, and the following test:

通过检查医用电气设备、风险管理文件、所用材料的规格和这些材料的加工规范，以及以下试验来检查合规性：

Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE. 在进行这些测试之前，患者支撑/悬挂系统水平放置在正常使用中最不利的位置。

A mass equal to two times 135 kg or two times the intended person load, whichever is greater is applied to the foot rest over an area of 0,1 m² for 1 min. After the test, a foot rest and its fixings that shows any damage or permanent deflection that could result in an unacceptable RISK from normal greater than 5° constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

将等于两倍135 kg或两倍于预期人员荷载的质量（以较大者为准）施加在0.1 m²面积的搁脚板上1分钟。试验后，如果搁脚板及其固定件出现任何损坏或永久变形，可能导致正常情况下超过5°的不可接受风险，则构成故障。应保持基本安全和基本性能。

NOTE 2 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.
注2: 可能影响基本安全的损坏示例包括爬电距离和空气间隙减小到8.9中规定的值以下, 接近超过8.4中限制的部件, 或接近可能造成危害的活动部件。

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

可用于确定该试验是否导致基本安全损失的评估标准包括:

- those in Clause 8 and 11.6;
第8条和第11.6条的规定;
- the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a
8.8.3中规定的介电强度试验, 以评估固体绝缘的完整性
MEANS OF PROTECTION; and
保护手段; 以及
- measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.
测量爬电距离或空气间隙, 以将数值与8.9中规定的最小距离进行比较。通常可以忽略不会对电击或湿气保护产生不利影响的小芯片。

- b) For an area of support/suspension where a PATIENT or OPERATOR can sit, deflection of a support surface from PATIENT or OPERATOR loading shall not result in an unacceptable RISK.

对于患者或操作员可坐的支撑/悬挂区域, 患者或操作员负载的支撑面偏转不得导致不可接受的风险。

Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials, and the following test:
通过检查医用电气设备、风险管理文件、所用材料的规格和这些材料的加工规范, 以及以下试验来检查合规性:

Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.
在进行这些测试之前, 患者支撑/悬挂系统水平放置在正常使用中最不利的位置。

A mass of 60 % of the part of the SAFE WORKING LOAD representing the PATIENT or OPERATOR, as defined in the instructions for use, or at a minimum 80 kg, is placed on the support/suspension system with the centre of the load 60 mm from the outer edge of the support/suspension system for a time of at least one minute. Any permanent deflection of the support/suspension system that could result in an unacceptable RISK from normal greater than 5□ constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.
按照使用说明的规定, 将代表患者或操作员的安全工作荷载的60%或至少80 kg的质量放置在支撑/悬挂系统上, 荷载中心距支撑/悬挂系统外缘60 mm, 持续至少一分钟。支撑/悬架系统的任何永久性偏转, 如果正常情况下超过5□会导致不可接受的风险, 则构成故障。应保持基本安全和基本性能。

NOTE 3 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.
注3: 可能影响基本安全的损坏示例包括爬电距离和空气间隙减小到8.9中规定的值以下, 接近超过8.4中限制的部件, 或接近可能造成危害的活动部件。

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

可用于确定该试验是否导致基本安全损失的评估标准包括：

- those in Clause 8 and 11.6; 第8条和第11.6条的规定；
- the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a 8.8.3中规定的介电强度试验，以评估固体绝缘的完整性 MEANS OF PROTECTION; and 保护手段；以及
- measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored. 测量爬电距离或空气间隙，以将数值与8.9中规定的最小距离进行比较。通常可以忽略不会对电击或湿气保护产生不利影响的小芯片。

9.8.3.3 * Dynamic forces due to loading from persons
***由人员荷载引起的动力**

Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on ME equipment parts intended to support or suspend a PATIENT or OPERATOR in NORMAL USE, they shall not result in an unacceptable RISK the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. 如果动态力（由于坐下、站起来、病人处理过程等）可施加在医用电气设备部件上，用于支撑或悬挂正常使用中的患者或操作员，则不会导致不可接受的风险，医用电气设备应保持基本安全和基本性能。

Compliance is checked by the following test:
通过以下试验检查合规性：

Prior to performing this test, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE. 在进行该测试之前，患者支撑/悬挂系统水平放置在正常使用中最不利的位置。

For the area of support/suspension where a PATIENT or OPERATOR can sit, a mass (as defined in Figure 33) equivalent to the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the instructions for use is dropped from a distance of 150 mm above the seat area. Any loss of function or structural damage that could result in an unacceptable RISK constitutes a failure. 对于患者或操作员可坐的支撑/悬挂区域，从座椅区域上方150 mm处掉落一个质量块（如图33所示），该质量相当于使用说明中规定的代表患者或操作员的安全工作负载。任何可能导致不可接受风险的功能丧失或结构损坏均构成故障。

For the area of support/suspension where a PATIENT or OPERATOR can sit, the top reservoir of the body upper-carriage module described in Figure 33 is loaded with the appropriate mass to obtain the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the ACCOMPANYING DOCUMENTS. The body upper-carriage module with appropriate mass is dropped from a distance of 150 mm above the seat area. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.
对于患者或操作员可坐的支撑/悬挂区域，图33中所述的身体上部托架模块的顶部贮存器装载适当的质量，以获得代表患者或操作员的安全工作负载，如随附文件所述。具有适当质量的车身上车架模块从座椅区域上方150 mm处掉落。应保持基本安全和基本性能。

NOTE Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts which could cause HARM.
注：可能影响基本安全的损坏示例包括爬电距离和空气间隙减小到8.9中规定的值以下，接近超出8.4中限制的部件，或接近可能造成危害的活动部件。

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

可用于确定该试验是否导致基本安全损失的评估标准包括：

- those in Clause 8 and 11.6;
第8条和第11.6条的规定；
- the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid providing a MEANS OF PROTECTION; and
8.8.3中规定的介电强度试验，以评估提供保护措施的固体的完整性；以及
- measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.
测量爬电距离或空气间隙，以将数值与8.9中规定的最小距离进行比较。通常可以忽略不会对电击或湿气保护产生不利影响的小芯片。

9.8.4 * Systems with MECHANICAL PROTECTIVE DEVICES

*带机械保护装置的系统

9.8.4.1 General

总则

- a) A MECHANICAL PROTECTIVE DEVICE shall be provided when a support system or any of its parts impaired by wear have a TENSILE SAFETY FACTOR greater than or equal to the values specified in rows 5 and 6 but less than those in rows 3 and 4 of Table 21.

当支撑系统或其任何磨损部件的拉伸安全系数大于或等于表21第5行和第6行中规定的值，但小于表21第3行和第4行中的值时，应提供机械保护装置。

- b) The MECHANICAL PROTECTIVE DEVICE shall:

机械保护装置应：

- be designed on the basis of TOTAL LOAD, which shall include the effects of the SAFE WORKING LOAD when applicable;
—根据总荷载进行设计，总荷载应包括安全工作荷载的影响（如适用）；
- have TENSILE SAFETY FACTORS for all parts not less than those in row 7 of Table 21;
所有零件的拉伸安全系数不小于表21第7行中的值；
- activate before travel (movement) produces an unacceptable RISK;
在旅行（移动）产生不可接受的风险之前激活；
- take into account 9.2.5 and 9.8.4.3.

考虑9.2.5和9.8.4.3。

Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.

通过检查医用电气设备、风险管理文件、所用材料的规格和这些材料的加工规范来检查合规性。

Compliance is checked by the following as necessary:

必要时，通过以下方式检查合规性：

- inspection of the overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation;
检查超程（从机械保护装置接合到不再移动的停止距离）计算和评估；
- any functional tests.
任何功能测试。

NOTE The overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation are part of the RISK MANAGEMENT FILE.

注：超程（从机械保护装置启动到不再移动的停止距离）计算和评估是风险管理文件的一部分。

Dimensions in millimetres
尺寸单位为毫米

300
300

IEC 2416/05
IEC 2416/05标准

NOTE The upper carriage of the human body test mass apparatus The top reservoir of the body upper-carriage module is formed of wood, metal or a similar material. The reservoir is intended to retain the appropriate human body mass, typically with high density material (e.g. lead). The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) is not specified, as with a large mass being dropped, the foam properties are likely inconsequential. The foam is cylindrical, rather than spherical.
注：人体测试质量仪的上车架车身上车架模块的顶部储液罐由木材、金属或类似材料制成。储液罐旨在保持适当的人体质量，通常使用高密度材料（如铅）。底部是泡沫。泡沫的弹性系数或弹簧系数（ILD或IFD额定值）没有规定，因为大量的质量被落下，泡沫性能可能不重要。泡沫是圆柱形的，而不是球形的。

Figure 33 – Human body test mass (see 9.8.3.3) Body upper-carriage module
图33-人体试验质量（见9.8.3.3）车身上车架模块

9.8.4.2 Use after activation of a MECHANICAL PROTECTIVE DEVICE 启动机械保护装置后使用

If ME EQUIPMENT can still be used after failure of the suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE such as a secondary cable (wire rope), it shall become obvious to the OPERATOR that the MECHANICAL PROTECTIVE DEVICE has been activated.
如果医用电气设备在悬挂或驱动装置发生故障并激活机械保护装置（如二次电缆（钢丝绳））后仍可使用，则操作员应清楚地看到机械保护装置已被激活。

The MECHANICAL PROTECTIVE DEVICE shall require the use of a TOOL to be reset or replaced.
机械保护装置应要求使用工具复位或更换。

Compliance is checked by inspection of the ME EQUIPMENT.
通过检查医用电气设备来检查合规性。

9.8.4.3 MECHANICAL PROTECTIVE DEVICE intended for single activation
一次激活用机械保护装置

If a MECHANICAL PROTECTIVE DEVICE is intended to function only once, the following requirements shall be fulfilled:

如果机械保护装置只起一次作用，则应满足以下要求：

- Further use of the ME EQUIPMENT shall be impossible until the MECHANICAL PROTECTIVE DEVICE has been replaced.
在更换机械保护装置之前，不可能进一步使用医用电气设备。
- The ACCOMPANYING DOCUMENTS shall instruct that once the MECHANICAL PROTECTIVE DEVICE has been activated, SERVICE PERSONNEL are to be called, and the MECHANICAL PROTECTIVE DEVICE must be replaced before the ME EQUIPMENT can be used again.
随附文件应说明，一旦机械保护装置启动，应呼叫维修人员，在医用电气设备可以再次使用之前，必须更换机械保护装置。
- The ME EQUIPMENT shall be permanently marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2).
医用电气设备应永久标记安全标志ISO 7010-W001（见表D.2，安全标志2）。
- The marking shall be adjacent to the MECHANICAL PROTECTIVE DEVICE or so located that its relation to the MECHANICAL PROTECTIVE DEVICE is obvious to the person performing service or repair.
标记应靠近机械保护装置，或其与机械保护装置的关系对于进行维修或修理的人员来说是显而易见的。

NOTE See also 15.3.7.

注：另见15.3.7。

Compliance is checked as follows:
合规性检查如下：

- by inspection of the ME EQUIPMENT, the ACCOMPANYING DOCUMENTS, the RISK MANAGEMENT FILE, and the specifications of materials used and the processing specifications for these materials;
通过检查医用电气设备、随机文件、风险管理文件、所用材料的规格和这些材料的加工规范；
- a chain, cable (wire rope), band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, is defeated (to test the MECHANICAL PROTECTIVE DEVICE) by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the ME EQUIPMENT. If the system supports a PATIENT or OPERATOR, the load is to include the SAFE WORKING LOAD defined in 9.8.3.1.
用于支撑荷载的链条、缆绳（钢丝绳）、钢带、弹簧、皮带、千斤顶螺丝螺母、气动或液压软管、结构件等，通过任何方便的方法（用于测试机械保护装置），从而使最大正常荷载从结构允许的最不利位置下降医用电气设备。如果系统支持患者或操作员，则负载应包括9.8.3.1中定义的安全工作负载。

Any evidence of damage to a MECHANICAL PROTECTIVE DEVICE that would affect its ability to perform its intended function constitutes a failure.
任何可能影响机械保护装置执行其预期功能能力的损坏迹象均构成故障。

9.8.5

Systems without MECHANICAL PROTECTIVE DEVICES

9.8.5无机械保护装置的系统

A MECHANICAL PROTECTIVE DEVICE is not required if:
在下列情况下，不需要机械保护装置：

- the support system parts are not impaired by wear and have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 1 and 2 of Table 21; or
支撑系统零件不会因磨损而受损，并具有拉伸安全系数大于或等于表21第1行和第2行中规定的值；或
- the support system parts are impaired by wear but have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 3 and 4 of Table 21.
支撑系统零件因磨损而受损，但拉伸安全系数大于或等于表21第3行和第4行中规定的值。

Compliance is checked by inspection of the ME EQUIPMENT, the design documentation and the RISK MANAGEMENT FILE.
通过检查医用电气设备、设计文件和风险管理文件。

10 *

Protection against unwanted and excessive radiation HAZARDS

*防止有害和过度辐射危害

10.1

X-Radiation X射线

10.1.1 *

ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation *医用电气设备不用于产生诊断或治疗性X射线

For ME EQUIPMENT not intended to produce X-radiation for diagnostic or therapeutic purposes, but which might produce ionizing radiation, the dose-rate AIR KERMA rate shall not exceed 36 pA/kg (5 μSv/h) (0,5 mR/h) 5 □Gy/h at a distance of 5 cm from a surface of the ME EQUIPMENT taking account of the background radiation.
对于不打算产生诊断或治疗用X射线，但可能产生电离辐射的医用电气设备，剂量率空气比释动能率不得超过36 pA/kg（5μSv/h）（0，5 mR/h）5μGy/h，距离医用电气设备表面5 cm，考虑到背景辐射。

If the INTENDED USE of the ME EQUIPMENT requires a permanent proximity to a PATIENT, the

resulting annual exposure should be made acceptable taking into account the irradiated body part and national regulations and/or international recommendations.
如果医用电气设备的预期用途需要长期靠近患者，则应考虑到受辐射的身体部位和国家法规和/或国际建议，使其每年暴露在可接受的范围内。

NOTE 1 The dose-rate value appears in ICRP 60 [39].

注1剂量率值见ICRP 60[39]。

NOTE 2 In the member countries of CENELEC, the amount of ionizing radiation is regulated by European Council Directive 96/29/Euratom of 13 May 1996. This Directive requires that at any point 10 cm from the surface of the equipment, the dose-rate shall not exceed 1 μ Sv/h (0,1 mR/h) taking account of the background level.

注2：在CENELEC成员国，电离辐射量由欧洲理事会1996年5月13日第96/29/Euratom号指令规定。本指令要求，在距离设备表面10 cm的任何位置，考虑到背景水平，剂量率不得超过1 μ Sv/h（0,1 mR/h）。

Compliance is checked by following test:

通过以下试验检查合规性：

The amount of radiation is determined by means of a radiation monitor of the ionizing chamber type with an effective area of 10 cm² or by measuring equipment of other types giving equivalent results.

辐射量通过有效面积为10 cm²的电离室式辐射监测器或其他类型的测量设备确定。

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any controls adjusted so as to give maximum radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.

医用电气设备在最不利的额定电源电压下运行，并对任何控制装置进行调整，以便在保持医用电气设备正常使用的同时提供最大的辐射。

Internal preset controls not intended to be adjusted during the EXPECTED SERVICE LIFE of the
内部预设控制装置在预期使用寿命内不进行调整

ME EQUIPMENT are not considered.
不考虑医用电气设备。

Measurements are made at a distance of 5 cm from any surface to which OPERATORS other than SERVICE PERSONNEL:

在距离任何表面5 cm处进行测量, 而非维修人员:

- can gain access without the use of a TOOL;
无需使用工具即可进入;
- is deliberately provided with the means of access; or
故意提供进入通道; 或
- is instructed to enter regardless of whether or not a TOOL is needed to gain access.
无论是否需要工具来访问, 都指示输入。

Any measurement exceeding 36 pA/kg (5 μSv/h) (0,5 mR/h) 5 □Gy/h adjusted for the level of background radiation constitutes a failure.

任何测量值超过36 pA/kg (5μSv/h) (0,5 mR/h) 5μGy/h (根据本底辐射水平进行调整) 即构成失败。

NOTE 3 This test PROCEDURE is equivalent to that in Annex H of IEC 60950-1:20012005.

注3: 本试验程序等同于IEC 60950-1:20012005附录H中的程序。

10.1.2 ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation

用于产生诊断或治疗性X射线的医用电气设备

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISK from unintended X-radiation from ME EQUIPMENT designed to produce X-radiation for diagnostic and therapeutic purposes. See IEC 60601-1-3 and also see 1.3.
制造商应解决X射线诊断过程中产生的意外风险。见IEC 60601-1-3和1.3。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

Unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X-radiation shall be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of the RISK MANAGEMENT PROCESS.

设计用于产生诊断或治疗性X射线的医用电气设备的意外X射线应通过适用的特殊和附带标准, 或在没有这些标准的情况下, 通过应用风险管理流程, 尽可能减少。

For intended X-radiation, also see 12.4.5.2 and 12.4.5.3.

关于预期的X射线, 另见12.4.5.2和12.4.5.3。

Compliance is checked by application of applicable particular and collateral standards or inspection of the RISK MANAGEMENT FILE.
通过应用适用的特殊和担保标准或检查风险管理文件来检查合规性。

10.2 Alpha, beta, gamma, neutron and other particle radiation

α、β、γ、中子和其他粒子辐射

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时, 制造商应在风险管理过程中解决

RISKS associated with alpha, beta, gamma, neutron and other particle radiation.

与α、β、γ、中子和其他粒子辐射有关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

10.3 Microwave radiation

微波辐射

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the

适用时，制造商应在风险管理过程中解决
RISKS associated with microwave radiation.
与微波辐射相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz shall not exceed 10 W/m² at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions. This requirement does not apply to parts of the apparatus where microwave radiation is propagated intentionally, for example, at waveguide output ports.

在参考试验条件下，在距离医用电气设备表面50 mm处，频率为1 GHz至100 GHz的非预期微波辐射的功率密度不得超过10 W/m²。此要求不适用于微波辐射有意传播的设备部件，例如，在波导管输出端口处。

NOTE This requirement is equivalent to that in subclause 12.4 of IEC 61010-1:2001.
注：本要求等同于IEC 61010-1:2001第12.4款的要求。

Compliance is checked by review of MANUFACTURER'S calculations and, if necessary, the following test:

通过审查制造商的计算结果以及（如有必要）进行以下试验来检查合规性：

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any control adjusted so as to give maximum microwave radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.
医用电气设备在最不利的额定电源电压下运行，并对任何控制装置进行调整，以便在保持医用电气设备正常使用的同时提供最大的微波辐射。

Internal pre-set controls not intended to be adjusted during the expected SERVICE LIFE of the
在预期使用寿命期间，不打算调整的内部预设控制
ME EQUIPMENT are not considered.
不考虑医用电气设备。

Measurements are made at a distance of 50 mm from any surface to which OPERATORS other than SERVICE PERSONNEL:
在距离操作员（维修人员除外）的任何表面50 mm的距离处进行测量：

- can gain access without the use of a TOOL;
无需使用工具即可进入；
- are deliberately provided with the means of access; or
故意提供进入途径；或
- are instructed to enter regardless of whether or not a TOOL is needed to gain access. Any measurement exceeding 10 W/m² under reference test conditions constitutes a failure.

无论是否需要工具进入。在参考试验条件下，任何超过10 W/m²的测量值均构成失败。

10.4 * Lasers and light emitting diodes (LEDs)

***激光器和发光二极管（LED）**

The relevant requirements of IEC 60825-1:1993 apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:1993. IEC 60825-1:1993的相关要求适用。如果在设备内使用激光挡光板或类似产品，它们应符合IEC 60825-1:1993的要求。

For lasers that produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm, the relevant requirements of IEC 60825-1:2007 shall apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:2007. 对于产生或放大波长范围为180 nm至1 mm的电磁辐射的激光器，应适用IEC 60825-1:2007的相关要求。如果在设备内使用激光挡光板或类似产品，它们应符合IEC 60825-1:2007的要求。

NOTE For laser equipment that is intended for use on humans or animals for surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications and classified as a Class 3b or Class 4 laser product as defined in IEC 60825-1, see also IEC 60601-2-22 注：对于拟用于人或动物的外科、治疗、医学诊断、化妆品或兽医应用的激光设备，如IEC 60825-1所定义，被归类为3b或4类激光产品，也可参见IEC 60601-2-22

Compliance is checked by following the relevant PROCEDURES of IEC 60825-1:1993/2007. 按照IEC 60825-1:1993/2007的相关程序检查合规性。

10.5 Other visible electromagnetic radiation

其他可见电磁辐射

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with visible electromagnetic radiation, other than that produced by lasers and light emitting diodes (see 10.4). 在适用的情况下，制造商应在风险管理过程中解决与可见电磁辐射有关的风险，激光和发光二极管产生的风险除外（见10.4）。

Compliance is checked by inspection of the RISK MANAGEMENT FILE. 通过检查风险管理文件来检查合规性。

10.6 Infrared radiation

红外辐射

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with infrared radiation, other than that produced by lasers and light emitting diodes (see 10.4). 适用时，制造商应在风险管理过程中解决与红外线辐射有关的风险，而不是激光和发光二极管产生的风险（见10.4）。

Compliance is checked by inspection of the RISK MANAGEMENT FILE. 通过检查风险管理文件来检查合规性。

10.7 Ultraviolet radiation
紫外线辐射

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ultraviolet radiation, other than that produced by lasers and light emitting diodes (see 10.4).
适用时，制造商应在风险管理过程中解决与紫外线辐射有关的风险，而不是激光和发光二极管产生的风险（见10.4）。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

11 Protection against excessive temperatures and other HAZARDS
防止温度过高和其他危险

11.1 * Excessive temperatures in ME EQUIPMENT
*医用电气设备温度过高

11.1.1 * Maximum temperature during NORMAL USE
*正常使用时的最高温度

When ME EQUIPMENT is operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description (see 7.9.3.1):
当医用电气设备在最坏情况下正常使用时，包括技术说明中规定的最高环境工作温度（见7.9.3.1）：

- ME EQUIPMENT parts shall not reach temperatures exceeding the values given in Table 22 and Table 23;
医用电气设备部件的温度不得超过表22和表23中给出的值；
- the ME EQUIPMENT shall not cause the surfaces of the test corner to exceed 90 °C; and
医用电气设备不得导致试验角表面超过90°C； 以及
 - THERMAL CUT-OUTS shall not operate in NORMAL CONDITION.
-热断路器在正常情况下不得工作。

Table 22 – Allowable maximum temperatures of parts
表22-零件的允许最高温度

Part s 部分	Maximum Temperature 最高温度 □C 摄氏度
Insulation, including winding insulation a 绝缘，包括绕组绝缘a	
- of Class A Material -A级材料	105 105
- of Class E Material -E类材料	120 120
- of Class B Material -B类材料	130 130
- of Class F Material -F类材料	155 155
- of Class H Material -H类材料	180 180
Parts with T marking 有T标记的零件	T b T b型
Other components and materials 其他部件和材料	c c
Parts in contact with flammable liquid with flash-point of T □C 与闪点为T□C的易燃液体接触的零件	T-25 T-25型
Wood 木头	90 90
a The classification of insulating materials is in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered. a绝缘材料的分类符合IEC 60085。任何绝缘系统的不相容性都应被视为低于最高温度限制。 b T marking refers to the marked maximum operating temperature. b T标记是指标记的最高工作温度。 c For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.8.4.1 should be performed. c对于每种材料和部件，应考虑每种材料或部件的温度额定值，以确定适当的最高温度。各部件的使用应符合其额定温度。如有疑问，应进行8.8.4.1中的球压试验。	

Table 23 – Allowable maximum temperatures for ME EQUIPMENT
parts that are likely to be touched
表23——医用电气设备可能接触部件的最高允许温度

ME EQUIPMENT and its	Maximum temperature a 最高温度a

parts 医用电气设备及其部件		□C 摄氏度		
		Metal 金属 and liquids 还有液体	Glass, porcelain, vitreous material 玻璃、陶瓷、玻 璃材料	Moulde d materi al, 模压材 料, plastic, rubber, wood 塑料、橡 胶、木材
External surfaces of 外表面 ME EQUIPMENT that are likely to be touched for a time “t” 可能接触一段时间的 医用电气设备“t”	t < 1 s t<1秒	74 74	80 80	86 86
	1 s □ t < 10 s 1s□t<10秒	56 56	66 66	71 71
	10 s □ t < 1 min 10 s□t<1分 钟	51 51	56 56	60 60
	1 min □ t 1分钟□t	48 48	48 48	48 48
a These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE. a这些温度限值适用于接触成人健康皮肤。当大面积的皮肤（占体表总面积的10%或更多）可能与热表面接触时，它们不适用。这也适用于皮肤接触超过10%的头部表面。在这种情况下，应确定适当的限额，并将其记录在风险管理文件中。				

Table 24 – Allowable maximum temperatures for skin contact
 with ME EQUIPMENT APPLIED PARTS

表24-皮肤接触医用电气设备应用部件的允许最高温度

APPLIED PARTS of ME EQUIPMENT 医用电气设备的应用部件		Maximum temperature a b 最高温度a b □C 摄氏度		
		Metal 金属 and liquids 还有液体	Glass, porcelain, vitreous material 玻璃、陶瓷、玻 璃材料	Moulde d materi al, 模压材 料, plastic, rubber, wood 塑料、橡 胶、木材
APPLIED PART having contact with the 与 PATIENT for a time “t” 一段时间的病人“t”	t < 1 min t<1分钟	51 51	5 6 5 6	60 60
	1 min □ t < 10 min 1分钟□t<10 分钟	48 48	4 8 4 8	48 48
	10 min □ t 10分钟□t	43 43	4 3 4 3	43 43
a These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE. a这些温度限值适用于成人健康皮肤。当大面积的皮肤（占体表总面积的10%或更多）可能与热表面接触时，它们不适用。它们不适用于皮肤接触超过10%的头部表面。在这种情况下，应确定适当的限额，并将其记录在风险管理文件中。 b Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK. b如果为了提供临床效益，应用部件有必要超过表24的温度限制，风险管理文件应包含文件，证明由此产生的效益超过了任何相关的风险增加。				

11.1.2 * Temperature of APPLIED PARTS

*应用部件温度

11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

为病人提供热量的应用部件

The temperature (hot or cold surfaces) or (where appropriate) the clinical effects shall be determined and documented in the RISK MANAGEMENT FILE. The temperatures and clinical effects shall be disclosed in the instructions for use.
应确定温度（热表面或冷表面）或（如适用）临床效果，并将其记录在风险管理文件中。使用说明书中应披露温度和临床效果。

11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

*不用于向患者供热的应用部件

The limits of Table 24 shall apply. If the surface temperature of an APPLIED PART exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use and the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE. Where 41°C is not exceeded, no justification is required.
表24的限值应适用。如果应用部位的表面温度超过41°C，则应在使用说明书中披露最高温度，并说明其临床效果，如体表、患者成熟度等，应确定正在服用的药物或表面压力，并将其记录在风险管理文件中。如果不超过41°C，则不需要理由。

Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in application parts being cooled below ambient temperatures and shall be evaluated as part of the RISK MANAGEMENT PROCESS.
应用部件的表面冷却到低于环境温度也会导致
HAZARD and shall be evaluated as part of the RISK MANAGEMENT PROCESS.
并应作为风险管理过程的一部分进行评估。

The limits of Table 24 shall apply in both NORMAL CONDITION and SINGLE FAULT CONDITION. If the surface temperature of an APPLIED PART exceeds 41 °C:

表24的限值应适用于正常条件和单一故障条件。如果应用部件的表面温度超过41°C:

- the maximum temperature shall be disclosed in the instructions for use;
最高温度应在使用说明书中披露;
- the conditions for safe contact, e.g. duration or condition of the PATIENT, shall be disclosed; and
应披露安全接触的条件，例如患者的持续时间或状况；以及
- the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE.
应确定与身体表面、患者成熟度、正在服用的药物或表面压力等特征相关的临床效果，并将其记录在风险管理文件中。

Where 41°C is not exceeded, no justification is required.
如果不超过41°C，则不需要理由。

If analyses documented in the RISK MANAGEMENT FILE demonstrate that APPLIED PART temperatures cannot be affected by operation of the ME EQUIPMENT including in SINGLE FAULT CONDITIONS, measurement of APPLIED PART temperature according to 11.1.3 is not required.
如果风险管理文件中记录的分析表明应用部件温度不会受到医用电气设备运行的影响，包括在单一故障条件下，则不需要根据11.1.3测量应用部件温度。

Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in an unacceptable RISK and shall be evaluated as part of the RISK MANAGEMENT PROCESS.

冷却至环境温度以下的应用部件表面也可能导致不可接受的风险，应作为风险管理过程的一部分进行评估。

11.1.3 * Measurements

*测量

Where engineering judgement by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. Where such judgements indicate that the test corner will not impact the measurements, it may be omitted. However, the rationale for such judgement shall be documented in the RISK MANAGEMENT FILE. If the test corner is used, its surfaces shall not exceed 90 °C.

如果制造商的工程判断表明不能超过温度限制，则无需测量。如果此类判断表明试验角点不会影响测量，则可以省略。但是，此类判断的理由应记录在风险管理文件中。如果使用试验角，其表面不得超过90°C。

For ME EQUIPMENT parts that are likely to be touched and for APPLIED PARTS, the probability of occurrence of contact and of the duration of contact is determined and documented in the RISK MANAGEMENT FILE. 对于可能接触的医用电气设备部件和应用部件，应确定发生接触的概率和接触的持续时间，并将其记录在风险管理文件中。

Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE and the instructions for use, operation of ME EQUIPMENT and temperature measurements as follows: 通过检查风险管理文件和医用电气设备的使用、操作和温度测量说明，检查是否符合11.1.1和11.1.2的要求，如下所示：

a) Positioning

定位

1) ME EQUIPMENT is tested in the position(s) of NORMAL USE.

医用电气设备在正常使用位置进行测试。

2) ME EQUIPMENT is placed in a test corner. The test corner consists of two walls at right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner are at least 115 % of the linear dimensions of the ME EQUIPMENT under test. 医用电气设备放置在测试角落。测试角由两个直角的墙、一个地板和一个天花板（如有必要）组成，所有这些都是20毫米厚的暗黑色油漆胶合板。试验角的线性尺寸至少为试验中医用电气设备线性尺寸的115%。

The ME EQUIPMENT is positioned in the test corner as follows:

医用电气设备放置在试验角落，如下所示：

- ME EQUIPMENT normally used on a floor or a table is placed as near to the walls as is likely to occur in NORMAL USE.
通常在地板或桌子上使用的医用电气设备应尽可能靠近正常使用时可能出现的墙壁。
- ME EQUIPMENT normally affixed to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in NORMAL USE.
通常贴在墙上的医用电气设备安装在其中一面墙上，与正常使用时可能出现的其他墙壁和地板或天花板尽可能接近。
- ME EQUIPMENT normally affixed to a ceiling is mounted on the ceiling as near to the walls as is likely to occur in NORMAL USE.
通常固定在天花板上的医用电气设备安装在天花板上，与正常使用时可能出现的墙壁尽可能接近。

3) HAND-HELD ME EQUIPMENT is suspended in its normal position, in still air.

手持医用电气设备悬挂在其正常位置，在静止的空气中。

4) ME EQUIPMENT intended for installation in a cabinet or wall is built in as required by the technical description (see 7.9.3.1), using dull black painted plywood walls, 10 mm

thick when representing cabinet walls if the technical description so specify and 20 mm thick when representing building walls. 拟安装在机柜或墙壁中的医用电气设备是按照技术说明（见7.9.3.1）的要求内置的，使用暗黑色油漆胶合板墙壁，如果技术说明中有规定，则使用10 mm厚的柜体墙壁，当代表建筑墙壁时，厚度为20 mm。

b) Supply
供应

- ME EQUIPMENT having heating elements is operated as in NORMAL USE, with all heating elements energized unless prevented by switching interlocks, the supply voltage being equal to 110 % of the maximum RATED voltage. 具有加热元件的医用电气设备在正常使用中运行，所有加热元件通电，除非开关联锁装置阻止，电源电压等于最大额定电压的110%。
- Motor operated ME EQUIPMENT is operated under normal load and normal DUTY CYCLE and the least favourable voltage between 90 % of the minimum RATED voltage and 110 % of the maximum RATED voltage. 电动医用电气设备在正常负载和正常占空比下运行，在最小额定电压的90%和最大额定电压的110%之间的最不利电压下运行。
- Combined heating and motor operated and other ME EQUIPMENT is tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage. 在110%的最大额定电压和90%的最小额定电压下对组合式加热、电动和其他医用电气设备进行试验。
- When modules are tested separately, the configuration for testing simulates the worst case conditions of NORMAL USE that might affect the test result. 当模块单独测试时，测试配置模拟可能影响测试结果的正常使用的最坏情况。

c) Thermal stabilization
热稳定

- For ME EQUIPMENT intended for non-CONTINUOUS OPERATION:
对于非连续运行的医用电气设备：

After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The “on” and “off” periods for each cycle are the RATED “on” and “off” periods; 在待机/静态模式下运行直到达到热稳定性后，医用电气设备在正常使用状态下连续运行，直到再次达到热稳定性，或持续7小时，以较短者为准。每个循环的“开”和“关”期是额定的“开”和“关”期；

– For ME EQUIPMENT for CONTINUOUS OPERATION:

对于连续运行的医用电气设备：

The ME EQUIPMENT is operated until THERMAL STABILITY is reached.

医用电气设备一直运行到达到热稳定性。

d) Temperature measurement

温度测量

– Resistance method (for windings):

–电阻法（绕组）：

The value of the temperature rise of a copper winding is calculated from the formula:

根据以下公式计算铜绕组的温升值：

$$\Delta T = \frac{R_2 - R_1}{R_1} \frac{234 + T_1}{5} \left(\frac{T_2}{T_1} \right)^2$$

where:
哪里：

□T is the temperature rise in □C;

ΔT是温升，°C；

R1 is the resistance at the beginning of the test in

□; R2 is the resistance at the end of the test in □;

R1为试验开始时的电阻，单位为□；R2为试验结束时的电阻，单位为□；

T1 is the room temperature at the beginning of the test in

□C; T2 is the room temperature at the end of the test in □C.

T1是试验开始时的室温，单位为摄氏度；T2是试验结束时的室温，单位为摄氏度。

At the beginning of the test, windings are to be at room temperature.

试验开始时，绕组应处于室温下。

NOTE When the resistance method is used, it is recommended that the resistance of windings at the end of the test be determined by taking measurements as soon as possible after switching off, and then at short intervals so that a curve of resistance against time can be plotted for ascertaining the value at the instant of switching off.

注：当使用电阻法时，建议在试验结束时通过切断电源后尽快进行测量来确定绕组的电阻，然后在很短的时间间隔内，绘制一条与时间的电阻曲线，以确定断电瞬间的值。

– Thermocouple and other methods (for all measurements):

–热电偶和其他方法（用于所有测量）：

Measurement is made by devices or sensors so chosen and positioned that they have a negligible effect on the temperature of the part under test.

测量是由设备或传感器进行的，其选择和定位使其对被测零件的温度影响可忽略不计。

When thermocouples are used to determine the temperature of windings, the temperature limits of Table 22 are to be reduced by 10 □C.

当使用热电偶确定绕组温度时，表22中的温度限值应降低10°C。

The temperature of electrical insulation, other than that of windings, is determined on the surface of the insulation at places where failure could cause a short circuit, bridging of a MEANS OF PROTECTION, bridging of insulation or reduction of

CREEPAGE DISTANCES or AIR CLEARANCES below the values specified for the insulation type in 8.9.

除绕组温度外，电气绝缘的温度应在绝缘表面确定，故障可能导致短路、保护装置桥接、绝缘桥接或爬电距离或空气间隙减小到8.9中规定的绝缘类型值以下的地方。

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures might be measured.

多芯线芯线的分离点和绝缘线进入灯座的地方就是可以测量温度的地方。

e) Test criteria

试验标准

During the test THERMAL CUT-OUTS are not de-activated.

在热测试过程中不激活断电。

The maximum temperature of a part is determined by measuring the temperature rise of the part under test and adding it to the maximum allowed ambient temperature specified in the technical description (see 7.9.3.1). Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.

通过测量被测零件的温升并将其加入技术说明中规定的最高允许环境温度（见7.9.3.1），确定零件的最高温度。如果热调节装置使该方法不适用，则在风险管理文件中说明替代测量方法的合理性。

11.1.4 GUARDS

警卫

GUARDS intended to prevent contact with hot or cold accessible surfaces of ME EQUIPMENT

防止接触医用电气设备热或冷接触表面的防护装置

shall be removable only with the aid of a TOOL.

只能借助工具拆卸。

Compliance is checked by inspection.

通过检查检查合规性。

11.2 * Fire prevention ***防火**

11.2.1 * Strength and rigidity required to prevent fire in ME EQUIPMENT ***防火设备所需的刚性和强度**

ENCLOSURES shall have the strength and rigidity necessary to avoid a fire that could occur as a result of a total or partial collapse caused by reasonably foreseeable misuse.
外壳应具有必要的强度和刚度, 以避免由于合理可预见的误用而导致的全部或部分倒塌而发生火灾。

Compliance is checked by the mechanical strength tests for ENCLOSURES (see 15.3).
通过外壳的机械强度试验检查合规性 (见15.3)。

11.2.2 * ME EQUIPMENT and ME SYSTEMS used in conjunction with **OXYGEN RICH ENVIRONMENTS** ***与富氧环境一起使用的医用电气设备和医用电气系统**

11.2.2.1 RISK of fire in an OXYGEN RICH ENVIRONMENT **富氧环境中的火灾风险**

In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION or SINGLE FAULT CONDITIONS (as identified in 11.2.3). An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.
在医用电气设备和医用电气系统中, 在正常条件或单一故障条件下 (如11.2.3所述), 应尽可能降低富氧环境中的火灾风险。在富氧环境中, 当火源与可燃性材料接触, 且无法限制火势蔓延时, 认为存在不可接受的火灾风险。

NOTE 1 For oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27,5 kPa for higher atmospheric pressures, the requirements in 13.1.1 are considered to be sufficient.

注1: 对于在一个大气压下氧气浓度高达25%, 或分压高达27.5 kPa, 对于更高的大气压力, 13.1.1中的要求被认为是足够的。

a) * A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when any of the following conditions exist in NORMAL CONDITION and SINGLE FAULT CONDITIONS (including voltage and current):

*当正常条件和单一故障条件 (包括电压和电流) 中存在下列任一条件时, 认为在富氧环境中存在着火源:

- 1) the temperature of the material is raised to its ignition temperature;
将材料的温度提高到其着火温度;
- 2) temperatures could affect solder or solder joints causing loosening, short circuiting or other failures that could result in sparking or raising the temperature of the material to its ignition temperature;
温度会影响焊料或焊点, 导致松动、短路或其他故障, 从而导致火花或将材料温度升高至其点火温度;
- 3) parts affecting safety crack or change their outer shape exposing temperatures exceeding 300 °C or sparks (see 4) and 5) below) due to overheating;
因过热而影响安全裂纹或改变其外部形状暴露温度超过300°C或火花 (见下文4) 和5) 的零件;
- 4) temperatures of parts or components could exceed 300 °C;
零件或部件的温度可能超过300°C;

5) sparks provide adequate energy for ignition by exceeding the limits of Figure 35 to Figure 37 (inclusive).

火花通过超过图35至图37（包括图37）中的限值，为点火提供足够的能量。

Items 4) and 5) address the worst case where the atmosphere is 100 % oxygen, the contact material (for item 5) is solder and the fuel is cotton. Available fuels and oxygen concentrations should be taken into consideration when applying these specific requirements. Where deviations from these worst case limits are made (based on lower oxygen concentrations or less flammable fuels) they shall be justified and documented in the RISK MANAGEMENT FILE. 第4)和5)项解决了最坏的情况，即大气为100%氧气，接触材料（第5项）为焊料，燃料为棉花。在应用这些具体要求时，应考虑可用燃料和氧气浓度。如果偏离这些最坏情况限值（基于较低的氧气浓度或较低的易燃燃料），则应证明其合理性并将其记录在风险管理文件中。

As an alternative to 11.2.2.1 a) 5), the following test may be used to determine whether a source of ignition exists.

作为11.2.2.1 a) 5) 的替代方法，可使用以下试验来确定是否存在火源。

First, the place(s) within the ME EQUIPMENT where sparking might cause ignition are identified. Then the material(s) of the parts between which sparks can occur is identified. Samples of the same material are then used to construct the contact pins for the test apparatus (see Figure 34). 首先，确定医用电气设备内火花可能导致点火的地方。然后确定可能产生火花的零件材料。然后使用相同材料的样品构造试验装置的触针（见图34）。

Other parameters for the test are: oxygen concentration, fuel, electrical parameters (current, voltage, capacitance, inductance or resistance). These parameters are chosen such that they represent the worst case for the ME EQUIPMENT. 测试的其他参数包括：氧气浓度、燃料、电气参数（电流、电压、电容、电感或电阻）。这些参数的选择应确保它们代表医用电气设备的最坏情况。

NOTE 2 For ME EQUIPMENT that includes a circuit not addressed in Figure 35 to Figure 37 (inclusive), either the test voltage or current may be set at three times the worst case values with the other parameter set at the worst case value for determining whether ignition can occur.

注2：对于医用电气设备（包括图35至图37（含）中未说明的电路），试验电压或电流可设置为最坏情况值的三倍，其他参数设置为最坏情况值，以确定是否会发生点火。

Two contact pins made of the material to be considered are placed in opposition (see Figure 34). One pin has a diameter of 1 mm, the other of 3 mm. The electrical source is connected to the pins as shown in Figure 35 to Figure 37. A piece of cotton is placed close to the contact surfaces of the two pins. The contacts are constantly flushed by oxygen with a speed of less than 0,5 m/s via a tube. The cathode is moved to the anode to close the contacts and pulled back to open them again. A minimum of 300 trials has to be performed before it can be decided that the sparks do not ignite. If the sparks get smaller because of bad surfaces of the electrodes, the electrodes are cleaned with a file. If the cotton gets black because it became oxidized then it is replaced. In Figure 36 and Figure 37, the resistance used to control current flowing into the inductor and the time constant for charging the capacitor is chosen such that it has minimal impact on the energy of the spark. This is tested by visual inspection without the capacitor in place or with the inductor shorted.

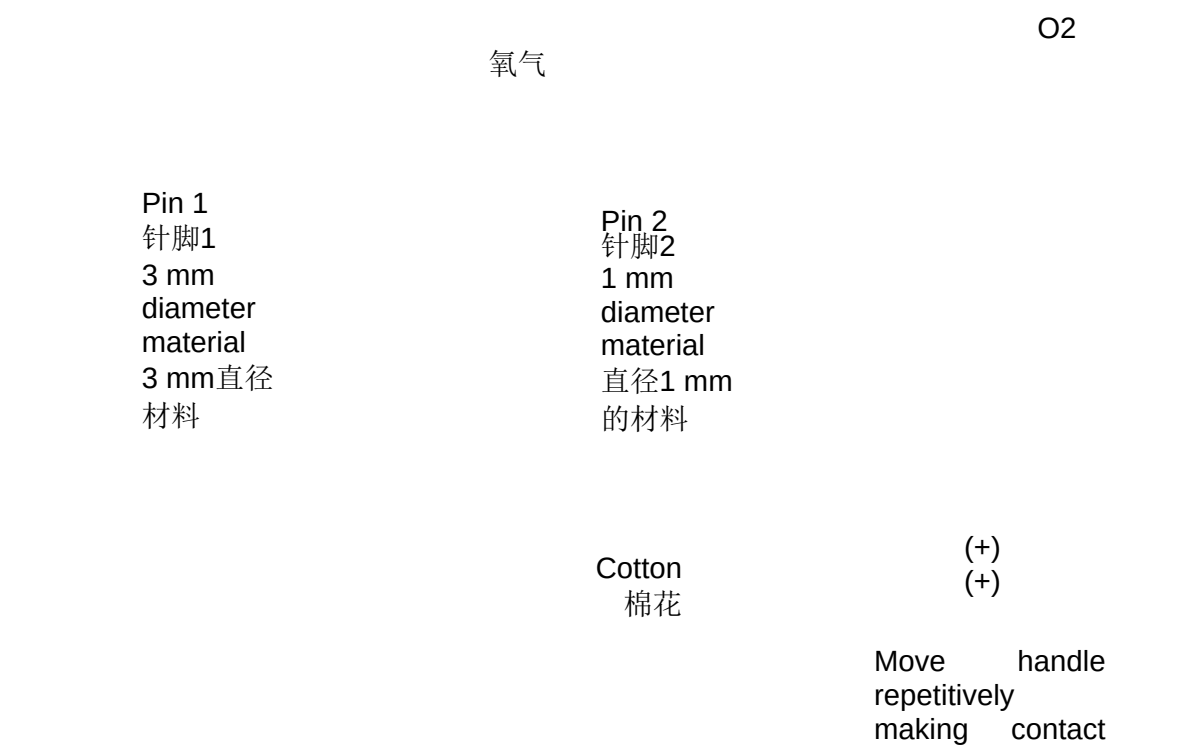
两个由待考虑材料制成的触针相对放置（见图34）。一个销的直径为1毫米，另一个直径为3毫米。电源连接到引脚上，如图35至图37所示。在两个销的接触面附近放置一块棉花。触点通过管道以低于0.5 m/s的速度不断地被氧气冲洗。阴极移到阳极上，闭合触点，然后拉回来再次打开触点。在确定火花不会点燃之前，至少要进行300次试验。如果由于电极表面不好而产生的火花变小，则用锉刀清理电极。如果棉花因为氧化而变黑，那么它就被替换掉了。在这个数字中，对流入电容器的电流的冲击最小。在电容器未就位或电感器短路的情况下，通过目视检查进行测试。

The situation with the highest voltage or current respectively and no ignition defines the upper limit. A safe upper limit is given by dividing the upper limit of voltage or current respectively with the safety margin factor of three.

最高电压或最高电流以及无点火的情况定义了上限。安全上限是将电压或电流的上限分别除以安全裕度系数3得到的。

NOTE 3 The safety margin factor is considered to cover the uncertainty of sparking experiments and the variability of the underlying parameters like pressure, quality of cotton or of the contact materials.

注3：安全裕度系数被认为涵盖了火花试验的不确定性和潜在参数的可变性，如压力、棉花或接触材料的质量。



between Pins 1 and 2
反复移动手柄，使插脚1和2接触

IEC 2417/05
IEC 2417/05标准

Figure 34 – Spark ignition test apparatus

图34–火花点火试验装置

(see 11.2.2.1)

(见11.2.2.1)

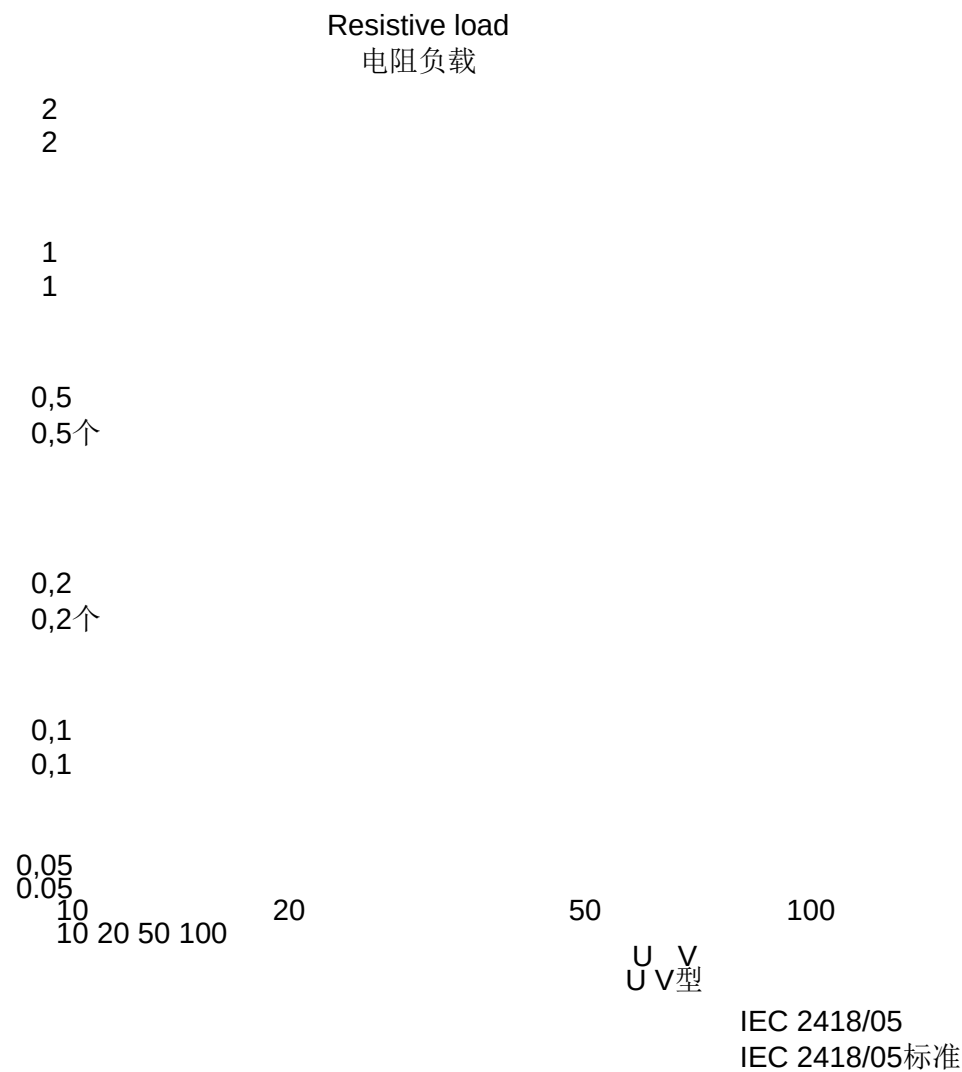
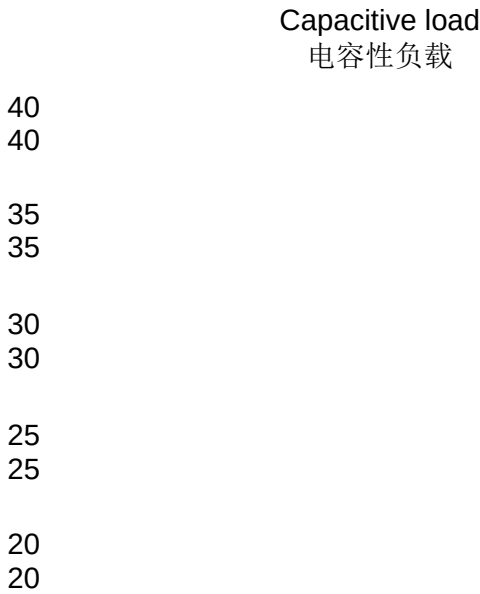


Figure 35 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT (see 11.2.2.1)

图35——富氧环境中纯电阻电路中测得的最大允许电流I与最大允许电压U的函数（见11.2.2.1）



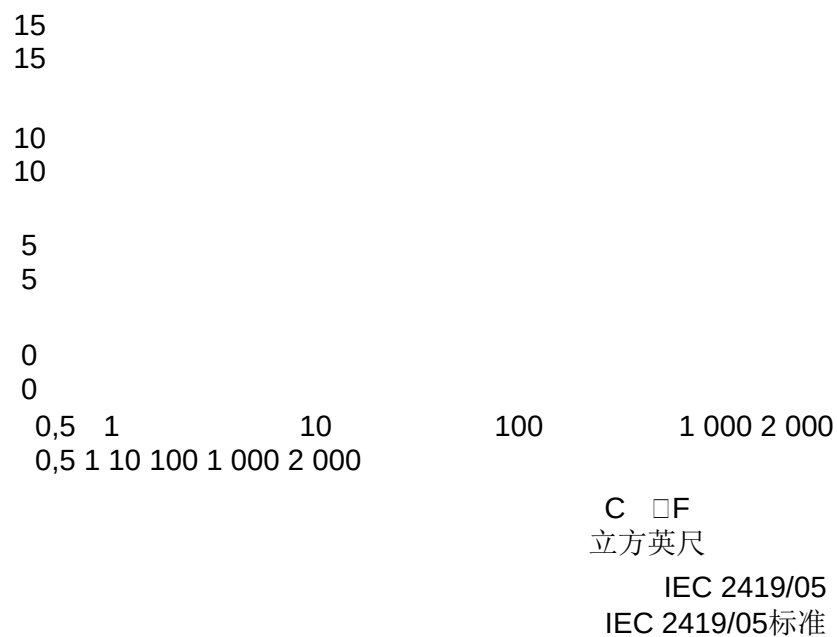
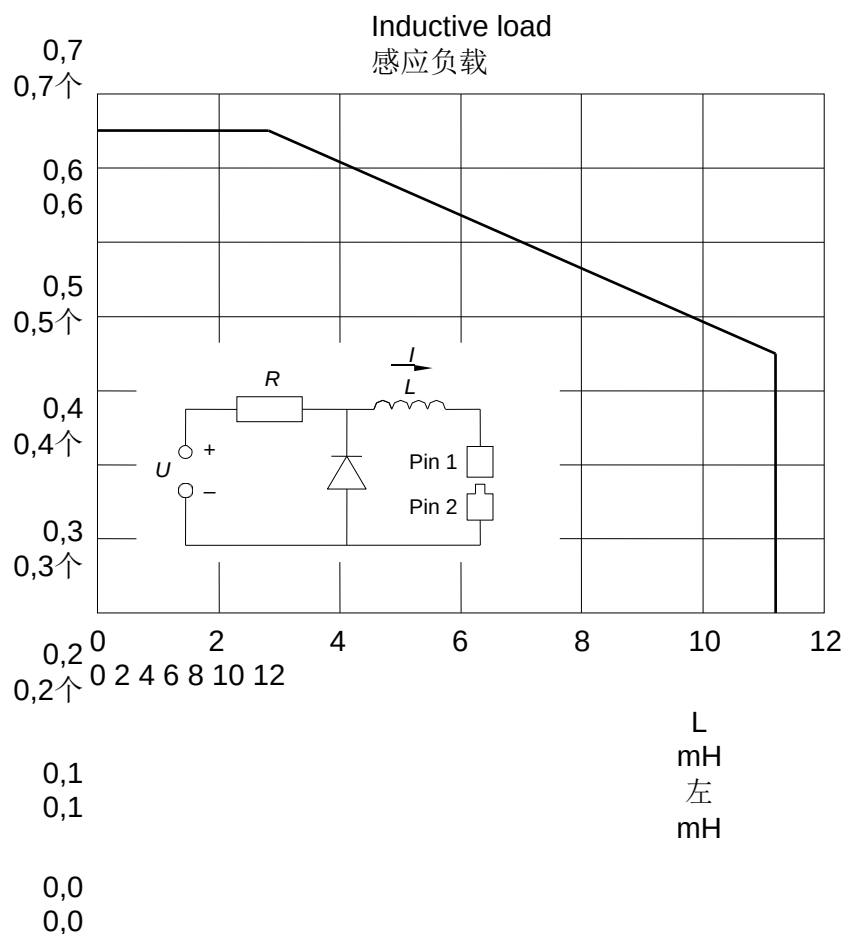


Figure 36 – Maximum allowable voltage U as a function of the capacitance C
图36-最大允许电压 U 作为电容 C 的函数
 measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT
 在富氧环境中用电容电路测量
 (see 11.2.2.1)
 (见11.2.2.1)



IEC 2420/05
 IEC 2420/05标准

Figure 37 – Maximum allowable current I as a function of the inductance L
图37-最大允许电流I作为电感L的函数
 measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT
 在富氧环境中用感应电路测量
 (see 11.2.2.1)
 (见11.2.2.1)

- b) The following configurations, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT.
 以下配置（视情况而定）单独或组合（根据风险管理过程的应用而定）被视为在富氧环境中提供可接受的残余火灾风险。
- 1) Electrical components in a compartment with an OXYGEN RICH ENVIRONMENT shall have power supplies with limited energy levels. Those energy levels shall be less than those which are considered to be sufficient for ignition (see 11.2.2.1 a)).
 在富氧环境中的隔间内的电气部件应具有有限能量水平的电源。这些能量水平应低于被认为足以点燃的能量水平（见11.2.2.1 a））。

Compliance is checked by inspection of the design and measurement or calculation of power, energy and temperature values in NORMAL CONDITION and SINGLE FAULT CONDITION (as identified in 11.2.3).
 检查单台条件下的能量和测量值是否符合设计条件和功率。

or

或

- 2) * Compartments that contain parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) and that can be penetrated by oxygen (e.g. because of an undetected leak) shall be ventilated such that the oxygen concentration will not exceed 25 %.
- *仅在单一故障条件下（如11.2.3所述）且可被氧气穿透（如未检测到的泄漏）的部件或部件（如11.2.2.1 a中所定义）的隔间应通风，使氧气浓度不超过25%。

Compliance is checked by the following test:

通过以下试验检查合规性：

The oxygen concentration is measured for such a period that the highest possible concentration of oxygen occurs. The least favourable control settings are selected. The leaking conditions of oxygen are selected such that they provide the minimum leak that could be detected by the OPERATOR (e.g. because of a failure of the function of the device). If the concentration of oxygen exceeds 25 % in the presence of parts or components that could be a source of ignition including at the moment energy is applied, it constitutes a failure.

测量氧气浓度的时间应确保氧气浓度达到最高值。选择最不利的控制设置。氧气泄漏条件的选择应确保操作员能够检测到的泄漏量最小（例如，由于设备功能失效）。如果氧气浓度超过25%，而部件或部件可能是火源，包括在施加能量时，则构成故障。

or

或

- 3) * A compartment that contains parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) IS separated from another compartment that contains an OXYGEN RICH ENVIRONMENT by sealing all joints and any holes for cables, shafts or for other purpose. The effect of possible leaks and failures under SINGLE FAULT CONDITION (as identified in 11.2.3) that could cause ignition shall be evaluated using a RISK ASSESSMENT to determine the appropriate maintenance intervals.
*仅在单一故障条件下（如11.2.3所述）含有可作为火源的零件或部件的隔室（如11.2.2.1 A中所述）通过密封电缆、轴或其他用途的所有接头和任何孔，与另一个含有富氧环境的隔室分开。在单一故障条件下（如11.2.3所述）可能导致点火的泄漏和故障的影响应使用风险评估来评估，以确定适当的维护间隔。

Compliance is checked by visual inspection and by inspection of the documentation provided by the MANUFACTURER including the RISK MANAGEMENT FILE.
通过目视检查和检查制造商提供的文件（包括风险管理文件）来检查合规性。

or
或

- 4) Electrical components in a compartment containing an OXYGEN RICH ENVIRONMENT that can become a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITIONS (as identified in 11.2.3) shall be enclosed in such a way that should ignition occur within the ENCLOSURE, the fire would self-extinguish rapidly and no hazardous amount of toxic gases would reach the PATIENT.
仅在单一故障条件下（如第11.2.3节所述），含有富氧环境的隔室中的电气部件（定义见第11.2.2.1 a节），其密封方式应确保外壳内发生点火，火势会迅速自行熄灭，不会有危险量的有毒气体到达病人体内。

Compliance shall be checked by starting a fire in the ENCLOSURE. If it is not evident that toxic gases cannot reach the PATIENT, the gas that could reach the PATIENT is analyzed.
应通过在外壳中点火来检查合规性。如果不明显有毒气体无法到达患者，则对可能到达患者的气体进行分析。

11.2.2.2 * External exhaust outlets for OXYGEN RICH ENVIRONMENT *富氧环境外部排气口

External exhaust outlets of an OXYGEN RICH ENVIRONMENT shall not be located so that RISK of ignition occurs because of any electrical component (which could cause a spark in NORMAL USE or SINGLE FAULT CONDITION as identified in 11.2.3) mounted on the outside of the ME EQUIPMENT or an ME SYSTEM. RISK of ignition is considered to be sufficiently low if oxygen concentration in the immediate surroundings of the electrical component does not exceed 25 % under the least favourable conditions of operation.
富氧环境的外部排气口的位置不应使安装在医用电气设备或医用电气系统外部的任何电气部件（在正常使用中可能引起火花或11.2.3中确定的单一故障条件）引起着火风险。如果在最不利的操作条件下，电气部件周围的氧气浓度不超过25%，则认为着火风险足够低。

Compliance is checked by inspection.
通过检查检查合规性。

11.2.2.3 Electrical connections in OXYGEN RICH ENVIRONMENTS 富氧环境中的电气连接

Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE shall not produce sparks because of loosening or breaking unless they are limited in power and energy to the values identified in 11.2.2.1 a) 5).
在正常使用条件下，含有富氧环境的隔间内的电气连接不得因松动或断裂而产生火花，除非其功率和能量限制在11.2.2.1 a) 5) 中确定的值。

Prevention of loosening or breaking is accomplished by the following or equivalent methods.
通过以下或同等方法防止松动或断裂。

- Screw-attachments shall be protected against loosening during use by methods such as varnishing, the use of spring washers or application of adequate torques.
在使用过程中，应通过上漆、使用弹簧垫圈或施加适当扭矩等方法防止螺钉附件松动。
- Soldered, crimped and pin-and-socket connections of cables that exit the ENCLOSURE shall include additional mechanical fixing.
从外壳引出的电缆的焊接、压接和插销和插座连接应包括额外的机械固定。

Compliance is checked by visual inspection.
通过目测检查合规性。

11.2.3 SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with 11.2.3与富氧环境相关的单一故障条件 ME EQUIPMENT and ME SYSTEMS 医用电气设备和医用电气系统

- Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).
根据11.2.2.1 b) 2) 建造的通风系统故障。
- Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).
根据11.2.2.1 b) 3) 建造的屏障失效。
- Failure of a component that creates a source of ignition (as defined in 11.2.2.1 a)).
产生火源的部件故障（如11.2.2.1 a所定义）。
- Failure of insulation (whether solid material or spacing) providing the equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1 a)).
绝缘失效（无论是固体材料还是间隔）至少相当于一种病人保护手段，但少于两种病人保护手段（如如8.8和8.9）所述，可能产生火源（定义见11.2.2.1 a））。
- Failure of a pneumatic component that results in leakage of oxygen-enriched gas.
导致富氧气体泄漏的气动元件故障。

11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT

医用电气设备防火外壳的结构要求

This subclause provides an alternative means of compliance with selected HAZARDOUS SITUATIONS and fault conditions as identified in 13.1.2. In doing so, the following constructional requirements shall be met or specifically analyzed in the RISK MANAGEMENT FILE and if not met, specific justification shall also be given. 本款提供了符合13.1.2中确定的选定危险情况和故障条件的替代方法。在此过程中，应满足或在风险管理文件中具体分析以下施工要求，如果不满足，还应给出具体理由。

- a) Insulated wire within the fire ENCLOSURE shall have a flammability classification equivalent FV-1, or better, according to the appropriate parts of the IEC 60695 series. Connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2, or better, according to IEC 60695-11-10.

根据IEC 60695系列的适当部分，防火外壳内的绝缘电线应具有相当于FV-1或更好的可燃性分类。根据IEC 60695-11-10，安装部件的连接器和印刷电路板和绝缘材料应具有FV-2或更高的可燃性分类。

Compliance is checked by inspection of data on materials, or by performing the FV tests specified in IEC 60695-11-10 on three samples of the relevant parts being tested. The samples can be any of the following: 通过对材料数据的检查，或对被测零件的三个样品进行IEC 60695-11-10中规定的FV试验来检查是否合格。样本可以是以下任何一种：

- 1) complete parts; or
完整部件；或
- 2) sections of a part, including the area with the least wall thickness and any ventilation openings.
通风孔的任何部分，包括壁厚最小的部分。

Components certified in accordance with IEC 60695-11-10 need not be tested.

根据IEC 60695-11-10认证的部件无需测试。

- b) The fire ENCLOSURE shall meet the following requirements:

防火外壳应符合下列要求：

- 1) The bottom shall have no openings or, to the extent specified in Figure 39, shall be constructed with baffles as specified in Figure 38, or be made of metal, perforated as specified in Table 25, or be a metal screen with a mesh not exceeding 2 mm □ 2 mm centre to centre and a wire diameter of at least 0,45 mm. 底部应无开口，或在图39中规定的范围内，应按照图38的规定使用挡板建造，或由金属制成，按表25的规定穿孔，或者是一个金属筛网，网眼中心距不超过2 mm×2 mm，钢丝直径至少为0.45 mm。
- 2) The sides shall have no openings within the area that is included within the inclined line C in Figure 39. 在图39中斜线C内的区域内，侧面不得有开口。
- 3) The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (except magnesium) or of non-metallic materials, except for constructions according to Table 25 and constructions with a mesh, having a flammability classification of FV-2 (or better) for TRANSPORTABLE ME EQUIPMENT and FV-1 (or better) for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT in accordance with IEC 60695-11-10. 外壳和任何挡板或阻火器应由金属（镁除外）或非金属材料制成，但表25规定的结构和网状结构除外，可运输医用电气设备的易燃性等级为FV-2（或更高），固定式医用电气设备或固定式医用电气设备的易燃性等级为FV-1（或更高）符合IEC 60695-11-10的医

用电气设备。

The ENCLOSURE, and any baffle or flame barrier, shall have adequate rigidity.
外壳和任何挡板或阻火器应具有足够的刚度。

Conformity is checked by inspection. In case of doubt, the flammability classification of requirement b) 3) is checked as in a).

通过检查检查是否合格。如有疑问，按a) 中的要求检查b) 3) 的可燃性分类。

Table 25 – Acceptable perforation of the bottom of an ENCLOSURE
表25——外壳底部的可接受穿孔

Minimum thickness 最小厚度 mm 毫米	Maximum diameter of holes 孔的最大直径 mm 毫米	Minimum spacing of holes centre to centre 孔中心到中心的最小间距 mm 毫米
0,66 0,66	1,14 1,14号	1,70 (233 holes/645 mm2) 1,70 (233个孔/645mm2)
0,66 0,66	1,19 1,19号	2,36 2,36个
0,76 0,76	1.15 1.15	1,70 1,70个
0,76 0,76	1,19 1,19号	2,36 2,36个
0,81 0,81	1,91 1,91个	3,18 (72 holes/645 mm2) 3,18 (72孔/645 mm2)
0,89 0,89	1,90 1,90个	3,18 3,18个
0,91 0,91	1,60 1,60个	2,77 2,77个
0,91 0,91	1,98 1,98个	3,18 3,18个
1,00 1,00	1,60 1,60个	2,77 2,77个
1,00 1,00	2,00 2,00个	3,00 3,00个

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Y = twice X but never less than 25 mm
Y=两倍X，但不得小于25 mm

Baffle plates (may be below the bottom of the
ENCLOSURE) Bottom of the ENCLOSURE

挡板（可能在外壳底部下方）外壳底部

Figure 38 – Baffle
图38–挡板
(see 11.3)
(见11.3)

A
A

B
B

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IEC 2422/05标准

Key
钥匙

- A Part or component of the ME EQUIPMENT that is considered to be a source of fire. This consists of an entire component or part of the ME EQUIPMENT if it is not otherwise shielded, or the unshielded portion of a component that is partially shielded by its casing.

医用电气设备被认为是火源的部件或部件。这包括医用电气设备的整个部件或一部分（如果没有其它防护措施），或者部件的非屏蔽部分被外壳部分屏蔽。

- B Projection of the outline of A on the horizontal plane.
A的轮廓在水平面上的投影。
- C Inclined line that traces out the minimum area of the bottom and sides to be constructed as specified in 11.3 b) 1) and 11.3 b) 2). This line projects at a 5° angle from the vertical at every point around the perimeter of A and is oriented so as to trace out the maximum area.
根据中的规定，勾勒出底部和侧面最小面积的斜线
11.3 b) 1) 和 11.3 b) 2)。这条线在a周围的每一点上与垂直线呈5°角投影，并定向以追踪最大面积。
- D Minimum area of the bottom to be constructed as specified in 11.3 b) 1).
按11.3 b) 1) 的规定建造底部的最小面积。

Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)

图39——11.3 b) 1) 中规定的外壳底部区域

(see 11.3)

(见11.3)

11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics
*用于易燃麻醉剂的医用电气设备和医用电气系统

ME EQUIPMENT, ME SYSTEMS or their parts described in the ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or flammable anaesthetics with oxidants (CATEGORY APG) shall meet the applicable requirements of Annex G.

随附文件中描述的与易燃麻醉剂（AP类）或含氧化剂（APG类）一起使用的医用电气设备、医用电气系统或其部件应符合附录G的适用要求。

11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents

*与易燃剂一起使用的医用电气设备和医用电气系统

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.
制造商的风险管理过程应解决火灾的可能性和相关的缓解措施。

Compliance is determined by inspection of the RISK MANAGEMENT FILE.
合规性通过检查风险管理文件来确定。

11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

溢出、溢出、泄漏、水或颗粒物进入、清洁、消毒、灭菌以及与医用电气设备所用物质的相容性

11.6.1 General
总则

The construction of ME EQUIPMENT and ME SYSTEMS shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.

医用电气设备和医用电气系统的结构应确保对溢流、溢出、泄漏、水或颗粒物的进入、清洁、消毒和灭菌以及与医用电气设备所用物质的相容性提供足够的防护。

11.6.2 * Overflow in ME EQUIPMENT
*医用电气设备溢出

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor shall an unacceptable RISK be created result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

如果医用电气设备包含一个在正常使用中容易被过度填充或溢出的储液罐或储液室，从储液罐或储液室溢出的液体不得弄湿任何可能受到此类液体不利影响的保护装置，不可接受的风险也不应导致基本安全或基本性能的损失。

If the maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3. 如果医用电气设备上的标记指示了最高填充水平，并发出警告或安全通知，如果储液罐或储液室充满至其最大容量，且可移动医用电气设备倾斜角度为10°，或移动式医用电气设备超过45 kg，则不会出现危险情况（如13.1所述）或不可接受的溢流风险，如果移动超过9.4.2.4.3中所述的阈值。

Unless restricted by a marking or by the instructions for use If no warning or safety notice is given regarding the maximum fill level, no HAZARDOUS SITUATION (as specified herein in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 15° 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3. 除非受到标记或使用说明的限制，如果没有发出关于最大填充水平的警告或安全通知，如果储液罐或储液室的填充量超过最大容量的15%，且可移动医用电气设备倾斜角度为15°10°或移动式医用电气设备超过45 kg，则不会出现危险情况（如13.1中所述）或不可接受的溢流风险，如果移动超过9.4.2.4.3中所述的阈值。

Compliance is checked by filling the liquid reservoir completely and subsequently adding a

further quantity equal to 15 % of the capacity of the reservoir, which is poured in steadily over a period of 1 min.
通过将储液罐完全注满，然后再添加相当于储液罐容量15%的量，在1分钟内稳定地倒入，以此来检查合规性。

Compliance is checked by the following:
通过以下方式检查合规性:

If warnings or safety notices regarding overfilling are marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled to the indicated maximum level.

如果移动式医用电气设备上标注了关于过量加注的警告或安全通知，则储液罐将被加注至指示的最高液位。

If there is no warning or safety notice regarding overfilling marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled completely and subsequently a further quantity equal to 15 % of the capacity of the reservoir is added poured in steadily over a period of 1 min.
如果在储液罐中持续加注超过1.15%的储液罐，则应在储液罐中加注超过1.5%的安全警告。

TRANSPORTABLE ME EQUIPMENT is subsequently tilted through an angle of $15 \pm 10^\circ$ in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

可运输医用电气设备随后从正常使用位置开始向最不利方向倾斜 $15 \pm 10^\circ$ （如有必要，重新加注）。

MOBILE ME EQUIPMENT exceeding 45 kg is moved over a threshold as described in 9.4.2.4.3. After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and

超过45 kg的移动医用电气设备移动超过9.4.2.4.3中所述的阈值。这些电介质经过这些程序后，是合适的

LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).
泄漏电流试验，且不显示未绝缘电气部件受潮的迹象，或部件的电气绝缘可能导致危险情况，即在正常条件下或在单一故障条件下丧失基本安全或基本性能（基于目视检查）。

11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS
***医用电气设备和医用电气系统泄漏**

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE, including ME EQUIPMENT or ME SYSTEMS used in an environment where the PROCESS has determined that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed that spillage does not wet parts that could result in a HAZARDOUS SITUATION are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE

需要处理正常使用液体的医用电气设备和医用电气系统, 包括医用电气设备或医用电气系统, 在工艺确定医用电气设备可能发生泄漏的环境中使用, 其结构应确保溢出物不会弄湿可能导致基本安全或基本性能丧失的危险情况的部件。

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the following test:
通过检查风险管理文件和以下测试检查合规性:

The ME EQUIPMENT is positioned according to 5.4 a). A quantity of liquid is poured steadily on a point on the top of the ME EQUIPMENT. The type of liquid, volume, duration of the spill, and location (point) are determined through application of the RISK MANAGEMENT PROCESS RISK ANALYSIS. All test conditions are identified through inspection of the RISK MANAGEMENT FILE. Test conditions that simulate the worst case for spillage shall be documented in the RISK MANAGEMENT FILE.
医用电气设备按照5.4 a) 进行定位。将一定量的液体稳定地倒在医用电气设备顶部的一个点上。通过应用风险管理流程风险分析确定液体类型、体积、泄漏持续时间和位置(点)。通过检查风险管理文件确定所有测试条件。模拟泄漏最坏情况的试验条件应记录在风险管理文件中。

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

完成这些程序后, 医用电气设备应通过适当的介电强度和泄漏电流测试, 并且不得出现未绝缘电气部件受潮或部件电气绝缘受潮的迹象, 这些迹象可能会导致危险情况, 即在正常条件下或在组合情况下丧失基本安全或基本性能单一故障情况下(基于目视检查)。

11.6.4 *
***泄漏**

Leakage

See
见13.2.6。

13.2.6.

11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS
***水或颗粒物进入医用电气设备和医用电气系统**

ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.9.
医用电气设备和医用电气系统的外壳应按照IEC 60529的分类提供这种保护, 以防止有害的水或颗粒物进入。另见7.2.9。

Compliance is checked by the tests of IEC 60529 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection.
通过IEC 60529试验和将医用电气设备放置在正常使用的最不利位置, 并通过检查来检查是否符合要求。

After these PROCEDURES, the ME EQUIPMENT is to show no signs of bridging of insulation (or electrical components) that could result in a HAZARDOUS SITUATION is likely

to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. 在这些程序之后，医用电气设备不得出现绝缘（或电气部件）桥接的迹象，这可能会导致在正常条件下或在单一故障条件下（根据目视检查）可能导致基本安全或基本性能损失的绝缘（或电气部件）桥接迹象强度和泄漏电流试验。

11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS 医用电气设备和医用电气系统的清洁和消毒

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection PROCESSES specified in the instructions for use. See also 7.9.2.12.

医用电气设备、医用电气系统及其部件，包括应用部件和附件，应能够承受使用说明书中规定的清洁或消毒过程，而不会损坏或损坏安全规定。另见7.9.2.12。

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that no unacceptable RISK will occur. The results of the evaluation shall be documented in the RISK MANAGEMENT FILE these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. 制造商应在医用电气设备、医用电气系统及其零部件和附件的预期使用寿命期间，评估使用说明书中所述的多次清洗/消毒的效果，并确保不会出现不可接受的风险。评估结果应记录在风险管理文件中。这些过程不会导致基本安全或基本性能的损失。

Where compliance with this standard could be affected effected by cleaning or disinfecting the ME EQUIPMENT, ME SYSTEM and their parts and ACCESSORIES, they are cleaned or disinfected once in accordance with the methods specified including any cooling or drying period. After these PROCEDURES, the ME EQUIPMENT, ME EQUIPMENT parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the affects of multiple cleanings. 如果医用电气设备、医用电气系统及其零部件和附件的清洁或消毒可能影响对本标准的遵守，则应按照规定的方法（包括任何冷却或干燥期）对其进行一次清洁或消毒。完成这些程序后，医用电气设备、医用电气设备零件或附件不得出现可能导致不可接受风险（目视检查）的退化迹象，然后进行适当的介电强度和泄漏电流测试。检查风险管理文件，以验证制造商是否评估了多次清洗的影响。

11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS 医用电气设备和医用电气系统的消毒

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11134, ISO 11135 or ISO 11137 ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12.
医用电气设备、医用电气系统及其零件或配件应根据ISO 11134、ISO 11135或ISO 11137 ISO 11135-1、ISO 11137-1或ISO 17665-1（视情况而定）进行评估和记录。另见7.9.2.12。

After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests and by inspection of the RISK MANAGEMENT FILE.
在对这些设备进行不合格的风险检测后，对其进行电介质检测，并对其进行相应的风险检测。

11.6.8 * Compatibility with substances used with the ME EQUIPMENT *与医用电气设备所用物质的相容性

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. Such RISKS may be addressed through the application of appropriate ISO or IEC standards (giving the presumption of acceptable RISK according to 4.2) such as ISO 15001 for components that contain oxygen at pressures greater than 50 kPa or through the MANUFACTURER'S own testing and RISK CONTROL measures.
适用时，制造商应在风险管理过程中解决与医用电气设备所用物质相容性相关的风险。此类风险可通过应用适当的ISO或IEC标准（根据4.2给出可接受风险的假设），如ISO 15001，针对压力大于50 kPa的部件，或通过制造商自己的测试和风险控制措施来解决。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS 医用电气设备和医用电气系统的生物相容性

ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993 series of standards.
医用电气设备、医用电气系统及其部件或配件，如果打算直接或间接接触生物组织、细胞或体液，应根据ISO 10993系列标准中给出的指南和原则进行评估和记录。

Compliance is checked by inspection of the information provided by the MANUFACTURER.
通过检查制造商提供的信息检查合规性。

11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT *医用电气设备电源/供电干线中断

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a HAZARDOUS SITUATION other than interruption of its intended function the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE .
医用电气设备的设计应确保电源的中断和恢复不会导致除预期功能中断以外的危险情况，即基本安全或基本性能的损失。

NOTE This can require testing at several durations and ME EQUIPMENT states.
注：这可能需要在几个持续时间和医用电气设备状态下进行测试。

Compliance is checked by interruption and restoration of relevant power supplies.
通过中断和恢复相关电源来检查合规性。

12 * Accuracy of controls and instruments and protection against hazardous

outputs

***控制装置和仪表的准确性以及对危险输出的防护**

12.1 Accuracy of controls and instruments
控制和仪表的精度

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时，制造商应在风险管理过程中解决
RISKS associated with accuracy of controls and instruments.
与控制 and 仪表准确性相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

12.2 USABILITY of ME EQUIPMENT
医用电气设备的可用性

The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK
of poor USABILITY, including those associated with identification, marking and documents
(see 7.1.1 and 16.2). See IEC 60601-1-6 and also see 1.3.
制造商应在可用性工程过程中解决可用性差的风险，包括与标识、标记和文件相关的风险（见
7.1.1和16.2）。见IEC 60601-1-6和1.3。

Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.
通过检查可用性工程过程的结果来检查合规性。

The MANUFACTURER shall address the RISK(S) of poor USABILITY, including those
associated with identification, marking and documents, through a USABILITY
ENGINEERING PROCESS complying with IEC 60601-1-6.
制造商应通过符合IEC 60601-1-6的可用性工程过程，解决低可用性风险，包括与标识、标记
和文件相关的风险。

Compliance is checked as specified in IEC 60601-1-6.
按照IEC 60601-1-6的规定检查合规性。

12.3 ALARM SYSTEMS

报警系统

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need for alarm systems as a means of RISK CONTROL and address any RISKS associated with the operation or failure of the alarm system. See IEC 60601-1-8 and also see 1.3.

在适用的情况下，制造商应在风险管理过程中说明作为风险控制手段的警报系统的需要，并解决与警报系统的操作或故障相关的任何风险。见IEC 60601-1-8和1.3。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

If the MANUFACTURER has implemented an ALARM SYSTEM, this ALARM SYSTEM shall comply with IEC 60601-1-8.

如果制造商实施了报警系统，则该报警系统应符合IEC 60601-1-8的要求。

Compliance is checked as specified in IEC 60601-1-8.

按照IEC 60601-1-8的规定检查合规性。

12.4 Protection against hazardous output

危险输出防护

12.4.1 * Intentional exceeding of safety limits

*故意超出安全限值

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the 适用时，制造商应在风险管理过程中解决

RISKS associated with hazardous output arising from the intentional exceeding of safety limits.

因故意超出安全限值而产生的与危险输出相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

12.4.2 Indication of parameters relevant to safety

安全相关参数指示

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need for the indication of parameters that are associated with to indicate any hazardous output.

在适用的情况下，制造商应在风险管理过程中说明与指示任何危险输出相关的参数的必要性。

EXAMPLE 1 Prior to the delivery of energy or substances to a PATIENT the energy, rate or volume should be indicated quantitatively.

例1在给病人提供能量或物质之前，应定量地指示能量、速率或体积。

EXAMPLE 2 During activation of an X-ray output, a flashing yellow light is displayed.

例2激活X射线输出时，显示闪烁的黄色指示灯。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

12.4.3 * Accidental selection of excessive output values

*意外选择过大的输出值

Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of excessive output values.

如果医用电气设备是一个多功能装置，设计用于为不同的治疗提供低强度和高强度输出，制造

商应在风险管理过程中解决与意外选择过高输出值相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

12.4.4 Incorrect output

输出不正确

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the 适用时，制造商应在风险管理过程中解决

RISKS associated with incorrect output.

与错误输出相关的风险。

EXAMPLE The RISKS associated with incorrect delivery of energy or substances to a PATIENT can be addressed by providing an alarm to alert the OPERATOR to any significant departure from the set level of delivery.

例如，与向患者错误输送能量或物质相关的风险可通过提供警报来解决，以提醒操作员任何严重偏离设定的输送水平。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

12.4.5 Diagnostic or therapeutic radiation

诊断或治疗性辐射

12.4.5.1 Limits

限制

For ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect PATIENTS, OPERATORS, other persons and sensitive devices in the vicinity, from unwanted or excessive radiation emitted by the ME EQUIPMENT. 对于设计用于诊断或治疗目的的医用电气设备，应制定适当的防护措施，以保护患者、操作员、其他人员和附近的敏感设备免受医用电气设备发出的有害或过量辐射。

NOTE Radiation from ME EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision could exceed limits normally acceptable for the population as a whole.

注：医用电气设备在医疗监督下用于诊断或治疗的医用电气设备的辐射可能超过一般人群可接受的范围。

As appropriate, particular standards shall specify requirements, limits and compliance tests to ensure radiation safety.

在适当情况下，特殊标准应规定要求、限值和符合性试验，以确保辐射安全。

12.4.5.2

Diagnostic X-ray equipment
诊断X射线设备

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时，制造商应在风险管理过程中解决
RISKS associated with diagnostic X-rays. See IEC 60601-1-3 and also see 1.3.
与诊断性X射线相关的风险。见IEC 60601-1-3和1.3。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging
purposes shall comply with IEC 60601-1-3.
医用电气设备和医用电气系统应符合IEC 60601-1-3的要求。

Compliance is checked as specified in IEC 60601-1-3.
按照IEC 60601-1-3的规定检查合规性。

12.4.5.3

Radiotherapy
放射治疗设备

equipment

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时，制造商应在风险管理过程中解决
RISKS associated with radiotherapy.
与放疗相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

12.4.5.4

Other ME EQUIPMENT producing diagnostic or therapeutic radiation
医用或其他放射诊断设备

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT
PROCESS the RISKS associated with ME EQUIPMENT producing diagnostic or
therapeutic radiation other than for diagnostic X-rays and radiotherapy (see 12.4.5.2 and
12.4.5.3).
如适用，制造商应在风险管理过程中说明医用电气设备产生诊断性或治疗性辐射的相关风险，
而非诊断性X射线和放射治疗（见12.4.5.2和12.4.5.3）。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

12.4.6

Diagnostic or therapeutic acoustic pressure
诊断或治疗性声压

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时，制造商应在风险管理过程中解决
RISKS associated with diagnostic or therapeutic acoustic pressure.
与诊断或治疗性声压相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

13 *

HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT
*医用电气设备的危险情况和故障条件

13.1

Specific HAZARDOUS SITUATIONS
特定危险情况

13.1.1 * General

*总则

When applying the SINGLE FAULT CONDITIONS as described in 4.7 and listed in 13.2, one at a time, none of the HAZARDOUS SITUATIONS in 13.1.2 to 13.1.4 (inclusive) shall occur in the ME EQUIPMENT.
当应用4.7所述和13.2中所列的单一故障条件时，一次一个，医用电气设备不得出现13.1.2至13.1.4（包括13.1.4）中的任何危险情况。

The failure of any one component at a time, which could result in a HAZARDOUS SITUATION, is described in 4.7.

4.7中描述了任何一个组件一次发生故障，可能导致危险情况。

13.1.2 * Emissions, deformation of ENCLOSURE or exceeding maximum temperature

*排放、外壳变形或超过最高温度

The following HAZARDOUS SITUATIONS shall not occur:

不得出现以下危险情况：

- emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;
排放大量的火焰、熔融金属、有毒或易燃物质；
- deformation of ENCLOSURES to such an extent that compliance with 15.3.1 is impaired;
外壳变形，使其不符合15.3.1的要求；
- temperatures of APPLIED PARTS exceeding the allowed values identified in Table 24 when measured as described in 11.1.3;
当按照11.1.3所述进行测量时，应用部件的温度超过表24中规定的允许值；
- temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;
当按照11.1.3所述进行测量和调整时，医用电气设备非应用部件但有可能接触的部件的温度超过表23中的允许值；
- exceeding the allowable values for “other components and materials” identified in Table 22 times 1,5 minus 12,5 °C. Limits for windings are found in Table 26, Table 27 and Table 31. In all other cases, the allowable values of Table 22 apply.
超过表22中“其他部件和材料”的允许值乘以1.5减去12.5°C。绕组的限值见表26、表27和表31。在所有其他情况下，表22的允许值适用。

Temperatures shall be measured using the method described in 11.1.3.
应使用11.1.3中所述的方法测量温度。

The SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2 and 13.2.2, with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where: 4.7、8.1 b)、8.7.2和13.2.2中关于火焰、熔融金属或可燃物质排放的单一故障条件不适用于以下零件和部件:

- The construction or of the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.
电源电路的结构或结构将单个故障条件下的功耗限制在15瓦以下, 或将能量耗散限制在900焦耳以下。

Compliance is checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min. the supply circuit can not supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation is also reviewed.
通过从电源电路中抽出15 W电源1分钟来检查合规性。如果1分钟后电源电路不能提供15 W电源, 则应考虑将电路的功耗限制在15 W以下。还应审查相关的设计文件。

or
或

- Secondary circuits meet all of the following conditions:
二次回路满足以下所有条件:
 - mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better;
安装在符合IEC 60695-11-10或更高可燃性分类FV1的材料上;
 - they are energized at a voltage of 60 V d.c. or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION;
它们在60 V直流电压或42.2 V峰值电压下通电, 正常和单一故障状态;
 - they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION;
在单一故障条件下, 限制在100VA或6000J;
 - they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide.
它们采用PVC、TFE、PTFE、FEP、聚氯乙烯或聚溴化物的电线绝缘。

Compliance is checked by evaluation of the design documentation.
通过评估设计文件来检查合规性。

or
或

- The component is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS as described in 4.9.
部件是具有4.9所述高完整性特性的部件。

Compliance is checked by evaluation of the design documentation.
通过评估设计文件来检查合规性。

or
或

- They are completely contained within a fire ENCLOSURE.
它们被完全控制在防火罩内。

Compliance is checked by inspection and evaluation of the design documentation to assure that the ENCLOSURE is constructed in accordance with 11.3.
通过检查和评估设计文件来检查合规性, 以确保外壳按照11.3的要求建造。

NOTE The tests according to this subclause should be performed in the sequence indicated in Annex B.
注：应按照附录B中规定的顺序进行本款规定的试验。

After the tests of this clause, THERMAL CUT-OUTS and OVER-CURRENT RELEASES are inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.
本条试验后，对热断路器和过电流脱扣器进行检查，以确定其设置未发生变化（通过加热、振动或其他原因），足以影响其安全功能。

13.1.3 Exceeding LEAKAGE CURRENT or voltage limits 超过泄漏电流或电压限值

The following HAZARDOUS SITUATIONS shall not occur:
不得出现以下危险情况：

- exceeding the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in 8.7.3;
超过8.7.3单故障情况下的泄漏电流限值；
- exceeding the voltage limits for the ACCESSIBLE PARTS including APPLIED PARTS indicated in 8.4.2.
超过8.4.2中所述的可触及部件（包括应用部件）的电压限值。

13.1.4 Specific MECHANICAL HAZARDS 特定机械危害

For specific MECHANICAL HAZARDS, see 9.1 to 9.8 (inclusive).
具体机械危害见9.1至9.8（含9.1）。

13.2 SINGLE FAULT CONDITIONS 单一故障条件

13.2.1 General 总则

During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) shall also be applied in the least favourable combination.
在应用13.2.2至13.2.13（含）中列出的单一故障条件时，8.1 a）中确定的正常条件也应以最不利的组合应用。

13.2.2 Electrical SINGLE FAULT CONDITION

电气单一故障状态

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1.
与该单一故障条件相关的要求和试验见8.1。

13.2.3 Overheating of transformers in ME EQUIPMENT

医用电气设备中变压器过热

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 15.5.
与该单一故障条件相关的要求和试验见15.5。

13.2.4 Failure of THERMOSTATS

恒温器故障

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 13.2.13和13.2.13和
15.4.2 for overloading situations.
15.4.2对于过载情况。

THERMOSTATS are short circuited or interrupted, whichever is less favourable.
自动调温器短路或中断，以较不利者为准。

13.2.5 Failure of temperature limiting devices

13.2.5温度限制装置故障

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 13.2.13和13.2.13和
15.4.2 for overloading situations.
15.4.2对于过载情况。

THERMOSTATS are short circuited or interrupted, whichever is less favourable.
自动调温器短路或中断，以较不利者为准。

13.2.6 Leakage of liquid

液体泄漏

ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK.

医用电气设备的构造应确保在单一故障条件下可能逸出的液体不会导致不可接受的风险。

Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

由于泄漏时只有少量液体会逸出，因此密封充电电池不受此要求的约束。

A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT.

应使用风险管理流程来确定医用电气设备的适当测试条件。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

通过检查风险管理文件来检查合规性。

13.2.7 Impairment of cooling that could result in a HAZARD HAZARDOUS SITUATION

可能导致危险情况的冷却障碍

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the failure of cooling systems to operate as intended.

医用电气设备的设计应确保在冷却系统无法按预期运行期间保持单一故障安全。

Impairments of cooling that can occur are simulated, for example:

模拟可能发生的冷却损伤，例如：

- single ventilation fans are locked consecutively;
单排风机连续闭锁；
- ventilation through openings in top and sides is impaired by covering of openings in the top of the ENCLOSURE or positioning of ME EQUIPMENT against walls;
通过顶部和侧面开口的通风因外壳顶部开口的覆盖或医用电气设备靠墙定位而受损；
- blocking of filters is simulated;
模拟滤波器的阻塞；
- the flow of a cooling agent is interrupted.
冷却剂的流动中断。

Temperatures that exceed the limits set in 13.1.2 constitute a failure.

温度超过13.1.2中规定的限值即构成故障。

Compliance is checked utilizing the test methods of 11.1, which are applied as far as possible.

使用11.1中尽可能适用的试验方法检查合规性。

13.2.8 Locking of moving parts

活动部件锁定

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE when moving parts become jammed.

医用电气设备的设计应使其在活动部件卡住时保持单一故障安全。

Moving parts are locked if ME EQUIPMENT:

如果医用电气设备：

- has moving ACCESSIBLE PARTS including APPLIED PARTS liable to be jammed, or
有可触及的活动部件，包括易卡住的应用部件，或
- is liable to be operated while unattended (this includes ME EQUIPMENT that is automatically or remotely controlled), or
可在无人值守的情况下操作（包括自动或远程控制的医用电气设备），或
- has one or more motors with a locked rotor torque smaller than the full load torque.
有一个或多个电机的堵转转矩小于满载转矩。

If ME EQUIPMENT has more than one moving part as described above, only one part at a time is locked. If a SINGLE FAULT CONDITION can lock multiple motors, then all motors are locked simultaneously. For further test criteria see 13.2.10.
如果医用电气设备有一个以上的移动部件, 一次只能锁定一个部件。如果一个单一的故障条件可以锁定多个电机, 则所有电机同时锁定。更多试验标准见13.2.10。

13.2.9 * Interruption and short circuiting of motor capacitors

***电动机电容器的中断和短路**

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the short circuit and open circuit of motor capacitors.

医用电气设备的设计应使其在电机电容器短路和开路期间保持单一故障安全。

Compliance is checked by performing the following test:

通过执行以下测试检查合规性:

Motors with a capacitor in the circuit of an auxiliary winding are operated according to 13.2.10 with a locked rotor, with the capacitor short circuited or open circuited in turn. Capacitor voltages are measured with one side disconnected (open circuit). A measured voltage that exceeds the RATED value constitutes a failure.
辅助绕组电路中有电容器的电动机按13.2.10的规定在转子锁定的情况下运行, 电容器依次短路或开路。在一侧断开(开路)的情况下测量电容器电压。测量电压超过额定值即构成故障。

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).
如果电机配有符合IEC 60252-1的电容器, 且医用电气设备不用于无人值守(包括自动或远程控制), 则不进行短路电容器试验。

For additional test criteria, see 13.2.10.

其他试验标准见13.2.10。

13.2.10 * Additional test criteria for motor operated ME EQUIPMENT

***电动医用电气设备的附加试验标准**

For every test in the SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, taking into account the exemptions stated in 13.1.2, motor-operated ME EQUIPMENT is operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:
对于13.2.8和13.2.9中单一故障条件下的每次试验, 考虑到13.1.2中所述的豁免, 电动医用电气设备从冷态开始, 在额定电压或额定电压范围的上限下运行以下时间段:

a) 30 s for:

30秒:

- HAND-HELD ME EQUIPMENT;
手持医用电气设备;
- ME EQUIPMENT that has to be kept switched on by hand;
必须手动打开的医用电气设备;
- ME EQUIPMENT that has to be kept under physical load by hand;
必须用手保持物理负荷的医用电气设备;

b) 5 min for other ME EQUIPMENT intended only for attended use (attended use excludes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present); 仅用于有人值守使用的其他医用电气设备(有人值守使用不包括在操作员不在场时可运行

的自动或远程控制医用电气设备)；

- c) for the maximum period of a timer, if such a device terminates the operation, for
对于计时器的最长时间段，如果此类设备终止操作，则
ME EQUIPMENT not listed under a) or b);
a) 或b) 项下未列出的医用电气设备；
- d) as long as necessary to establish THERMAL STABILITY for all the remaining ME EQUIPMENT.
只要有必要为所有剩余的医用电气设备建立热稳定性。

Temperatures of windings are determined at the end of the specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices and the like.

绕组温度在规定试验周期结束时或在熔断器、热断路器、电动机保护装置等运行瞬间测定。

Temperatures are measured as specified in 11.1.3 d).

按照11.1.3 d) 的规定测量温度。

Temperatures that exceed the limits of Table 26 constitute a failure.

超过表26限值的温度即为故障。

13.2.11 Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

医用电气设备中与富氧环境一起使用的部件故障

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in 11.2.2.

与这些单一故障条件相关的要求和试验见11.2.2。

13.2.12 Failure of parts that might result in a MECHANICAL HAZARD

可能导致机械危险的零件故障

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 9 and 15.3.

与这些单一故障条件有关的要求和试验见第9条和第15.3条。

Table 26 – * Temperature limits of motor windings
表26-*电机绕组的温度限制

Type of ME EQUIPMENT 医用电气设备类型	Insulation class 绝缘等级				
	Class A A级	Class B B类	Class E E类	Class F F类	Class H H类
	Temperature in □C 温度（℃）				
ME EQUIPMENT provided with a timer and not 医用电气设备配备计时器 intended for unattended use and ME EQUIPMENT to be operated for 30 s or 5 min 用于无人值守使用，医用电气设备运行30秒或5分钟	200 200	225 225	215 215	240 240	260 260
Other ME EQUIPMENT 其他医用电气设备					
– if impedance-protected, maximum value –如果阻抗保护，最大值	150 150	175 175	165 165	190 190	210 210
– if protected by protection devices that operate during the first hour, maximum value –如果保护装置在第一个小时内运行，则最大值	200 200	225 225	215 215	240 240	260 260
– after the first hour, maximum value –第一小时后，最大值	175 175	200 200	190 190	215 215	235 235
– after the first hour, arithmetic average 第一个小时后的算术平均值	150 150	175 175	165 165	190 190	210 210
NOTE The temperature limits in this table were derived from IEC 61010-1:2001 [22]. 注：本表中的温度限值源自IEC 61010-1:2001[22]。					

13.2.13 *
*超载

13.2.13.1 *
*一般过载试验条件

General overload test conditions

Overload

After the tests of 13.2.13.2 to 13.2.13.4 (inclusive), the ME EQUIPMENT, when cooled down to approximately room temperature within 3 □C of the temperature in the test environment, shall remain safe.

在完成13.2.13.2至13.2.13.4（包括13.2.13.4）的试验后，当医用电气设备冷却至试验环境温度3℃范围内的室温时，应保持安全。

Compliance is determined by inspection of the ME EQUIPMENT or the appropriate tests (such as dielectric strength of motor insulation according to 8.8.3).

通过检查医用电气设备或进行适当的试验（如8.8.3中规定的电机绝缘的介电强度）来确定是否合格。

For insulation of thermoplastic materials that is relied upon as a MEANS OF PROTECTION

(see 8.8), the ball-pressure test specified in 8.8.4.1 a) is performed at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.13.2 to 13.2.13.4 (inclusive).

对于作为保护手段的热塑性材料的绝缘（见8.8），在比13.2.13.2至13.2.13.4（含）中测量的绝缘温度高25°C的温度下进行8.8.4.1 a）中规定的球压试验。

13.2.13.2 ME EQUIPMENT with heating elements

带加热元件的医用电气设备

a) ME EQUIPMENT having heating elements is checked for compliance as follows:

按照以下要求检查具有加热元件的医用电气设备是否符合要求：

- 1) for thermostatically controlled ME EQUIPMENT having heating elements that is intended for built-in or for unattended operation or that has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of
对于恒温控制医用电气设备，其加热元件为内置式或无人值守操作，或电容器不受与恒温器触点并联的保险丝或类似装置保护：通过
13.2.13.2 b) and 13.2.13.2 c);
13.2.13.2 b) 和13.2.13.2 c) ；
- 2) for ME EQUIPMENT having heating elements RATED for non-CONTINUOUS OPERATION: by the tests of 13.2.13.2 b) and 13.2.13.2 c);
对于具有加热元件额定非连续运行的医用电气设备：通过13.2.13.2 b) 和13.2.13.2 c) 的试验；
- 3) for other ME EQUIPMENT having heating elements: by the test of 13.2.13.2 b).
对于具有加热元件的其他医用电气设备：通过13.2.13.2 b) 的试验。

If more than one of the tests is applicable to the same ME EQUIPMENT, these tests are performed consecutively.

如果多个试验适用于同一医用电气设备，则应连续进行这些试验。

If, in any of the tests, a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before THERMAL STABILITY is established without the possibility of automatic restoration, the heating period is ended. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test is repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. However, if either sample fails to comply with the conditions specified in 13.1.2, it constitutes a failure. 如果在任何试验中，非自动复位热断路器工作，加热元件或故意薄弱部分破裂，或者如果在建立热稳定性之前电流被中断而不可能自动恢复，则加热期结束。但是，如果中断是由于加热元件或故意薄弱部分破裂造成的，则在第二个样品上重复试验。加热元件或第二个样品中故意薄弱部分的开路本身并不意味着不符合要求。但是，如果任何一个样品不符合13.1.2中规定的条件，则构成不合格。

- b) ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favourable. 具有加热元件的医用电气设备在11.1中规定的条件下进行试验, 但没有足够的热放电, 电源电压为额定电源电压的90%或110%, 以最不利者为准。

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before THERMAL STABILITY is established, the operating period is ended. If interruption of the current does not occur, ME EQUIPMENT is switched off as soon as THERMAL STABILITY is established and is allowed to cool to approximately room temperature. 如果非自复位热断路器工作, 或者如果在建立热稳定性之前电流被中断而不可能自动恢复, 则操作周期结束。如果电流没有中断, 医用电气设备将在热稳定性建立后立即关闭, 并允许冷却至接近室温。

For ME EQUIPMENT RATED for non-CONTINUOUS OPERATION, the duration of the test is equal to the RATED operating time. 对于额定非连续运行的医用电气设备, 试验持续时间等于额定运行时间。

- c) Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions are met. 医用电气设备的加热部件在医用电气设备正常运行的情况下, 在额定电源电压的110%和11.1中的规定下进行测试。满足以下试验条件。
- 1) Any control that serves to limit the temperature in NORMAL CONDITION, except a THERMAL CUT-OUT, is disabled. 除热断路器外, 任何用于在正常条件下限制温度的控制都将被禁用。
 - 2) If the ME EQUIPMENT is provided with more than one control, they are disabled in turn. 如果医用电气设备配备有多个控制装置, 它们将依次禁用。
 - 3) The ME EQUIPMENT is operated at the RATED DUTY CYCLE until THERMAL STABILITY is achieved, irrespective of the RATED operating time. 医用电气设备在额定工作循环下运行, 直到达到热稳定性, 而不考虑额定工作时间。

13.2.13.3 ME EQUIPMENT with motors

带电机的医用电气设备

- a) ME EQUIPMENT having motors is checked for compliance as follows:

对装有电机的医用电气设备进行如下检查:

- 1) For the motor part of the ME EQUIPMENT, compliance is checked by the tests of 13.2.8 to 13.2.10 (inclusive), 13.2.13.3 b), 13.2.13.3 c) and 13.2.13.4, as applicable. For motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. and where difficulty is experienced in obtaining accurate temperature measurements due to the small size or design of the motor, it is permitted to use the following test instead of temperature measurement in order to determine compliance with 13.2.9 and 13.2.10. (包括13.2.13.3 b)、13.2.13.3 c) 和13.2.13.4 (如适用)。对于位于交流峰值电压不超过42.4V或直流电压不超过60V的电路中的电机, 以及由于电机尺寸小或设计原因难以获得准确的温度测量值的电机, 为了确定是否符合13.2.9和13.2.10, 允许使用以下试验代替温度测量。

The motor is covered with a single layer of cheesecloth with the following characteristics:

电机上覆盖有以下特点的单层粗棉布：

- bleached cotton material;
漂白棉料；
- 26–28 m2 per kg mass; and
每千克质量26–28 m2； 以及
- 13 threads per cm in one direction and 11 threads per cm in the other.
一个方向每厘米有13个螺纹，另一个方向每厘米有11个螺纹。

Ignition of the cheesecloth during the test or at its conclusion constitutes a failure.
在试验过程中或试验结束时点燃粗棉布即构成失败。

- 2) For ME EQUIPMENT that also contains heating parts, the tests are performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition.
对于包含加热部件的医用电气设备，在规定的电压下进行试验，电机部件和加热部件同时运行，以产生最不利的条件。
- 3) If more than one of the tests is applicable for the same ME EQUIPMENT, these tests are performed consecutively.
如果多个试验适用于同一医用电气设备，则应连续进行这些试验。

b) Motors are checked for running overload protection if they are:
检查电机的运行过载保护，前提是：

- 1) intended to be remotely controlled or automatically controlled (by a single control device without redundant protection), or
拟进行远程控制或自动控制（由单个控制装置进行无冗余保护），或
- 2) likely to be subjected to CONTINUOUS OPERATION whilst unattended.
可能在无人看管的情况下连续操作。

Compliance is determined by operating the ME EQUIPMENT under normal load conditions at RATED voltage or at the maximum of the RATED voltage range, until THERMAL STABILITY is achieved (see 11.1.3).
通过在正常负载条件下以额定电压或最大额定电压范围运行医用电气设备，直到达到热稳定性（见11.1.3）来确定合规性。

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.
然后增加负载，使电流以适当的步骤增加，电源电压保持在其原始值。

When THERMAL STABILITY is established, the load is again increased. The load is thus progressively increased in appropriate steps until the overload protection operates, or until no further temperature rise is noted.
当热稳定性建立后，负荷再次增加。因此，负荷以适当的步骤逐渐增加，直到过载保护动作，或直到没有发现进一步的温升。

The motor winding temperature is determined during each steady period. If the maximum value recorded exceeds the value in Table 27, it constitutes a failure.
电机绕组温度在每个稳定期内确定。如果记录的最大值超过表27中的值，则构成故障。

Table 27 – Maximum motor winding steady-state temperature
表27——最大电机绕组稳态温度

Insulation class 绝缘等级	Maximum temperature 最高温度 □C 摄氏度
A	140
A	140
B	165
B	165
E	155
E	155
F	180
F	180
H	200
H	200

If the load cannot be changed in appropriate steps in ME EQUIPMENT, the motor is removed from the ME EQUIPMENT in order to perform the test.
如果不能在医用电气设备中以适当的步骤改变负载，则将电机从医用电气设备上拆下，以便进行测试。

The running overload test for motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. is performed only if a possibility of an overload occurring is determined by inspection or by review of the design. The test need not be performed, for example, where electronic drive circuits maintain a substantially constant drive current.
仅当通过检查或审查设计确定过载可能性时，才对位于交流峰值电压不超过42.4V或直流电压不超过60V的电路中的电机进行运行过载试验。例如，在电子驱动电路保持基本恒定的驱动电流的情况下，不需要进行测试。

- c) ME EQUIPMENT with three-phase motors is operated with normal load, connected to a three- phase (SUPPLY MAINS) with one phase disconnected. Periods of operation are according to 13.2.10.
带三相电机的医用电气设备在正常负载下运行，与三相（供电干线）连接，单相断开。操作周期见13.2.10。

ME EQUIPMENT RATED for non-CONTINUOUS OPERATION other than:
医用电气设备额定用于非连续运行，除了：

- HAND-HELD ME EQUIPMENT;
手持医用电气设备；
- ME EQUIPMENT that has to be kept switched on manually;
必须手动开启的医用电气设备；
- ME EQUIPMENT that has to be kept under physical load by hand;
必须用手保持物理负荷的医用电气设备；
- ME EQUIPMENT with a timer and a back-up timer system
带定时器和备用定时器系统的医用电气设备

is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until the peak temperature does not increase by more than 5 °C in one hour, or until any protective device operates.
在正常负载和额定电压下或在额定电压范围的上限下运行，直到峰值温度在一小时内升高不超过5°C，或直到任何保护装置运行。

Motor winding temperatures are determined when THERMAL STABILITY is established or immediately before the operation of the protective device. Motor winding temperatures that exceed the values specified in 13.2.10 constitute a failure.
电机绕组温度在建立热稳定性时或保护装置运行前立即确定。电机绕组温度超过13.2.10中规定的值即构成故障。

If in NORMAL USE a load-reducing device in the ME EQUIPMENT operates, the test is continued with the ME EQUIPMENT running idle.
如果在正常使用中，医用电气设备中的减载装置运行，则在医用电气设备空转运行的情况下继续进行试验。

14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)
*可编程电气医疗系统（PEMS）

14.1 * General
*总则

The requirements of this clause shall apply to PEMS unless:
本条要求应适用于PEMS，除非：

- the PESS provides no BASIC SAFETY or ESSENTIAL PERFORMANCE; or
PESS不提供基本安全或基本性能；或

- the application of ISO 14971 demonstrates that the failure of the PESS does not lead to an unacceptable RISK.

ISO 14971的应用证明PESS的故障不会导致不可接受的风险。

The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless:

14.2至14.12（包括14.2）中的要求应适用于PEMS，除非：

- none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or
任何可编程电子子系统（PESS）均不提供基本安全或基本性能所需的功能；或
- the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK.
4.2中所述的风险管理应用表明，任何PES的故障不会导致不可接受的风险。

The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an IT-NETWORK whether or not the requirements in 14.2 to 14.12 apply.

无论14.2至14.12中的要求是否适用，14.13中的要求适用于拟并入IT网络的任何PEM。

NOTE 1 This clause requires that a PROCESS be followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and that a RECORD of that PROCESS be produced. The concepts of RISK MANAGEMENT and a PEMS DEVELOPMENT LIFE-CYCLE are the basis of such a PROCESS. However, because a RISK MANAGEMENT PROCESS is already required by this standard, this clause will define the minimum elements of the PEMS DEVELOPMENT LIFE-CYCLE and only the additional elements for the PEMS that needs to be considered as part of the RISK MANAGEMENT PROCESS (see 4.2).

注1：本条要求在整个PEMS开发生命周期内遵循一个过程，并生成该过程的记录。风险管理和PEMS开发生命周期的概念是这一过程的基础。但是，由于本标准已经要求了风险管理流程，本条款将定义PEMS开发生命周期的最低要素，并且只定义了需要作为风险管理流程一部分考虑的PEMS的附加要素（见4.2）。

NOTE 2 If a RISK CONTROL measure is implemented within the PEES, it is necessary to apply Clause 14 to demonstrate that the failure of the PEES does not lead to an unacceptable RISK.

注2：如果在PEES中实施了风险控制措施，则有必要应用第14条来证明PEES的故障不会导致不可接受的风险。

NOTE 2 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in Clause 14 for each constituent component of the PEMS, such as off-the-shelf (OTS) software of unknown provenance (SOUP), subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures. SOUP is defined in IEC 62304:2006 as a “software item that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as ‘off-the-shelf software’) or software previously developed for which adequate RECORDS of the development PROCESSES are not available”.

注2 3：制造商可能无法遵循第14条中针对PEMS各组成部分确定的所有流程，例如来源未知的现成（OTS）软件（SOUP）、非医疗来源的子系统和遗留设备。在这种情况下，制造商应特别考虑是否需要额外的风险控制措施。在IEC 62304:2006中，SOUP被定义为“已经开发并普遍可用的软件项，尚未被开发用于纳入医疗器械（也称为‘现成软件’）或先前开发的软件，其开发过程有充分的记录不可用”。

Compliance is determined by application of the requirements in 14.2 to 14.13 (inclusive), by inspection of the RISK MANAGEMENT FILE, and assessment of PROCESSES cited in this clause.

合规性通过应用14.2至14.13（包括14.2至14.13）中的要求，通过检查风险管理文件和评估本条款中引用的过程来确定。

Compliance is determined by inspection of all documentation required, and when necessary,

assessment of the requirements in 14.2 to 14.13 (inclusive).
通过检查所需的所有文件，并在必要时评估14.2至14.13（包括14.2）中的要求来确定合规性。

NOTE 3 4 This assessment could be performed by internal audit.

注3 4该评估可由内部审计进行。

When the requirements in 14.2 to 14.13 apply, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS.

当14.2至14.13中的要求适用时，IEC 62304:2006第4.3款、第5款、第7款、第8款和第9款的要求也应适用于每个PES的软件开发或修改。

Compliance is determined by inspection and assessment as required by subclause 1.4 of IEC 62304:2006.

根据IEC 62304:2006第1.4款的要求，通过检查和评估确定合规性。

NOTE 5 The software development PROCESS required for compliance with this standard does not include the post- production monitoring and maintenance required by Clause 6 of IEC 62304:2006.

注5：符合本标准所需的软件开发过程不包括IEC 62304:2006第6条要求的生产后监测和维护。

14.2 * Documentation

***文件**

In addition to the RECORDS and documents required by ISO 14971, the documents produced from application of Clause 14 shall be maintained and shall form part of the RISK MANAGEMENT FILE. 除ISO 14971要求的记录和文件外，应用第14条产生的文件应予以保存，并应构成风险管理文件的一部分。

NOTE See Figure H.3 as guidance.

注：参考图H.3作为指南。

The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE.

第14条要求的文件应按照正式的文件控制程序进行评审、批准、发布和更改。

14.3 * RISK MANAGEMENT plan

***风险管理计划**

The RISK MANAGEMENT plan required by 3.5 of ISO 14971 4.2.2 shall also include a reference to the PEMS VALIDATION plan (see 14.11).

ISO 14971 4.2.2第3.5条要求的风险管理计划还应包括PEMS验证计划的参考（见14.11）。

14.4 * PEMS DEVELOPMENT LIFE-CYCLE

***PEMS开发生命周期**

A PEMS DEVELOPMENT LIFE-CYCLE shall be documented.

应记录PEMS开发生命周期。

NOTE 1 Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLE in more detail.

注1第H.2条更详细地解释了PEMS开发生命周期。

NOTE 2 IEC 62304 [26] defines general requirements for additional PROCESSES and activities specific to software development.

注2 IEC 62304[26]定义了软件开发特定附加过程和活动的一般要求。

The PEMS DEVELOPMENT LIFE-CYCLE shall include a set of defined milestones.

PEMS开发生命周期应包括一组定义的里程碑。

At each milestone, the activities to be completed and the VERIFICATION methods to be applied to those activities shall be defined.

在每个里程碑处，应确定待完成的活动以及应用于这些活动的验证方法。

Each activity shall be defined including its inputs and outputs.

应定义每项活动，包括其输入和输出。

Each milestone shall identify the RISK MANAGEMENT activities that must be completed before that milestone.

每个里程碑应确定在该里程碑之前必须完成的风险管理活动。

The PEMS DEVELOPMENT LIFE-CYCLE shall be tailored for a specific development by making plans which detail activities, milestones and schedules.

PEMS开发生命周期应通过制定详细说明活动、里程碑和时间表的计划，针对特定开发进行调整。

The PEMS DEVELOPMENT LIFE-CYCLE shall include documentation requirements.

PEMS开发生命周期应包括文件要求。

14.5 * Problem resolution

***问题解决方案**

Where appropriate, a documented system for problem resolution within and between all phases and activities of the PEMS DEVELOPMENT LIFE-CYCLE shall be developed and maintained.

在适当的情况下，应开发和维护PEMS开发生命周期所有阶段和活动之间的问题解决文件系统。

Depending on the type of product, the problem resolution system may:

根据产品类型，问题解决系统可以：

- be documented as a part of the PEMS DEVELOPMENT LIFE-CYCLE;
作为PEMS开发生命周期的一部分进行记录；
- allow the reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE;
允许报告影响基本安全或基本性能的潜在或现有问题；
- include an assessment of each problem for associated RISKS;
包括对每个问题相关风险的评估；
- identify the criteria that must be met for the issue to be closed;
确定解决问题必须满足的标准；
- identify the action to be taken to resolve each problem.
确定要采取的措施来解决每个问题。

14.6 RISK MANAGEMENT PROCESS

风险管理流程

14.6.1 * Identification of known and foreseeable HAZARDS

***识别已知和可预见的危险**

When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with NETWORK/DATA COUPLING the incorporation of the PEMS into an IT-NETWORK, components of third-party origin and legacy subsystems.

在编制已知或可预见危害清单时，制造商应考虑与PEMS软件和硬件相关的危害，包括与网络/

数据耦合相关的危害，包括将PEMS并入IT网络、第三方来源部件和遗留子系统的相关危害。

NOTE In addition to the material given in Annex D E of ISO 14971:2007, the list of possible causes for HAZARDS

注：除ISO 14971:2007附录D E中给出的材料外，可能的危害原因列表 associated with PEMS should can include:

与PEMS相关的应包括：

- failure of the NETWORK/DATA COUPLING to provide the characteristics necessary for the PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE;
网络/数据耦合未能提供PEMS实现其基本安全或基本性能所需的特性；
- undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference);
非期望反馈[物理和数据]（可能包括：未经请求的输入、超出范围或不一致的输入，以及来自电磁干扰的输入）；
- unavailable data;
数据不可用；
- lack of integrity of data;
数据缺乏完整性；
- incorrect data;
数据不正确；
- incorrect timing of data.
数据计时不正确。
- unintended interactions within and among PESS;
PES内部和之间的意外交互；
- unknown aspects or quality of third-party software;
第三方软件的未知方面或质量；
- unknown aspects or quality of third-party PESS;
第三方PES的未知方面或质量；
- lack of data security, including its effects on data privacy, and particularly vulnerability to tampering, unintended interaction with other programs and viruses.
缺乏数据安全性，包括对数据隐私的影响，特别是易受篡改、与其他程序和病毒的意外交互。
- failure of the IT-NETWORK to provide the characteristics necessary for the PEMS to achieve its BASIC SAFETY or
IT网络未能提供PEMS实现其基本安全或
ESSENTIAL PERFORMANCE. See Annex H.7.2 for examples.
基本性能。示例见附录H.7.2。

14.6.2 * RISK CONTROL

***风险控制**

The following requirements for PEMS supplement Subclause 6.1 of ISO 14971 4.2.2.
以下PEMS要求补充ISO 14971 4.2.2子条款6.1。

Suitably validated tools and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. These tools and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(S). 应选择和识别适当验证的工具和程序，以实施各项风险控制措施。这些工具和程序应适当，以确保各项风险控制措施能令人满意地降低已识别的风险。

14.7 * Requirement specification

***需求说明书**

For the PEMS and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.

对于PEMS及其每个子系统（例如PESS），应制定一份书面要求规范。

NOTE Example structures of a PEMS are given in H.1.

注：质子交换膜的结构示例见H.1。

The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.

系统或子系统的需求规范应包括并区分该系统或子系统实施的任何基本性能和任何风险控制措施。

14.8 * Architecture

***建筑**

For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification.

对于PEMS及其每个子系统，应规定满足要求规范的体系结构。

Where appropriate, to reduce the RISK to an acceptable level, the architecture specification shall make use of:

在适当的情况下，为了将风险降低到可接受的水平，架构（architecture）规范应利用：

- a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS;
具有高完整性特征的部件；
- b) fail-safe functions;
故障保护功能；
- c) redundancy;
冗余；
- d) diversity;
多样性；
- e) * partitioning of functionality;
*功能划分；
- f) defensive design, e.g. limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators.
防御性设计，例如通过限制可用输出功率或引入限制执行器行程的方法来限制潜在的危险影响。

The architecture specification shall take into consideration:

架构规范应考虑：

- g) * allocation of RISK CONTROL measures to subsystems and components of the PEMS; NOTE Subsystems and components include sensors, actuators, PESS

and interfaces.

*将风险控制措施分配给PEMS的 subsystems和 components；注： subsystems和 components包括 sensors、 actuators、 PES和 interfaces。

- h) failure modes of components and their effects;
部件的失效模式及其影响；
- i) common cause failures;
共因故障；
- j) systematic failures;
系统故障；
- k) test interval duration and diagnostic coverage;
试验间隔时间和诊断范围；
- l) maintainability;
可维护性；
- m) protection from reasonably foreseeable misuse;
防止合理可预见的滥用；
- n) the NETWORK/DATA COUPLING IT-NETWORK specification, if applicable.
网络/数据耦合IT网络规范（如适用）。

14.9 * Design and implementation

***设计与实施**

Where appropriate, the design shall be decomposed into subsystems, each having both a design and test specification.

在适当的情况下，设计应分解为 subsystems，每个 subsystem 都有设计和测试规范。

Descriptive data regarding the design environment shall be included in the RISK MANAGEMENT FILE documented.

有关设计环境的描述性数据应包含在风险管理文件中。

NOTE See H.3 H.4 a) for examples of design environment elements.

注：有关设计环境元素的示例，请参见 H.3 H.4 a)。

14.10 * VERIFICATION

***验证**

VERIFICATION is required for all functions that implement BASIC SAFETY, ESSENTIAL PERFORMANCE or RISK CONTROL measures.

实施基本安全、基本性能或风险控制措施的所有功能都需要验证。

A VERIFICATION plan shall be produced to show how these functions shall be verified. The plan shall include:

应制定验证计划，说明如何验证这些功能。计划应包括：

- at which milestone(s) VERIFICATION is to be performed for each function;
对每个功能进行里程碑验证；
- the selection and documentation of VERIFICATION strategies, activities, techniques, and the appropriate level of independence of the personnel performing the VERIFICATION;
验证策略、活动、技术的选择和记录，以及执行验证的人员的适当独立性水平；
- the selection and utilization of VERIFICATION tools;
验证工具的选择和使用；
- coverage criteria for VERIFICATION.
验证标准。

NOTE Examples of methods and techniques are:

注：方法和技术的示例如下：

- walkthroughs;
演练；
- inspections;
检查；
- static analysis;
静态分析；
- dynamic analysis;
动态分析；
- white box testing;
白盒测试；
- black box testing;
黑盒测试；
- statistical testing.
统计检验。

The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the
按验证计划进行验证。结果

VERIFICATION activities shall be documented.

验证活动应形成文件。

14.11 * PEMS VALIDATION

***PEMS验证**

A PEMS VALIDATION plan shall include the validation of BASIC SAFETY and ESSENTIAL PERFORMANCE, and shall require checks for unintended functioning of the PEMS.

PEMS验证计划应包括基本安全和基本性能的验证，并要求检查PEMS的非预期功能。

Methods used for PEMS VALIDATION shall be documented.

应记录用于PEMS验证的方法。

The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of
PEMS验证应根据PEMS验证计划进行。结果

PEMS VALIDATION activities shall be documented.

应记录PEMS验证活动。

The person having the overall responsibility for the PEMS VALIDATION shall be independent of the design team. The MANUFACTURER shall document the rationale for the level of independence.

全面负责PEMS验证的人员应独立于设计团队。制造商应记录独立性水平的基本原理。

No member of a design team shall be responsible for the PEMS VALIDATION of their own design.
设计团队的任何成员都不应对自己设计的PEMS验证负责。

All professional relationships of the members of the PEMS VALIDATION team with members of the design team shall be documented in the RISK MANAGEMENT FILE.
PEMS验证团队成员与设计团队成员之间的所有专业关系应记录在风险管理文件中。

A reference to the methods and results of the PEMS VALIDATION shall be included in the RISK MANAGEMENT FILE.
PEMS验证方法和结果的参考应包含在风险管理文件中。

14.12 * Modification

***修改**

If any or all of a design results from a modification of an earlier design then either all of this clause applies as if it were a new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change PROCEDURE.
如果任何或所有设计是由于对早期设计的修改而产生的，则本条中的任何一条适用于新设计，或者任何先前设计文件的持续有效性应根据文件化的修改/变更程序进行评估。

When software is modified, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the modification.
修改软件时，IEC 62304:2006第4.3款、第5款、第7款、第8款和第9款的要求也适用于修改。

14.13 * Connection of PEMS by NETWORK/DATA COUPLING to other equipment

***通过网络/数据耦合将PEMS连接到其他设备**

*** PEMS intended to be incorporated into an IT-NETWORK**

***PEMS计划并入IT网络**

If the PEMS is intended to be connected by NETWORK/DATA COUPLING to other equipment that is outside the control of the PEMS MANUFACTURER, the technical description shall:

如果PEMS拟通过网络/数据耦合连接至PEMS制造商控制范围之外的其他设备，则技术说明应：

- a) specify the characteristics of the NETWORK/DATA COUPLING necessary for the PEMS to achieve its INTENDED USE;
规定PEMS实现预期用途所需的网络/数据耦合特性；

b) list the HAZARDOUS SITUATIONS resulting from a failure of the NETWORK/DATA COUPLING to provide the specified characteristics;

列出因网络/数据耦合故障而导致的危险情况, 以提供规定的特性;

e) instruct the RESPONSIBLE ORGANIZATION that:

指示责任组织:

- connection of the PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
可能导致与其他第三方网络连接的未识别的设备或设备的风险;
- the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;
责任组织应识别、分析、评价和控制这些风险;
- subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analysis; and
网络/数据耦合的后续变化可能会带来新的风险, 并需要进行额外的分析; 以及
- changes to the NETWORK/DATA COUPLING include:
对网络/数据耦合的更改包括:
 - changes in NETWORK/DATA COUPLING configuration;
网络/数据耦合配置的变化;
 - connection of additional items to the NETWORK/DATA COUPLING;
附加项目与网络/数据耦合的连接;
 - disconnecting items from the NETWORK/DATA COUPLING;
从网络/数据耦合断开项目;
 - update of equipment connected to the NETWORK/DATA COUPLING;
更新连接到网络/数据耦合的设备;
 - upgrade of equipment connected to the NETWORK/DATA COUPLING.
升级连接到网络/数据耦合的设备。

If the PEMS is intended to be incorporated into an IT-NETWORK that is not validated by the PEMS MANUFACTURER, the MANUFACTURER shall make available instructions for implementing such connection including the following:
如果PEMS拟并入未经PEMS制造商验证的IT网络, 则制造商应提供实施此类连接的可用说明, 包括:

- a) the purpose of the PEMS's connection to an IT-NETWORK;
PEMS与IT网络连接的目的;
- b) the required characteristics of the IT-NETWORK incorporating the PEMS;
包含PEMS的IT网络所需的特性;
- c) the required configuration of the IT-NETWORK incorporating the PEMS;
包含PEMS的IT网络所需的配置;
- d) the technical specifications of the network connection of the PEMS including security specifications;
PEMS网络连接的技术规范, 包括安全规范;
- e) the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and
PEM、IT网络和IT网络上其他设备之间的预期信息流, 以及通过IT网络的预期路由; 以及

NOTE 1 This can include aspects of effectiveness and data and system security as related to BASIC

SAFETY

注1：这可以包括与基本安全相关的有效性、数据和系统安全性方面
and ESSENTIAL PERFORMANCE (see also Clause H.6 and IEC 80001-1:2010).
和基本性能（另见第H.6条和IEC 80001-1:2010）。

- f) a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT-NETWORK.

IT网络故障导致的危险情况列表，无法提供满足PEMS与IT网络连接目的所需的特征。

NOTE 2 Connecting a PEMS to another piece of equipment for the purpose of transferring data creates a two-node IT-NETWORK. For example, connecting a PEMS to a printer creates an IT-NETWORK. If the MANUFACTURER has validated the PEMS with the printer, the resulting network would be considered within the control of the MANUFACTURER.

注2：为了传输数据，将PEMS连接到另一台设备，从而创建了一个双节点IT网络。例如，将PEMS连接到打印机可创建IT网络。如果制造商已使用打印机验证了PEMS，则生成的网络将被视为在制造商的控制范围内。

Compliance is checked by inspection of the instructions.
通过检查说明书检查合规性。

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER shall instruct the RESPONSIBLE ORGANIZATION that:

在随附文件中，制造商应指示责任机构：

- connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;
将PEMS连接到包括其他设备的IT网络可能会对患者、操作员或第三方造成先前未确定的风险；
- the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS; NOTE 3 IEC 80001-1:2010 provides guidance for the RESPONSIBLE ORGANIZATION to address these RISKS.
责任组织应识别、分析、评估和控制这些风险；注3 IEC 80001-1:2010为责任组织应对这些风险提供了指导。
- subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis; and
IT网络的后续变化可能会带来新的风险，并需要进行额外的分析；以及
- changes to the IT-NETWORK include:
对IT网络的更改包括：
 - changes in the IT-network configuration;
IT网络配置的变化；
 - connection of additional items to the IT-NETWORK;
将附加项目连接到IT网络；

- disconnecting items from the IT-NETWORK;
断开项目与IT网络的连接；
- update of equipment connected to the IT-NETWORK; and
更新连接到IT网络的设备； 以及
- upgrade of equipment connected to the IT-NETWORK.
升级连接到IT网络的设备。

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.
通过检查随附文件检查合规性。

15 Construction of ME EQUIPMENT 医用电气设备施工

15.1 * Arrangements of controls and indicators of ME EQUIPMENT *医用电气设备控制装置和指示器的布置

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT in the USABILITY ENGINEERING PROCESS. See 12.2.
适用时，制造商应在风险管理过程中解决可用性工程过程中与医用电气设备控制和指标安排相关的风险。见12.2。

Compliance is checked by inspection of the RISK MANAGEMENT FILE as specified in IEC 60601- 1-6.
通过检查IEC 60601-1-6中规定的风险管理文件来检查合规性。

15.2 * *适用性

Serviceability

Parts of ME EQUIPMENT subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.
医用电气设备中易受机械磨损、电气和环境退化或老化影响的部件，如果允许长时间不受检查，可能会导致不可接受的风险，应便于检查、更换和维护。

Parts of ME EQUIPMENT that are likely to be replaced or adjusted shall be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.
医用电气设备中可能需要更换或调整的部件的位置和固定方式应确保能够在不损坏或干扰相邻部件或接线的情况下进行检查、维修、更换和调整。

Compliance is checked by inspection of the parts mentioned above in this subclause and of their location.
通过检查本款中上述部件及其位置来检查是否符合要求。

15.3 Mechanical 机械强度

strength

15.3.1 General 总则

ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in an unacceptable RISK loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.
医用电气设备或其部件应具有足够的机械强度，且不得因模压应力或因推、冲击、跌落和粗暴搬运而产生的机械应力而导致基本安全或基本性能的不可接受风险损失。

Compliance is checked by application of the tests in Table 28. The tests are not applied to

handles, levers, knobs, the face of cathode ray tubes (see 9.5.2), or to transparent or translucent covers of indicating or measuring devices unless with the handle, lever, knob, or cover removed there is an unacceptable RISK of electric shock. 通过应用表28中的试验检查合规性。试验不适用于手柄、杠杆、旋钮、阴极射线管表面（见9.5.2），或指示或测量装置的透明或半透明盖，除非移除手柄、杠杆、旋钮或盖子，存在不可接受的触电风险。

NOTE Examples of damage that can result in unacceptable RISK affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.

注：可能导致影响基本安全的不可接受风险的损坏示例包括爬电距离和空气间隙降低到8.9中规定的值以下，接近超出8.4中限制的部件，或接近可能造成危害的活动部件。

Assessment criteria that can be useful in determining if the tests in Table 28 have this test has resulted in an unacceptable RISK loss of BASIC SAFETY include: 评估标准可用于确定表28中的试验是否导致了不可接受的基本安全风险损失，包括：

- those in Clause 8 and 11.6; 第8条和第11.6条的规定；
- the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid SUPPLEMENTARY or REINFORCED INSULATION providing a MEANS OF PROTECTION; and 8.8.3中规定的介电强度试验，以评估提供保护手段的固体补充或增强绝缘的完整性；以及
- measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored. 测量爬电距离或空气间隙，以将数值与8.9中规定的最小距离进行比较。通常可以忽略不会对电击或湿气保护产生不利影响的小芯片。

Table 28 – Mechanical strength test applicability**表28——机械强度试验适用性**

ME EQUIPMENT type 医用电气设备类型	Tes t 试 验
HAND-HELD 手持式	Push (15.3.2) 推送（15）
	Drop (15.3.4.1) 跌落（15.3.4.1）
	Moulding stress relief (15.3.6) 成型应力消除（15.3.6）
BODY-WORN 身体磨损	Push (15.3.2) 推动（15.3.2）
	Impact (15.3.3) 冲击（15.3.3）
	Drop (15.3.4.1) 跌落（15.3.4.1）
	Moulding stress relief (15.3.6) 成型应力消除（15.3.6）
PORTABLE 便携式	Push (15.3.2) 推动（15.3.2）
	Impact (15.3.3) 冲击（15.3.3）
	Drop (15.3.4.2) 跌落（15.3.4.2）
	Moulding stress relief (15.3.6) 成型应力消除（15.3.6）
MOBILE 移动	Push (15.3.2) 推动（15.3.2）
	Impact (15.3.3) 冲击（15.3.3）
	Rough handling (15.3.5) 粗暴搬运（15.3.5）
	Moulding stress relief (15.3.6) 成型应力消除（15.3.6）
FIXED or STATIONARY 固定或固定	Push (15.3.2) 推动（15.3.2）
	Impact (15.3.3) 冲击（15.3.3）
	Moulding stress relief (15.3.6) 成型应力消除（15.3.6）

15.3.2 * Push test
*推压试验

ENCLOSURES of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptable RISK.
医用电气设备的外壳应具有足够的刚度，以防不合格风险。

Compliance is checked by the following test.
通过以下试验检查合规性。

External parts of an ENCLOSURE are subject to a steady force of $250\text{ N} \pm 10\text{ N}$ for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE of ME EQUIPMENT having a mass of more than 18 kg.
外壳外部部件承受 $250\text{ N} \pm 10\text{ N}$ 的稳定力，持续5 s，使用合适的试验工具在直径为30 mm的圆形平面上提供接触。但是，本试验不适用于质量超过18 kg的医用电气设备外壳底部。

After the test, any damage sustained that results in an unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE, constitutes a failure.
测试后，通过检查风险管理文件确定，任何导致不可接受风险的损坏均构成失败。

NOTE See the compliance criteria in 15.3.1.
注：见15.3.1中的合规标准。

15.3.3 * Impact test
*冲击试验

ENCLOSURES of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable RISK.
医用电气设备的外壳应具有足够的抗冲击性，以防止不可接受的风险。

Compliance is checked by the following test.
通过以下试验检查合规性。

Except for HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are HAND-HELD, ENCLOSURES and other external insulating parts, the deterioration of which could result in unacceptable RISK, are tested as indicated below.
除手持式医用电气设备和手持医用电气设备部件外，外壳和其他外部绝缘部件（其劣化可能导致不可接受的风险）应按如下所示进行测试。

A sample consisting of the complete ENCLOSURE, or a portion thereof representing the largest unreinforced area, is supported in its normal position. A solid smooth steel ball, approximately
在其正常位置支撑由完整外壳或其代表最大未加固区域的一部分组成的样品。一个坚固光滑的钢球，大约

50 mm in diameter and with a mass of $500 \text{ g} \pm 25 \text{ g}$, is permitted to fall freely from a 1,3 m height once onto each relevant part of the test sample.
直径为50 mm, 质量为 $500 \text{ g} \pm 25 \text{ g}$, 允许从1.3 m高度自由落下一次, 落在试样的每个相关部分上。

To test vertical surfaces, the steel ball is suspended by a cord and allowed to swing like a pendulum in order to apply a horizontal impact, dropping through a vertical distance of 1,3 m once against each relevant part of the test sample.
为了测试垂直表面, 钢球由绳索悬挂, 并允许像摆锤一样摆动, 以施加水平冲击, 通过1.3 m的垂直距离落下, 一次落在试样的每个相关部分上。

The test is not applied to flat panel displays, to the platen glass of ME EQUIPMENT (for example film scanners), or to cathode ray tubes (see 9.5.2).
本试验不适用于平板显示器、医用电气设备的平板玻璃(例如胶片扫描仪)或阴极射线管(见9.5.2)。

After the test, any damage sustained that results in an unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE, constitutes a failure.
测试后, 通过检查风险管理文件确定, 任何导致不可接受风险的损坏均构成失败。

NOTE See the compliance criteria in 15.3.1.

注: 见15.3.1中的合规标准。

15.3.4 * Drop test

***跌落试验**

15.3.4.1 HAND-HELD ME EQUIPMENT

手持式医用电气设备

HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts that are HAND-HELD shall not result in an unacceptable RISK as a result of a free fall.

手持式医用电气设备、配件和医用电气设备零件不得因自由落体而导致不可接受的风险。

Compliance is checked by the following test.

通过以下试验检查合规性。

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part is used (as specified in the ACCOMPANYING DOCUMENTS), or from a height of 1 m, whichever is greater, onto a $50 \text{ mm} \pm 5 \text{ mm}$ thick hardwood board (hardwood $> 600 \text{ kg/m}^3$) lying flat on a concrete or a similar rigid base.
在任何安全工作负载就位的情况下, 允许待测样品从正常使用过程中遇到的三个不同启动方向中的每一个, 从医用电气设备、附件或医用电气设备部件的使用高度(如随附文件中的规定)或从1米的高度自由下落, 以较大者为准, 平放在混凝土或类似刚性基础上的 $50 \text{ mm} \pm 5 \text{ mm}$ 厚硬木板(硬木 $>600 \text{ kg/m}^3$)。

After the test, the HAND-HELD ME EQUIPMENT and, ACCESSORY or ME EQUIPMENT parts that are
试验后, 手持医用电气设备和附件或医用电气设备零件

HAND-HELD shall not result in an unacceptable RISK.

手持设备不应导致不可接受的风险。

15.3.4.2 * PORTABLE ME EQUIPMENT

***便携式医用电气设备**

PORTABLE ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts that are PORTABLE shall
便携式医用电气设备、附件和便携式医用电气设备部件应

withstand the stress caused by a free fall from the height indicated in Table 29 onto a hard surface.

承受从表29所示高度自由跌落至坚硬表面所产生的应力。

Compliance is checked by the following test.

通过以下试验检查合规性。

The sample to be tested, with the SAFE WORKING LOAD in place, is lifted to a height as indicated in Table 29 above a 50 mm $\pm$ 5 mm thick hardwood board (for example, 在安全工作荷载到位的情况下，将待测样品提升至表29所示的高度，高于50 mm $\pm$ 5 mm厚的硬木板（例如，

> 600 kg/m³) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board are at least those of the sample tested. The sample is dropped three times from each orientation in which it can be placed during NORMAL USE. >600 kg/m³），平放在混凝土地板或类似刚性基础上。电路板的尺寸至少是被测样品的尺寸。在正常使用过程中，样品从可放置的每个方向下落三次。

Table 29 – Drop height

表29——跌落高度

Mass (m) of PORTABLE ME EQUIPMENT 便携式医用电气设备的质量 (m) or its parts 或者它的部分 kg 公斤	Drop height 跌落高度 cm 厘米
m $\leq$ 10 10英里	5 5
10 < m $\leq$ 50 10<m $\leq$ 50	3 三
m > 50 米>50	2 2

After the test, any damage sustained that results in a unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE and inspection of the ME EQUIPMENT or the ME EQUIPMENT parts that are PORTABLE, constitutes a failure. 试验后，通过检查风险管理文件和检查医用电气设备或便携式医用电气设备部件，任何导致不可接受风险的损坏均构成故障。

NOTE See the compliance criteria in 15.3.1.

注：见15.3.1中的合规标准。

15.3.5 * Rough handling test *粗暴装卸试验

MOBILE ME EQUIPMENT and ME EQUIPMENT parts that are MOBILE shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable RISK.

移动式医用电气设备和移动式医用电气设备部件应能承受因粗暴搬运和移动而产生的应力，且不得导致不可接受的风险。

Compliance is checked by the following tests.
通过以下测试检查合规性。

The sample is tested in transport position with any SAFE WORKING LOAD in place and in the most adverse condition permitted in NORMAL USE. During the test, suitable precautions shall be taken to prevent over-balance caused by the rough handling stress/shock. 在运输位置对样品进行测试，并在正常使用中允许的最不利条件下使用任何安全工作负载。在试验过程中，应采取适当的预防措施，以防止粗暴搬运应力/冲击造成的过度平衡。

a) Ascending step shock 上步电击

The sample is pushed three times in its normal direction of travel at a speed of 0,4 0,8 m/s $\pm$ 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, against an ascending hardwood step obstruction with vertical a solid hardwood plane obstruction with a face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample need not go over the 40 mm obstruction. 以0,4 0,8 m/s $\pm$ 0,1 m/s的速度，或电机驱动移动式医用电气设备，以能够保持的最大速度，在其正常行驶方向上推动样品三次，在垂直上升的硬木台阶障碍物上，一个表面为40 mm的实心硬木平面障碍物，该障碍物牢固地连接到其他平坦的地板上。运动方向垂直于障碍物的表面。样品不必越过40毫米的障碍物。

b) Descending step shock 下降阶跃冲击

The sample is pushed three times in its normal direction of travel at a speed of 0,4 0,8 m/s $\pm$ 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, in order to fall over a vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step. 以0,4 0,8 m/s $\pm$ 0,1 m/s的速度，或电机驱动移动式医用电气设备，以能够保持的最大速度在其正常行驶方向上推动样品三次，以便从固定在刚性底座（如混凝土）上的40 mm高的垂直台阶上跌落。运动方向垂直于下降台阶的表面。

During performance of the descending step shock test, if a part other than the castor comes in contact with the obstruction before the castor touches the ground, the ME EQUIPMENT continues to be pushed until it has fully descended. 在进行下降阶跃冲击试验期间，如果脚轮接触地面之前，脚轮以外的部件接触到障碍物，则继续推动医用电气设备，直到其完全下降。

c) Door frame shock 门框减震器

The sample is moved three times in its normal direction of travel at a speed of 0,4 0,8 m/s $\pm$ 0,1 m/s, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the

vertical obstacle must be higher than the ME EQUIPMENT contact point(s). The direction of movement is perpendicular to the face of the obstacle.
以0,4 0,8 m/s $\pm$ 0,1 m/s的速度，或电机驱动移动式医用电气设备，在垂直刚性支架（如混凝土）上，以40 mm宽和厚的硬木垂直障碍物（如混凝土）在其正常行驶方向上移动三次。垂直障碍物的高度必须高于医用电气设备接触点。运动方向垂直于障碍物的表面。

After each test, any damage sustained that results in an unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE and inspection of the ME EQUIPMENT or the ME EQUIPMENT parts that are MOBILE, constitutes a failure.
每次试验后，通过检查风险管理文件和检查医用电气设备或移动式医用电气设备部件，任何导致不可接受风险的损坏均构成故障。

NOTE 1 See compliance criteria in 15.3.1.

注1见15.3.1中的合规标准。

NOTE 2 Instability of ME EQUIPMENT, when the ME EQUIPMENT remains undamaged from the rough handling shock/stress, is evaluated in accordance with 9.4.

注2：当医用电气设备未因粗暴操作冲击/应力而受损时，医用电气设备的不稳定性应根据第9.4节进行评估。

15.3.6 * Mould stress relief test

*模具应力消除试验

ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.
模制或成型热塑性材料外壳的构造应确保由于模塑或成型操作引起的内应力释放而导致的材料收缩或变形不会导致不可接受的风险。

Compliance is checked by inspection of the construction and available data were appropriate or by the following test.
通过检查结构和可用数据是否合适或通过以下试验检查合规性。

One sample consisting of the complete ME EQUIPMENT, or of the ENCLOSURE together with any supporting framework, is placed in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the ENCLOSURE during the test of 11.1.3, but not less than 70 °C, for a period of 7 h, then permitted to cool to room temperature.

将一个由完整的医用电气设备或外壳以及任何支撑框架组成的样品放置在循环空气烘箱中，温度高于11.1.3试验期间观察到的外壳最高温度10°C，但不低于70°C，持续7 h，然后冷却到室温。

NOTE Relative humidity need not be maintained at a specific value during this conditioning.

注：在此调节过程中，相对湿度不需要保持在特定值。

For large ME EQUIPMENT where it is not practical to condition a complete ENCLOSURE, it is permitted to use a portion of the ENCLOSURE representative of the complete assembly with regard to thickness and shape, including any mechanical support members. 对于大型医用电气设备，如果无法对整个外壳进行调节，则允许在厚度和形状方面使用代表完整组件的外壳的一部分，包括任何机械支撑构件。

Any damage that results in an unacceptable RISK constitutes a failure. 任何导致不可接受风险的损坏均构成故障。

15.3.7 * Environmental influences *环境影响

The selection and treatment of materials used in the construction of ME EQUIPMENT shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage. 医用电气设备施工中使用的材料的选择和处理应考虑预期用途、预期使用寿命以及运输和储存条件。

The ME EQUIPMENT shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of bacteria, plants, animals and the like, shall not reduce its mechanical properties in a way that results in an unacceptable RISK. See also 15.2. 医用电气设备的设计和制造应确保在其预期使用寿命期间，由于细菌、植物、动物等的影响而导致的任何腐蚀、老化、机械磨损或生物材料降解，不得以导致不可接受风险的方式降低其机械性能。另见15.2。

Compliance is checked by inspection:
通过检查检查合规性：

- of the ME EQUIPMENT, of the ACCOMPANYING DOCUMENTS and of the MANUFACTURER'S specifications of materials used and of the processing specifications for these materials; 医用电气设备、随附文件和制造商的所用材料的规格和这些材料的加工规范；
- of the MANUFACTURER'S relevant tests or calculations. 制造商的相关试验或计算。

15.4 ME EQUIPMENT components and general assembly 医用电气设备部件和总成

15.4.1 Construction of connectors 连接器构造

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where an unacceptable RISK would otherwise exist. In particular: 医用电气设备的电气、液压、气动和气体连接端子和连接器的设计和构造应确保，在存在不可接受风险的情况下，应防止不使用工具即可拆卸的可接近连接器的错误连接。特别地：

- a) Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result. 用于连接病人导线或病人电缆的插头的设计应确保它们不能连接到用于其他功能的同一医用电气设备上的其他插座，除非可以证明不会产生不可接受的风险。

Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE. 通过检查患者导线、患者电缆、连接器和插座来检查合规性，如果可以互换导线、电缆、

连接器或插座，则通过检查风险管理文件进行检查。

- b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

医用电气设备上用于正常使用的不同气体的医用气体接头不得互换。另见ISO 407[27]。

Compliance is checked by inspection of the RISK MANAGEMENT FILE all medical gas connectors.
通过检查所有医用气体连接器的风险管理文件来检查合规性。

15.4.2 Temperature and overload control devices **温度和过载控制装置**

15.4.2.1 Application **应用**

- a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use could result in lead to a HAZARDOUS SITUATION described in

如果热断路器和自动复位过电流脱扣器的使用可能导致中所述的危险情况，则不得在医用电气设备中使用

13.1 by such resetting.

13.1通过此类重置。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

通过检查设计文件和风险管理文件检查合规性。

- b) THERMAL CUT-OUTS with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.

医用电气设备中不得安装具有安全功能的热断路器，该断路器必须通过焊接操作复位，从而影响操作值。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

通过检查设计文件和风险管理文件检查合规性。

- c) In ME EQUIPMENT, where a failure of a THERMOSTAT could constitute lead to a HAZARD HAZARDOUS SITUATION described in 13.1, an independent non-SELF-RESETTING THERMAL CUT- OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device (THERMOSTAT) but shall be within the safe temperature limit for its the intended function of the ME EQUIPMENT .
在医用电气设备中，如果恒温器的故障可能导致13.1中所述的危险危险情况，则应另外提供一个独立的非自复位热断路器。附加装置的运行温度应在正常控制装置（恒温器）极限设置下可达到的温度范围外，但应在医用电气设备预期功能的安全温度范围内。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

通过检查设计文件和风险管理文件检查合规性。

- d) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVER- CURRENT RELEASE shall not result in a the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1.
由热切断或过电流释放操作引起的医用电气设备功能丧失不应导致基本性能损失或13.1中所述的任何危险情况。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

通过检查设计文件和风险管理文件检查合规性。

- e) Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.
医用电气设备的电容器或其他火花抑制装置不得连接在热断路器的触点之间。

Compliance is checked by inspection.

通过检查检查合规性。

- f) The use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE in the design shall not affect the safety of the ME EQUIPMENT.
在设计中使用热断路器或过电流脱扣器不得影响医用电气设备的安全性。

Compliance is checked by inspection and, if applicable, by the following tests.

通过检查和（如适用）以下试验检查合规性。

Verify compliance of positive temperature coefficient devices (PTC's) with IEC 60730-1: 19992010, clauses 15, 17, J.15 and J.17 as applicable.

验证正温度系数装置（PTC）是否符合IEC 60730-1:19992010第15、17、J.15和J.17条（如适用）。

THERMAL CUT-OUTS and OVER-CURRENT RELEASES are tested by operating the ME EQUIPMENT

通过操作医用电气设备来测试热断路器和过电流脱扣器
under the conditions described in Clause 13.

在第13条所述的条件下。

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES including circuits that perform equivalent functions (other than PTC's) are caused to operate 200 times unless approved to the appropriate IEC component standard.

自动复位热断路器和自复位过电流脱扣器（包括执行等效功能的电路（PTC除外）的电路）应运行200次，除非获得相应的IEC元件标准的批准。

Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES are caused to

operate 10 times, if they are not approved to the appropriate IEC component standard (see 4.5) or the MANUFACTURER has not provided adequate data to demonstrate the reliability of the component to perform its safety-related function. 如果手动复位热断路器和过电流脱扣器不符合相应的IEC部件标准（见4.5），或者制造商没有提供足够的数据来证明部件执行其安全相关功能的可靠性，则会导致它们运行10次。

Thermal protection devices can be tested separately from ME EQUIPMENT where engineering judgement indicates that doing so would not impact the test results. 热保护装置可与医用电气设备分开测试，工程判断表明这样做不会影响测试结果。

- g) ME EQUIPMENT that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable RISK shall not occur from overheating. 装有充液容器（具有加热设施）的医用电气设备应配备保护装置，以防止加热器在容器空的情况下打开时过热。过热不会产生不可接受的风险。

Compliance is checked by operating the relevant ME EQUIPMENT with an empty container until the protection device activates. 通过使用空容器操作相关医用电气设备，直到保护装置激活，来检查合规性。

- h) ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating. 包含管状加热元件的医用电气设备应具有防止两根引线过热的保护措施，因为与接地的导电连接可能导致过热。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE. 通过检查设计文件和风险管理文件检查合规性。

**15.4.2.2 Temperature
温度设置**

settings

Where means are provided for varying the temperature setting of THERMOSTATS in ME EQUIPMENT, the temperature setting shall be clearly indicated.
如果提供了改变恒温器温度设置的方法，医用电气设备，应清楚显示温度设置。

Compliance is checked by inspection.
通过检查检查合规性。

**15.4.3 *
*电池**

Batteries

**15.4.3.1 Housing
住房**

In ME EQUIPMENT, housings containing batteries from which gases that are likely to result in a HAZARD can escape during charging or discharging shall be ventilated to minimize the RISK of accumulation and ignition so that there is no unacceptable RISK from the accumulation of gases and possible ignition is prevented.
在医用电气设备中，装有电池的外壳（在充电或放电过程中可能导致危险的气体可能逸出）应通风，以将积聚和着火的风险降到最低，这样就不会出现不可接受的气体积聚风险，并防止可能的点火。

Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a the HAZARDOUS SITUATIONS described in 13.1.
医用电气设备的电池室应设计为防止电池意外短路，此类短路可能导致13.1中所述的危险情况。

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.
通过检查设计文件和风险管理文件检查合规性。

**15.4.3.2 Connection
连接**

If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, ME EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also 7.3.3 and 8.2.2.
如果错误连接或更换电池可能导致危险情况，医用电气设备应配备防止错误连接极性的装置。另见7.3.3和8.2.2。

Compliance is checked by inspection.
通过检查检查合规性。

**15.4.3.3 Protection against overcharging
防止过充电**

Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging.
如果医用电气设备的任何电池过度充电可能导致不可接受的风险，设计应防止过度充电。

Compliance is checked by inspection of the design documentation.
通过检查设计文件检查合规性。

**15.4.3.4 Lithium batteries
锂电池**

Lithium batteries used in ME EQUIPMENT that could become a HAZARD shall comply with the requirements of IEC 60086-4. See also 7.3.3.
医用电气设备中使用的可能构成危险的锂电池应符合IEC 60086-4的要求。另见7.3.3。

Primary lithium batteries shall comply with the requirements of IEC 60086-4. Secondary lithium batteries shall comply with the requirements of IEC 62133. See also 7.3.3.
锂电池应符合IEC-60086的要求。二次锂电池应符合IEC 62133的要求。另见7.3.3。

NOTE Batteries includes both single cells and assemblies of cells, i.e. battery packages.
注：电池包括单电池和电池组，即电池组。

Compliance is checked by inspection of the battery design documentation or by performance of the tests identified in IEC 60086-4 for primary lithium batteries and IEC 62133 for secondary lithium batteries.
通过检查电池设计文件或执行IEC 60086-4中规定的一次锂电池和IEC 62133中规定的二次锂电池测试的性能来检查合规性。

15.4.3.5 * Excessive current and voltage protection ***过电流、过电压保护**

An INTERNAL ELECTRICAL POWER SOURCE in ME EQUIPMENT shall be provided with an appropriately RATED device for protection against fire caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of a short circuit. Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow. Justification for omission of fuses or OVER-CURRENT RELEASES shall be included in the RISK MANAGEMENT FILE documented.
医用电气设备内的内部电源应配备适当额定值的装置，以防止因电流过大而引起的火灾，如果内部接线的横截面积和布局或连接部件的额定值可能在短路时引发火灾。保护装置应具有足够的断开能力，以中断可能流动的最大故障电流（包括短路电流）。遗漏保险丝或过电流释放的理由应包含在记录的风险管理文件中。

The short circuit test between the positive pole and the negative pole of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE

内部电源之间区域内内部电源正极和负极之间的短路测试

output contacts and the subsequent protection device may be omitted if two MEANS OF OPERATOR PROTECTION are provided. Alternatively, a short-circuit test shall not result in any of the HAZARDOUS SITUATIONS in 13.1.2. 如果提供两种操作员保护装置,则可以省略输出触点和后续保护装置。或者,短路试验不得导致13.1.2中的任何危险情况。

Compliance is checked by inspection for the presence of protective means, and if necessary, by inspection of the design documentation and the RISK MANAGEMENT FILE. Alternatively, conduct the short-circuit test and none of the HAZARDOUS SITUATIONS in 13.1.2 shall occur. 通过检查是否存在保护措施,以及如有必要,通过检查设计文件和风险管理文件来检查合规性。或者,进行短路试验,不得出现13.1.2中的任何危险情况。

15.4.4 * Indicators

15.4.4*指示器

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 除非从正常操作位置对操作员来说很明显,否则应提供指示灯,以指示医用电气设备已准备好正常使用。标记

7.4.1 is not sufficient for this purpose.

7.4.1不足以达到此目的。

If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light unless it is otherwise apparent to the OPERATOR from the normal operating position. 如果配备有待机状态或持续时间超过15秒的预热状态,医用电气设备应配备额外的指示灯,除非操作员从正常操作位置看到。

Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARDOUS SITUATION could exist unless it is otherwise apparent to the OPERATOR from the normal operating position. 如果可能存在危险情况,则应在装有非发光加热器的医用电气设备上提供指示灯,以指示加热器可运行,除非操作员从正常操作位置看到这一点。

NOTE This does not apply to heated stylus-pens for recording purposes.

注:这不适用于用于记录目的的加热笔。

Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a HAZARDOUS SITUATION. 医用电气设备上应提供指示灯,以指示输出电路意外或长时间运行可能构成危险情况的输出。

Colours of indicator lights are described in 7.8.1.

指示灯的颜色如7.8.1所述。

In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR.

在装有内部电源充电装置的医用电气设备中,充电模式应清楚地显示给操作员。

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

通过检查正常使用位置可见的指示装置的存在和功能来检查是否符合要求。

15.4.5 Pre-set 预设控制

controls

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the
适用时，制造商应在风险管理过程中解决
RISKS associated with pre-set controls.
与预设控制相关的风险。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

15.4.6 Actuating parts of controls of ME EQUIPMENT
医用电气设备控制装置的执行部件

15.4.6.1 Fixing, prevention of maladjustment
固定，防止失调

a) All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.
医用电气设备的所有驱动部件应固定，以便在正常使用期间不会被拔出或松脱。

b) Controls, the adjustment of which can result in a HAZARDOUS SITUATION for the PATIENT or OPERATOR while ME EQUIPMENT is in use, shall be so secured that the indication of any scale always corresponds with the position of the control.
当医用电气设备正在使用时，其调节可能会给病人或操作员带来危险的情况，应确保任何刻度的指示始终与控制装置的位置一致。

The indication in this case refers to “on” or “off” position, scale markings or other indications of position.
这种情况下的指示是指“开”或“关”位置、刻度标记或其他位置指示。

c) Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.
指示装置与相关部件的错误连接应通过适当的结构加以防止，前提是无需使用工具即可将其分离。

Compliance is checked by inspection and tests. For rotating controls, the torques as shown in Table 30 are applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test is repeated 10 times.
通过检查和试验检查是否符合要求。对于旋转控制装置，表30中所示的扭矩在控制旋钮和轴之间交替施加在每个方向上不少于2 s。试验重复10次。

A knob that rotates with respect to the shaft constitutes a failure.
相对于轴旋转的旋钮构成故障。

If an axial pull is required in NORMAL USE, compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.
如果在正常使用中需要轴向拉力，则通过对电气部件施加60 N的轴向力和对其他部件施加100 N的轴向力1 min来检查合规性。

Table 30 – Test torques for rotating controls
表30–旋转控制装置的试验扭矩

Gripping diameter (d) of control knob 控制旋钮夹持直径d mm a 嗯a	Torque 扭矩 Nm 海里
10 □ d < 23 10□d<23	1,0 1,0个
23 □ d < 31 23□d<31	2,0 2,0个
31 □ d < 41 31□d<41	3,0 3,0个
41 □ d < 56 41□d<56	4,0 4,0个
56 □ d □ 70 56□天□70	5,0 5,0分
d > 70 直径>70	6,0 6,0分
a The gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer). a夹持直径（d）是控制旋钮的最大宽度，无论其形状如何（例如带指针的控制旋钮）。	

15.4.6.2 Limitation of movement
移动限制

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME EQUIPMENT, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a HAZARDOUS SITUATION.
医用电气设备控制装置的旋转或可移动部件上应提供具有足够机械强度的止动装置，以防止受控参数从最大值到最小值的意外变化，或反之亦然，从而产生危险情况。

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table 30 are applied for not less than 2 s in each direction alternately. The test is repeated 10 times.
通过检查和手动测试检查合规性。对于旋转控制装置，表30中所示的扭矩在每个方向交替施加

不少于2 s。试验重复10次。

If an axial pull is likely to be applied to the rotating or movable parts of controls of ME EQUIPMENT in NORMAL USE, no unacceptable RISK shall develop there shall be no unexpected change of the controlled parameter.
如果在正常使用中，医用电气设备控制装置的旋转或可移动部件可能受到轴向拉力，则不应产生不可接受的风险，控制参数不得发生意外变化。

Compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.
通过对电气部件施加60 N的轴向力1 min，对其他部件施加100 N的轴向力来检查合规性。

15.4.7 Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4) 有线连接的手持式和脚踏式控制装置（另见8.10.4）

15.4.7.1 Mechanical strength **机械强度**

a) HAND-HELD control devices of ME EQUIPMENT shall comply with 15.3.4.1.
医用电气设备的手持控制装置应符合15.3.4.1的规定。

b) Foot-operated control devices of ME EQUIPMENT shall be able to support the weight of an adult human being.
医用电气设备的脚踏控制装置应能够支撑成人的重量。

Compliance is checked by application to the foot-operated control device, in its position of NORMAL USE, of an actuating force of 1 350 N for 1 min. The force is applied over an area of 30 mm diameter. There shall be no damage to the device resulting in an unacceptable RISK.
在正常使用位置，向脚操纵控制装置施加1350N的驱动力，持续1分钟，以检查其合规性。该力施加在直径为30mm的区域上。不得对设备造成不可接受风险的损坏。

15.4.7.2 Accidental operation of ME EQUIPMENT 医用电气设备意外操作

HAND-HELD and foot-operated control devices shall not result in an unacceptable RISK by changing their control setting when accidentally placed in an abnormal position.
手持式和脚踏式控制装置不应因意外放置在异常位置时改变其控制设置而导致不可接受的风险。

Compliance is checked by turning the control device in all possible abnormal positions and placing it on a flat surface. Any inadvertent change of control setting resulting in an unacceptable RISK constitutes a failure.
通过在所有可能的异常位置转动控制装置并将其放在平坦的表面上来检查其合规性。任何导致不可接受风险的控制设置的无意更改均构成故障。

15.4.7.3 * Entry of liquids *液体进入

- a) Foot-operated control devices of ME EQUIPMENT shall be at least IPX1 according to IEC 60529.

根据IEC 60529, 医用电气设备的脚踏控制装置应至少为IPX1。

Compliance is checked by the tests of IEC 60529.
符合性通过IEC 60529的试验进行检查。

- b) In ME EQUIPMENT, ENCLOSURES of foot operated control devices used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529 if they are intended for NORMAL USE in areas where liquids are likely to be found (such as emergency rooms and operating theatres). The probability of occurrence shall be estimated as part of the RISK MANAGEMENT PROCESS.
在医用电气设备中, 用于急诊室或手术室等区域的脚踏式控制装置外壳, 如果其用于可能存在液体的区域, 则应根据IEC 60529将其至少分类为IPX6发现 (如急诊室和手术室)。发生概率应作为风险管理过程的一部分进行估算。

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS, the design documentation, the RISK MANAGEMENT FILE and by performing the appropriate tests of IEC 60529.
通过检查随附文件、设计文件、风险管理文件以及执行IEC 60529中的相应测试来确定合规性。

15.4.8 Internal wiring of ME EQUIPMENT 医用电气设备内部接线

Aluminium wires of less than 16 mm² cross-section shall not be used in ME EQUIPMENT.
医用电气设备不得使用横截面小于16 mm²的铝线。

Compliance is checked by inspection.
通过检查检查合规性。

15.4.9 Oil containers 油罐

- a) Oil containers in PORTABLE ME EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.
便携式医用电气设备中的油箱应充分密封, 以防止任何位置的油流失。容器设计应考虑到油的膨胀。

- b) Oil containers in MOBILE ME EQUIPMENT shall be sealed to prevent the loss of oil

during transport but may be fitted with a pressure-release device that can operate during NORMAL USE.

移动式医用电气设备中的油箱应密封，以防止在运输过程中发生油的损失，但可以安装一个可以在正常使用期间操作的压力释放装置。

- c) Partially sealed oil-filled ME EQUIPMENT or its parts shall be provided with means for checking the oil level so that leakage can be detected (see 7.9.3.1).

部分密封充油医用电气设备或其部件应配备检查油位的装置，以便能够检测到泄漏（见 7.9.3.1）。

Compliance is checked by inspection of the ME EQUIPMENT, the technical description, and by manual test.

通过检查医用电气设备、技术说明和手动测试来检查符合性。

15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

*医用电气设备的电源变压器和按照8.5提供隔离的变压器

15.5.1 Overheating
过热

15.5.1.1 * Transformers
*变压器

Transformers of ME EQUIPMENT shall be protected against overheating in the event of short circuit or overload of any output winding.

医用电气设备的变压器应在任何输出绕组短路或过载的情况下防止过热。

Compliance is checked by the tests of 15.5.1.2 and 15.5.1.3 as appropriate under the following conditions.

在下列条件下，通过15.5.1.2和15.5.1.3中的试验检查是否符合要求。

Each winding is tested, in turn, with the following parameters at the most adverse value:
依次用以下参数在最不利值下测试每个绕组：

- primary voltage maintained between 90 % to 110 % of RATED voltage
一次电压保持在额定电压的90%至110%之间
- RATED input frequency
额定输入频率
- loads on other windings between no load and their NORMAL USE load
其他绕组在空载和正常使用负载之间的负载

Short circuit or resistive load, as appropriate, is applied at the ends of the windings or at the first point that can be short circuited under SINGLE FAULT CONDITION.
短路或电阻负载，视情况而定，施加在绕组末端或在单一故障条件下可短路的第一个点。

Components intended to prevent overheating of the transformer during short circuit and overload conditions are included as part of the tests of 15.5.1.2 and 15.5.1.3 provided that it is unlikely that a short circuit or overload condition could arise for which they would not provide protection. Failure of such circuits to provide protection are considered unlikely to occur where insulation (including spacing) is equal to at least one MEANS OF OPERATOR PROTECTION as defined in Clause 8 and COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS
在短路和过载条件下，用于防止变压器过热的部件包括在15.5.1.2和15.5.1.3的试验中，前提是不太可能出现短路或过载情况，而这些部件不能提供保护。如果绝缘（包括间距）等于第8条中定义的至少一种操作员保护方法和具有高完整性特征的部件，则认为此类电路不太可能发生保护失效
are used.:
使用：

- the component is one with high-integrity characteristics, and
该组件具有高完整性特征，并且
- two MEANS OF OPERATOR PROTECTION are provided between the output contacts of the transformer up to the COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.
在变压器的输出触点与具有高完整性特性的部件之间提供了两种操作员保护装置。

During the tests, no winding are to open, no HAZARDOUS SITUATION occurs, and the maximum temperatures of windings are not to exceed the values in Table 31. After the short circuit and overload tests, the transformer is to pass the dielectric strength test (as described in 8.8.3) between primary and secondary windings, between the primary windings and the frame and between the secondary windings and the frame. The tests are performed under the conditions specified in 11.1, either in the ME EQUIPMENT or under simulated conditions on the bench.
试验期间，不得打开绕组，不得出现危险情况，且绕组的最高温度不得超过表31中的值。短路和过载试验后，变压器应通过一次绕组和二次绕组之间、一次绕组和框架之间以及二次绕组和框架之间的介电强度试验（如8.8.3所述）。在11.1中规定的条件下，在医用电气设备中或在试验台上的模拟条件下进行试验。

Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 □C (± 5 □C) ambient temperature
表31-环境温度为25°C (±5°C) 下的过载和短路条件下变压器绕组的最大允许温度

Part s 部分	Maximum temperature 最高温度 □ C 摄氏

	度
Windings and core laminations in contact therewith, if the winding insulation is: 如果绕组绝缘为:	
– of Class A material –A级材料	15 0 15 0
– of Class B material –B类材料	17 5 17 5
– of Class E material –E类材料	16 5 16 5
– of Class F material –F类材料	19 0 19 0
– of Class H material –H类材料	21 0 21 0

15.5.1.2 Short-circuit test
短路试验

The output winding under test is short circuited. The test is continued until the protective device operates or THERMAL STABILITY is achieved. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2 a) or the 2X frequency and 2X voltage test of 15.5.2 b), the short circuit is applied directly across the output windings.

被测输出绕组短路。试验继续进行，直到保护装置运行或达到热稳定性。对于未按照15.5.2 a)中的5X频率和5X电压测试或15.5.2 b), 短路直接施加在输出绕组上。

15.5.1.3 Overload test
15.5.1.3过载试验

Windings with more than one protective device could require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.

带有多个保护装置的绕组可能需要多次过载试验，以充分评估最坏情况下的正常使用负载和熔断。

The overload test may be applied after rectification.

整改后可进行过载试验。

If the short-circuit test is completed without operation of a protective device (such as a current limiting circuit), the overload test is not required.

如果短路试验在没有保护装置（例如限流电路）的情况下完成，则不需要进行过载试验。

- a) This test (a) is performed if the current at which the protective device operates cannot be determined based on a review of the provided protective devices and their performance data; otherwise test b) is performed.
如果根据对所提供的保护装置及其性能数据的审查无法确定保护装置的工作电流，则进行本试验（a）； 否则进行试验b）。

The winding under test is loaded to its NORMAL USE load until THERMAL STABILITY is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates. Each adjustment of the load is followed by a sufficient time to reach THERMAL STABILITY, and the load current and temperature are to be noted.
将被测绕组加载到其正常使用负载，直到达到热稳定性。然后，逐步调整保护装置在最小负荷下运行的电流。每次调整负载后，都要有足够的时间达到热稳定性，并注意负载电流和温度。

Following operation of a protective device, b) is performed.
在保护装置动作后，b）被执行。

- b) If the protective device that operated in a) is external to the transformer, it is shunted. The winding under test is loaded based on the type of protective device as follows.
如果在a）中操作的保护装置在变压器外部，则将其分流。受试绕组根据以下保护装置类型进行加载。

- Fuse in accordance with IEC 60127-1:
符合IEC 60127-1的保险丝：
30 min at the appropriate test current determined from Table 32.
在表32确定的适当试验电流下30分钟。

Table 32 – Test current for transformers
表32-变压器试验电流

Marked value of RATED current (I) of protecting fuse-link 保护熔断体额定电流 (I) 标记值 A A	Ratio between test current and RATED current of the fuse-link 试验电流与额定电流之比 fuse-link 熔断器
I □ 4 四号州际公路	2,1 2, 1
4 < I □ 10 4<10	1,9 1,9个
10 < I □ 25 10<25	1,75 1,75个
I > 25 I>25	1,6 1,6个

- Fuses not in accordance with IEC 60127-1:
不符合IEC 60127-1:
30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.
30分钟，根据保险丝制造商提供的特性，特别是30分钟的清除时间电流。如果没有30

分钟的清除时间电流数据可用，则使用表32中的试验电流，直到达到热稳定性。

- Other protective device:
其他保护装置:

until THERMAL STABILITY at a current just below that which caused the device to operate in a).
直到热稳定性在电流略低于导致装置在a)下工作的电流。

This portion of the overload test is concluded at the specified time or when a second protective device opens.
过载试验的这一部分在规定时间或第二个保护装置打开时结束。

15.5.2 * Dielectric strength *介电强度

This subclause is not applicable to transformers operating at a frequency above 1 kHz, which are tested in accordance with 8.8.3.
本款不适用于按照8.8.3进行试验的频率高于1 kHz的变压器。

ME EQUIPMENT transformer windings shall have adequate insulation to prevent internal short-circuits that could cause overheating where such overheating could result in a HAZARDOUS SITUATION.

医用电气设备变压器绕组应具有足够的绝缘，以防止内部短路导致过热，而过热可能导致危险情况。

The dielectric strength of the electrical insulation between turns and layers of each winding of a transformer of ME EQUIPMENT where failure of the transformer could result in a HAZARDOUS SITUATION shall be such that after the humidity preconditioning treatment (see 5.7) it passes the following tests.

医用电气设备变压器各绕组匝间和各层之间的电绝缘介电强度（变压器故障可能导致危险情况）应确保在经过湿度预处理（见5.7）后，通过以下试验。

- a) Transformer windings having a RATED voltage □ 500 V or RATED frequency □ 60 Hz are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five times the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).
额定电压□500 V或额定频率□60 Hz的变压器绕组在绕组上的电压为额定电压的5倍或绕组额定电压范围上限的5倍，频率不低于额定频率的5倍（其中额定频率为正常值变压器输入电压的工作频率）。
- b) Transformer windings having a RATED voltage exceeding 500 V or RATED frequency exceeding 60 Hz are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).
额定电压超过500V或额定频率超过60Hz的变压器绕组，在该绕组上的电压为额定电压的两倍或该绕组额定电压范围上限的两倍，频率不低于额定频率的两倍（其中额定频率为正常运行变压器输入电压的频率）。

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer is to be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the test voltage specified in Table 6, for one MEANS OF PROTECTION, if the RATED voltage of such a winding is considered as the WORKING VOLTAGE. If this should occur, the test voltage on the primary winding is reduced accordingly. The test frequency can be adapted to produce in the core approximately the magnetic induction present in NORMAL USE. Where the core of the transformer is isolated from all external conductive connections (such as in most toroidal transformers), connections to the core described below may be omitted.
然而，在上述两种情况下，变压器任何绕组的匝间和绝缘层上的应力应确保在最高额定电压的绕组上出现的试验电压不超过表6中规定的试验电压，对于一种保护方式，如果这种绕组的额定电压被认为是工作电压。如果发生这种情况，一次绕组上的试验电压将相应降低。测试频率可以调整，以在磁芯中产生近似于正常使用中存在的磁感应强度。如果变压器的铁芯与所有外部导电连接（例如在大多数环形变压器中）隔离，则可以省略与下述铁芯的连接。

- Three-phase transformers can be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.
三相变压器可通过三相试验装置进行试验，或采用单相试验装置进行三次连续试验。
- The value of the test voltage with respect to the core and to any screen between primary and secondary windings is in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.
铁芯和一次绕组和二次绕组之间任何屏蔽的试验电压值应符合相关变压器的规范。如果一次绕组有一个确定的电源干线中性点的连接点，则该连接点应连接到铁芯（如果存在屏蔽层），除非规定将铁芯（和屏蔽层）连接到电路的未接地部分。为了模拟这一点，核心（和屏幕）被连接到一个电源与一个适当的电压和频率相对于确定的连接点。

If such a connection point has not been identified, each side of the primary winding in turn is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.
如果没有确定这种连接点，则一次绕组的每侧依次连接到铁芯（如果存在屏蔽层），除非规定将铁芯（和屏蔽层）连接到电路的未接地部分。

To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

为了模拟这一点，磁芯（和屏蔽）依次连接到一次绕组每侧具有适当电压和频率的电源。

- During the test, all windings not intended for connection to the SUPPLY MAINS are left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a point nearly at earth potential are to have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit. 在试验过程中，所有不用于连接电源的绕组都保持空载（开路）。拟在某一点接地或在接近接地电位的点上运行的绕组，应将该点连接至铁芯，除非该铁芯指定用于连接电路的未接地部分。

To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings. 为了模拟这一点，铁心连接到一个电源上，该电源的电压和频率与绕组有关。

- Initially not more than half the prescribed voltage is applied, then, it is raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage is reduced gradually and switched off. 最初施加的电压不超过规定电压的一半，然后在10 s内升高至最大值，然后保持1 min，之后逐渐降低电压并关闭。
- Tests are not conducted at resonant frequencies.

Compliance is checked by the following:

不在共振频率下进行试验。通过以下方式检查合规性：

During the test, any flashover or breakdown of any part of the insulation constitutes a failure. There is to be no detectable deterioration of the transformer after the test. 在试验过程中，绝缘任何部分的闪络或击穿均构成故障。试验后，变压器不得出现可检测的劣化。

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the WORKING VOLTAGE and that the discharges do not provoke a drop in test voltage. 忽略轻微电晕放电，前提是当试验电压暂时降至较低值时停止，该值高于工作电压，且放电不会引起试验电压下降。

15.5.3 * Construction of transformers used to provide separation as required by 8.5

*按照8.5的要求建造用于提供隔离的变压器

Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply with IEC 61558-1:1997, Subclause 5.12. the following:

构成8.5要求的保护装置的医用电气设备的变压器应符合IEC 61558-1:1997第5.12款的要求。以下内容:

- Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.
应提供防止端部匝间位移超过绕组间绝缘的方法。
- If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.
如果保护接地屏蔽只有一圈, 则其绝缘重叠应不小于3mm。筛网的宽度应至少等于一次绕组的轴向绕组长度。
- The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for two MEANS OF PROTECTION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding.
环形变压器内部绕组的电线出口应配备双套管, 符合两种保护方式的要求, 总壁厚至少为0.3mm, 在绕组外延伸至少20mm。
- The insulation between primary and secondary windings shall comply with 8.8.2.
一次绕组和二次绕组之间的绝缘应符合8.8.2的规定。
- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.4 with the following exceptions:
爬电距离和空气间隙应符合8.9.4的规定, 但以下情况除外:
 - Enamelled or lacquered winding wires are considered as contributing 1 mm each to the CREEPAGE DISTANCES specified in 8.9.4 for MEANS OF PATIENT PROTECTION.
对于8.9.4中规定的用于保护患者的爬电距离, 漆包或漆包绕组线各有1 mm。
 - CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:
爬电距离是通过绝缘屏障两部分之间的接头测量的, 除非:
 - either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;
形成接头的两个零件在重要位置通过热密封或其他类似方式粘合;
 - or
或
 - the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.
接头在必要的位置完全用粘合剂填充, 粘合剂粘合在绝缘屏障的表面上, 这样湿气就不会被吸入接头中。
 - CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages U not exceeding 250 V and increased proportionally for higher reference voltages.
如果可以证明不存在气泡, 并且在参考电压U不超过250 V时, 搪瓷或涂漆一次绕组和二次绕组之间的绝缘厚度至少为1 mm, 并且对于更高的参考电压, 则认为模制变压器内的爬电距离不存在。

Compliance is checked as specified in IEC 61558-1.

按照IEC 61558-1的规定检查合规性。

Compliance is checked by inspection of the transformer construction and measurement of required distances.

通过检查变压器结构和测量所需距离来检查合规性。

16 * ME SYSTEMS

*ME系统

16.1 * General requirements for the ME SYSTEMS

*医用电气系统的一般要求

After installation or subsequent modification, an ME SYSTEM shall not result in an unacceptable
安装或后续修改后，医用电气系统不得导致不合格

RISK.

风险。

Only HAZARDS arising from combining various equipment to constitute an ME SYSTEM shall be
considered.

仅应考虑将各种设备组合在一起构成医用电气系统的危险。

NOTE RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME
SYSTEMS and modifications during the actual service life require evaluation to the
requirements of this standard.

注：提醒责任机构，医用电气系统的装配和实际使用寿命期间的修改需要对本标准的要求进行评估。

An ME SYSTEM shall provide:

医用电气系统应提供：

- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT
complying with this standard; and
在患者环境中，与符合本标准的医用电气设备相当的安全水平；以及
- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment
complying with their respective IEC or ISO safety standards.
在患者环境外，安全等级相当于符合各自IEC或ISO安全标准的设备。

Tests shall be performed:

应进行以下试验：

- in NORMAL CONDITION unless otherwise specified, and
正常情况下，除非另有规定，以及
- under the operating conditions specified by the MANUFACTURER of the ME SYSTEM.
在医用电气系统制造商规定的操作条件下。

Safety tests that have already been performed on individual equipment of the ME SYSTEM
已经对医用电气系统的单个设备进行的安全测试
according to relevant standards shall not be repeated.
按相关标准不得重复。

The MANUFACTURER of an ME SYSTEM that is (re)configurable by the RESPONSIBLE ORGANIZATION or OPERATOR may use RISK MANAGEMENT methods to determine which configurations constitute the highest RISKS and which measures are needed to ensure that the ME SYSTEM in any possible configuration does not present an unacceptable RISK.
可由责任组织或操作员（重新）配置的医用电气系统的制造商可使用风险管理方法来确定哪些配置构成最高风险，以及需要采取哪些措施来确保任何可能配置中的医用电气系统不存在不可接受的风险。

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC or ISO safety standards that are relevant to that equipment.
在医用电气系统中使用的非医用电气设备应符合与该设备相关的IEC或ISO安全标准。

Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.
医用电气系统中不得使用仅依靠基本绝缘的电击防护设备。

Compliance is checked by inspection of appropriate documents or certificates.
通过检查适当的文件或证书来检查合规性。

16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM

*医用电气系统随附文件

An ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for the ME SYSTEM to be used as intended by the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.
医用电气系统（包括改装后的医用电气系统）应随附文件，其中包含制造商预期使用的医用电气系统所需的所有数据，以及责任机构可参考的地址。随附文件应视为医用电气系统的一部分。

NOTE ACCOMPANYING DOCUMENTS can be provided electronically, e.g. electronic file format or CD-ROM, for an

注：随附文件可以以电子方式提供，例如电子文件格式或CD-ROM
ME SYSTEM capable of displaying or printing those documents.
能够显示或打印这些文件的ME系统。

These documents shall include:
这些文件应包括：

- a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT that is provided by the
由
MANUFACTURER (see 7.8.2);
制造商（见7.8.2）；
- b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT that is provided by the
由
MANUFACTURER;

制造商；

c) the

following

information:

以下信息：

- the specification of the ME SYSTEM, including the use as intended by the MANUFACTURER
医用电气系统规范，包括制造商预期的用途
and a listing of all of the items forming the ME SYSTEM;
以及构成ME系统的所有项目的清单；
- instructions for the installation, assembly and modification of the ME SYSTEM to
ensure continued compliance with this standard;
医用电气系统的安装、装配和修改说明，以确保持续符合本标准；
- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of
equipment or equipment part forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);
医用电气系统各设备或设备部件的清洁和消毒说明（如适用）（见11.6.6和11.6.7）；
- additional safety measures that should be applied, during installation of the ME SYSTEM;
医用电气系统安装期间应采取的附加安全措施；
- which parts of the ME SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
医用电气系统的哪些部分适合在患者环境中使用；
- additional measures that should be applied during preventive maintenance;
预防性维护期间应采取的其他措施；
- if a MULTIPLE SOCKET-OUTLET is present and it is a separate item, a warning that
it shall not be placed on the floor;
如果有多个插座，并且是一个单独的项目，则警告不要将其放置在地板上；
- a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not
be connected to the ME SYSTEM;
警告：不得将额外的多个插座或延长线连接至医用电气系统；
- a warning to connect only items that have been specified as part of the ME SYSTEM
or that have been specified as being compatible with the ME SYSTEM;
仅连接指定为医用电气系统一部分或与医用电气系统兼容的物品的警告；
- the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the
与之一起使用的任何多个插座的最大允许负载
ME SYSTEM;
医用电气系统；
- an instruction that MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM
shall only be used for supplying power to equipment that is intended to form part of
the ME SYSTEM;
医用电气系统配备的多个插座只能用于为医用电气系统组成部分的设备供电的说明；

- an explanation of the RISKS of connecting non-ME EQUIPMENT that has been supplied as a part of the ME SYSTEM directly to the wall outlet when the non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer;
当非医用电气设备拟通过带隔离变压器的多个插座供电时，将作为医用电气系统一部分供应的非医用电气设备直接连接到墙上插座的风险说明；
- an explanation of the RISKS of connecting any equipment that has not been supplied as a part of the ME SYSTEM to the MULTIPLE SOCKET-OUTLET;
说明将未作为医用电气系统一部分提供的任何设备连接到多个插座的风险；
- the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and
医用电气系统的允许使用环境条件，包括运输和储存条件；以及
- instructions to the OPERATOR not to touch parts referred to in 16.4 and the PATIENT simultaneously.
操作人员不得接触16.4中提到的部件和患者的指示同时。

d) advice to the RESPONSIBLE ORGANIZATION:

对责任组织的建议：

- to carry out all adjustment cleaning, sterilization and disinfection PROCEDURES specified therein; and
执行其中规定的所有调整清洁、灭菌和消毒程序；以及
- that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.
医用电气系统的装配和实际使用寿命期间的修改需要对本标准的要求进行评估。

Compliance is checked by inspection.

通过检查检查合规性。

16.3 * Power supply

*电源

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.10.1, 5.5 f) and 7.9.2.3). See also Figure F.5.
如果医用电气设备拟从医用电气系统中的其他设备接收电源，则使用说明书应充分说明其他设备，以确保符合本标准（见4.10.1、5.5 f）和7.9.2.3的要求。另见图F.5。

If an ME SYSTEM:

如果ME系统：

- is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and
旨在从隔离电源（IPS）或不间断电源（UPS）接收电源，以及
- the ME SYSTEM can draw large transient currents when being switching on or off or when operating,
医用电气设备系统在接通或断开或运行时会产生较大的瞬态电流，

the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.

制造商应根据提供医用电气系统的IPS或UPS规范，将此类瞬态电流限制在允许的水平。

If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.

如果未规定IPS或UPS，则应在技术说明和任何安装说明中披露实际瞬态电流水平。

Compliance is checked by inspection.
通过检查检查合规性。

16.4 ENCLOSURES

外壳

Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that can be contacted by the OPERATOR during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a TOOL shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION (see 8.5.1).
患者环境中的非医用电气设备，在拆除盖子、连接器等之后，在日常维护、校准等过程中，无需使用工具即可接触到的非医用电气设备部件，其工作电压应不超过8.4.2 c)中规定的电压，该电压由与电源分离的电源供电采用两种操作员保护方式（见8.5.1）。

Compliance is checked by inspection.
通过检查检查合规性。

16.5 * SEPARATION DEVICES

*分离装置

When FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then safety measures incorporating a SEPARATION DEVICE shall be applied.
当医用电气设备与医用电气系统或其他系统的其他设备之间的功能连接可能导致泄漏电流超过允许值时，应采取包括隔离装置的安全措施。

The SEPARATION DEVICE shall have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.
隔离装置应具有介电强度、爬电距离和空气间隙，以适用于故障条件下隔离装置上出现的最高电压的一种操作员保护方式。

The WORKING VOLTAGE shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the MAXIMUM MAINS VOLTAGE.
工作电压应为故障条件下隔离装置的最高电压，但不得低于最大电源电压。

NOTE 1 For CLASS I equipment, potential differences can occur between the protective earth of the ME EQUIPMENT

I类保护设备之间可能出现电位差

and the protective earth of other parts of the ME SYSTEM in the absence of a common protective earth.
以及医用电气系统其他部分的保护接地（在没有共用保护接地的情况下）。

NOTE 2 Situations that can require a SEPARATION DEVICE include FUNCTIONAL CONNECTIONS to an emergency calling system or a data processing system.

注2：可能需要分离装置的情况包括与紧急呼叫系统或数据处理系统的功能连接。

Compliance is checked by the tests in 8.8 and 8.9.

通过8.8和8.9中的试验检查合规性。

16.6 * LEAKAGE CURRENTS

*泄漏电流

16.6.1 TOUCH CURRENT

接触电流

In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 □A.

在正常情况下，来自医用电气系统各部分的接触电流

PATIENT ENVIRONMENT shall not exceed 100 □A.
病人环境不应超过100μA。

In the event of the interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, the TOUCH CURRENT from or between parts of an ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 500 □A.

如果任何非永久性安装的保护接地导体中断，来自患者环境中医用电气系统各部分之间的接触电流不得超过500μA。

NOTE For the purposes of this clause, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be TOUCH CURRENT.

注：在本条中，设备可触及外表面的泄漏电流也被视为接触电流。

16.6.2 EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET

多插座对地漏电电流

If the ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 5 mA.

如果医用电气系统或医用电气系统的一部分由多个插座供电，则多个插座的保护接地导体中的电流不得超过5 mA。

16.6.3 * PATIENT LEAKAGE CURRENT

*病人漏电流

The PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL

医用电气系统正常情况下的病人漏电流和病人总漏电流

CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 3 and Table 4 (see also 8.7.3 and 16.1).

条件不得超过医用电气设备的规定值，如表3和表4所示（另见8.7.3和16.1）。

The total PATIENT LEAKAGE CURRENT may be measured at installation.

病人总漏电流可在安装时测量。

Compliance with the requirements of 16.6.1, 16.6.2 and 16.6.3 is checked by inspection and measurement using a measuring device as specified in 8.7.4.4.

通过使用8.7.4.4中规定的测量装置进行检查和测量，检查是否符合16.6.1、16.6.2和16.6.3的要求。

16.6.4 Measurements

测量

16.6.4.1 General conditions for ME SYSTEMS

医用电气系统通用条件

- a) The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT, the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT of any MULTIPLE SOCKET-OUTLET are measured after the ME SYSTEM has been brought up to operating temperature as follows:
在医用电气系统达到工作温度后，测量任何多个插座的接触电流、病人漏电电流、病人总漏电电流和总对地漏电电流，如下所示：

The ME SYSTEM is operated:

医用电气系统操作：

- For ME SYSTEMS intended for non-CONTINUOUS OPERATION;
用于非连续运行的医用电气系统；

After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME SYSTEM is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for seven hours, whichever is shorter. The “on” and “off” periods for each cycle are the RATED “on” and “off” periods;

在待机/静态模式下运行直到达到热稳定性后，医用电气系统在连续循环中正常使用，直到再次达到热稳定性，或持续7小时，以较短者为准。每个循环的“开”和“关”期是额定的“开”和“关”期；

- For ME SYSTEMS intended for CONTINUOUS OPERATION;
对于ME，用于连续运行的系统；

The ME SYSTEM is operated until THERMAL STABILITY is reached.

ME系统将一直运行，直到达到热稳定性。

- b) The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION, prior to its clinical use, the ME SYSTEM is connected to the local SUPPLY MAINS. 医用电气设备系统连接到一个电压等于最高额定电源电压的电源。当医用电气系统的特性只有在责任机构现场安装后才能正确测量时，在临床使用前，医用电气系统应连接到当地的电源干线。

NOTE Where examination of the circuit arrangement and the arrangement of components and material of the

注意检查电路布置、部件和材料的布置

ME SYSTEM shows no possibility of any HAZARD, the number of tests could be reduced.

医用电气系统显示没有任何危险的可能性，可以减少试验次数。

16.6.4.2 Connection of the ME SYSTEM to the measuring supply circuit **医用电气系统与测量电源电路的连接**

a) The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS.
医用电气系统根据其随附文件组装后进行测试。

b) Measuring arrangement
测量装置

If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME SYSTEMS), the reference earth of the measuring circuits is connected to the protective earth of the SUPPLY MAINS.

如果不使用隔离变压器测量泄漏电流（例如，在测量非常高输入功率ME系统的泄漏电流时），则测量电路的参考接地连接至电源干线的保护接地。

NOTE 1 It is recommended to position the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following subclauses) to avoid placing the ME SYSTEM on or near a large earthed metal surface.
注1: 建议将测量电路放置在离未屏蔽电源线尽可能远的地方，并且（除非以下子条款中另有规定），以避免将医用电气系统放置在大型接地金属表面上或附近。

NOTE 2 However, APPLIED PARTS, including PATIENT cables (when present), should be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

注2: 但是，应用部件，包括病人电缆（如有）应放置在介电常数约为1（例如，发泡聚苯乙烯）的绝缘表面上，并高于接地金属表面约200 mm。

16.7 * Protection against MECHANICAL HAZARDS ***机械危险防护**

If a MECHANICAL HAZARD exists, the ME SYSTEM shall comply with the applicable requirements of Clause 9.

如果存在机械危险，医用电气系统应符合第9条的适用要求。

Compliance is checked by inspection or applicable tests.
通过检查或适用的试验来检查符合性。

16.8 Interruption of the power supply to parts of an ME SYSTEM **医用电气系统部分电源中断**

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in a HAZARDOUS SITUATION other than interruption of its intended function the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.
医用电气系统的设计应确保整个医用电气系统或医用电气系统任何部分的电源中断和恢复不会导致除预期功能中断、基本安全或基本性能损失以外的危险情况。

Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously.

通过中断和恢复相关电源连接（一次一个，同时所有连接）来检查合规性。

16.9 ME SYSTEM connections and wiring **医用电气系统连接和接线**

16.9.1 Connection terminals and connectors **接线端子和连接器**

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a HAZARDOUS SITUATION could otherwise exist. unless it can be proven that no unacceptable RISK can result. In particular:
电气、液压、气动和气体连接端子和连接器的设计和构造应确保在可能存在危险情况的情况下，防止不使用工具即可拆卸的可接近连接器的错误连接。除非能够证明不会产生不可接受的风险。特别地：

- Connectors shall comply with 15.4.1.
连接器应符合15.4.1的规定。
- Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT unless it can be proved that no HAZARDOUS SITUATION unacceptable RISK can result.
用于连接患者导线或患者电缆的插头应设计成，除非能够证明不会造成危险情况，否则不得连接到可能位于患者环境中的同一医用电气系统的其他插座。

Compliance is checked by inspection and, if possible, by interchanging connectors of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.
合规性通过检查进行检查，如果可能的话，通过互换患者导线、患者电缆、连接器和插座的连接器，如果可以互换导线、电缆、连接器或插座，则通过检查风险管理文件来检查合规性。

- Medical gas connections on the ME SYSTEM for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].
医用电气系统上用于正常使用的不同气体的医用气体连接不得互换。另见ISO 407[27]。

Compliance is checked by inspection of all medical gas connections.
通过检查所有医用气体接头来检查合规性。

16.9.2 MAINS PARTS, components and layout 电源部件、组件和布局

16.9.2.1 * MULTIPLE SOCKET-OUTLET *多插座

a) A MULTIPLE SOCKET-OUTLET shall: 多个插座应：

- only allow connection by using a TOOL (see Figure I.1), or
仅允许使用工具进行连接（见图I.1），或
- be of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or
不能接受IEC/TR 60083中规定的任何类型的电源插头，或
- be supplied via a separating transformer (see 16.9.2.1 d) and Annex I).
通过隔离变压器供电（见16.9.2.1 d）和附录I）。

Compliance is checked by inspection.
通过检查检查合规性。

b) A MULTIPLE SOCKET-OUTLET: 多插座：

- shall be marked with safety sign ISO 7010-W 001 (see Table D.2, safety sign 2) such that it is visible in NORMAL USE; and:
应标有安全标志ISO 7010-W 001（见表D.2，安全标志2），以便在正常使用中可见；以及：
- shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or
应单独或组合标记最大允许连续输出电流（安培或伏安），或
- shall be marked to indicate which equipment or equipment parts may be safely attached.
应标明哪些设备或设备部件可以安全连接。

– may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT. NOTE Each outlet does not have to be marked.

可能是医用电气设备或非医用电气设备的一个单独项目或组成部分。注：不必标记每个出口。

Compliance is checked by inspection.
通过检查检查合规性。

c) The MULTIPLE IEC 60884-1 SOCKET-OUTLET shall comply with and the following requirements. 多个插座应符合IEC 60884-1和以下要求。

- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.
爬电距离和空气间隙应符合8.9。
- It shall be of CLASS I construction and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the socket-outlets.
其应为I级结构，保护接地导线应连接至插座中的接地触点。
- * PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6, except that the total impedance of the protective earth path for an ME SYSTEM may be up to 400 m□, or higher if the conditions of 8.6.4 b) are

satisfied.

—*保护接地端子和保护接地连接应符合8.6的要求，但医用电气系统保护接地路径的总阻抗可高达400 m Ω ，或更高（如果满足8.6.4 b）的条件。

- ENCLOSURES shall comply with 8.4.2 d).
外壳应符合8.4.2 d) 的要求。
- MAINS TERMINAL DEVICES and wiring shall comply with 8.11.4, if applicable.
电源终端设备和接线应符合8.11.4的要求（如适用）。
- RATINGS of components shall not conflict with the conditions of use (see 4.8).
部件的额定值不得与使用条件相冲突（见4.8）。
- Design and construction of electrical connection terminals and connectors of MULTIPLE SOCKET-OUTLETS shall prevent the incorrect connection of accessible connectors that are removable without the use of a TOOL.
多个插座的电气连接端子和连接器的设计和构造应防止无需使用工具即可拆卸的可触及连接器的错误连接。
- Requirements for the POWER SUPPLY CORD as described in 8.11.3 shall be fulfilled.
应满足8.11.3中所述的电源线要求。

d) * If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply.

*如果多个插座与分离变压器组合，则以下附加要求适用。

- The separating transformer shall comply with the requirements of IEC 61558-2-1, this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.
隔离变压器应符合本标准IEC 61558-2-1的要求。或者，隔离变压器可符合IEC 61558-2-1的要求，但最大额定输出功率1 kVA和防护等级IPX4的要求不适用。

NOTE 1 As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than

注1：由于隔离变压器不是主电源变压器，它不需要超过
BASIC INSULATION.
基本绝缘。

NOTE 2 Limitation of output power is not explained in IEC 61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment.

注2：IEC 61558-2-1中未解释输出功率的限制，额定输出功率由安装中的保险丝和允许使用的电源电缆确定。但是，需要仔细选择隔离变压器的特性，同时考虑医用电气系统负载电流的变化，以确保提供给医用电气系统各部件的电压保持在设备规定的限值内。

NOTE 3 IEC 61558-2-1 should be used with the general standard IEC 61558-1.

注3 IEC 61558-2-1应与通用标准IEC 61558-1一起使用。

- The separating transformer assembly shall be of CLASS I construction.
隔离变压器组件应为I级结构。
- The degree of protection against ingress of water as given in IEC 60529 shall be specified.
应规定IEC 60529中规定的防水等级。
- The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.
隔离变压器组件应按照7.2和7.3。
- The MULTIPLE SOCKET-OUTLET shall be permanently connected to the separating transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in IEC/TR 60083 (see Figure I.1 and Figure I.2).
多个插座应永久连接至分离变压器，或分离变压器组件的插座应为不能接受IEC/TR 60083中规定的任何类型电源插头的类型（见图I.1和图I.2）。

Compliance is checked by inspection and as described in the relevant subclauses of this standard.
通过检查和本标准相关子条款中的说明检查合规性。

16.9.2.2 * PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS *医用电气系统中的保护接地连接

For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.
对于共用电源连接的医用电气系统的每个部件，当作为一个单元进行试验时，医用电气系统总保护接地路径的阻抗和载流能力应符合8.6.4的规定。电源插头中保护接地引脚与任何保护接地部件之间的阻抗不得超过200 mΩ。

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part.
应进行保护性接地连接，以便在拆除医用电气系统中的任何单个设备时，不会中断医用电气系统任何其他部分的保护接地，同时不断开该部分的电源。

Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.
附加保护接地导线只能通过使用工具拆卸。

Compliance is checked by inspection.
通过检查检查合规性。

16.9.2.3 Protection of conductors 导线保护

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.
医用电气系统内连接不同设备的导线应受到保护，以防机械损坏。

Compliance is checked by inspection.
通过检查检查合规性。

17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS *医用电气设备和医用电气系统的电磁兼容性

The MANUFACTURER shall address In the RISK MANAGEMENT PROCESS the RISKS associated with:
制造商应在风险管理过程中解决与以下相关的风险:

- the electromagnetic phenomena existing at the locations where the ME EQUIPMENT or
医用电气设备或
ME SYSTEM is intended to be used as indicated in the ACCOMPANYING DOCUMENTS; and
医用电气设备系统的用途如随附文件所示; 以及
- the introduction by the ME EQUIPMENT or ME SYSTEM of electromagnetic phenomena
into the environment that might degrade the performance of other devices, electrical
equipment and systems.
医用电气设备或医用电气系统将电磁现象引入环境中, 可能会降低其他设备、电气设备和
系统的性能。

See IEC 60601-1-2 and also see 1.3.
见IEC 60601-1-2和1.3。

Compliance is checked by inspection of the RISK MANAGEMENT FILE.
通过检查风险管理文件来检查合规性。

Annex A
附件A
(informative)
（资料性）

General guidance and rationale
一般指导和基本原理

A.1 General
一般指导

guidance

The requirements for ME EQUIPMENT and ME SYSTEMS differ from those for other kinds of electrical equipment because of the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:
医用电气设备和医用电气系统的要求不同于其他类型的电气设备，因为医用电气设备或医用电气系统与病人、操作员和周围环境的特殊关系。以下几个方面在这种关系中起着重要作用：

- a) the inability of the PATIENT or OPERATOR to detect the presence of certain HAZARDS, such as ionizing and non-ionizing radiation;
病人或操作者不能探测到某些危险的存在，如电离和非电离辐射；
- b) absence of normal reactions of the PATIENT who can be ill, unconscious, anaesthetized, immobilized, etc.;
患者无正常反应，可能生病、昏迷、麻醉、固定等。；
- c) absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance;
如果穿透或治疗以获得低皮肤电阻，则对患者皮肤提供的电流缺乏正常保护；
- d) support or replacement of vital body functions, which depends on the reliability of ME EQUIPMENT or ME SYSTEM;
支持或替换重要的身体功能，这取决于医用电气设备或医用电气系统；
- e) the simultaneous connection to the PATIENT of more than one piece of ME EQUIPMENT;
多台医用电气设备与患者同时连接；
- f) combination of high-power ME EQUIPMENT and sensitive low-signal ME EQUIPMENT often in ad hoc combinations;
大功率医用电气设备和敏感低信号医用电气设备的组合，通常是临时组合；
- g) the application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs;
通过接触皮肤或将探针插入内脏，直接将电路应用于人体；
- h) conditions, particularly in operating theatres, that can present a combination of humidity, moisture or HAZARDS of fire or explosion HAZARDS caused by air, oxygen or nitrous oxide.
尤其是在手术室，空气、氧气或一氧化二氮会导致湿度、湿度或火灾或爆炸危险。

When ME EQUIPMENT is combined with another electrical equipment to form an ME SYSTEM, additional requirements apply. These are given in Clause 16. In some instances, reference to other parts of this standard is made. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause could be applicable to ME SYSTEMS as well as to ME EQUIPMENT.

当医用电气设备与其他电气设备组合形成医用电气系统时，附加要求适用。这些在第16条中给出。在某些情况下，参考本标准的其他部分。如果某一条款或子条款仅适用于医用电气设备，则该条款或子条款的标题和内容应注明。如果情况并非如此，该条款或子条款可适用于医用电气系统和医用电气设备。

A.2 Safety of ME EQUIPMENT and ME SYSTEMS

医用电气设备和医用电气系统的安全

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS, as described in

医用电气设备和医用电气系统的基本安全和基本性能，如

IEC/TR 60513 [12], are part of the total safety situation, comprising safety of ME EQUIPMENT, safety of the installation to which the ME EQUIPMENT or ME SYSTEM is connected and safety of application.

IEC/TR 60513[12]是整个安全状况的一部分，包括医用电气设备的安全、医用电气设备或医用电气系统所连接的装置的安全以及应用的安全。

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS are required for NORMAL USE and for reasonably foreseeable misuse and in NORMAL CONDITION and SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting ME EQUIPMENT and where interruption of an examination or treatment is considered as a HAZARD HAZARDOUS SITUATION for the PATIENT. 医用电气设备和医用电气系统的基本安全性和基本性能要求用于正常使用和合理可预见的误用，以及在正常条件和单一故障条件下。功能可靠性被视为生命支持医用电气设备的一个安全方面，检查或治疗的中断被视为对患者的危险情况。

Adequate construction, lay-out and ACCOMPANYING DOCUMENTS that serve to prevent use errors are regarded as safety aspects. 适当的结构、布局和用于防止使用错误的随附文件被视为安全方面。

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function. 如果安全预防措施提供了足够的保护，而没有对正常功能的不良限制，则认为安全预防措施是可以接受的。

Generally, it is presumed that ME EQUIPMENT and ME SYSTEMS are operated under the jurisdiction of qualified or licensed persons and that the OPERATOR has the skill required for a particular medical application and acts according to the instructions for use. 一般情况下，医用电气设备和医用电气系统在合格或持牌人员的管辖下运行，操作员具备特定医疗应用所需的技能，并按照使用说明进行操作。

The total safety of ME EQUIPMENT can consist of:
医用电气设备的总体安全性包括：

- inherent safety by design;
—设计固有安全性；
- protective measures incorporated into the ME EQUIPMENT or additional protective measures, such as the use of shields or protective clothing; and
医用电气设备的防护措施或附加防护措施，如使用防护罩或防护服；以及
- information for safety, such as restrictions in the instructions for use concerning transport, mounting or positioning, connection, putting into service, operation and the position of the OPERATOR and his/her assistants in relation to the ME EQUIPMENT during use.
安全信息，如使用说明书中有关运输、安装或定位、连接、投入使用、操作和操作员及其助手在使用过程中与医用电气设备相关的位置的限制。

A.3 Guidance to the third edition 第三版指南

In this edition, a number of clauses and subclauses from the second edition have been deleted, e.g. when the clause or subclause was indicated as “Not used.” However, those clauses or subclauses from the second edition that stated “No general requirement” have been retained so that particular or collateral standards can refer to them. The statement, “No general requirement”, has been replaced with a reference to the RISK MANAGEMENT PROCESS because the “general requirement” is that, in the absence of a particular or collateral standard, these issues are dealt with through the application of RISK MANAGEMENT.
在本版中，删除了第二版中的一些条款和子条款，例如当该条款或子条款被注明为“未使用”时，保留了第二版中声明“无一般要求”的条款或子条款，以便参考特定或附带标准他们。“无一般要求”一词已改为提及风险管理程序，因为“一般要求”是指，在没有特定或附带标准的情况下，这些问题将通过应用风险管理来处理。

While preparing the third edition, basic safety standards and ISO/IEC guides have been taken into consideration to the extent possible consistent with the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings.
在编写第三版时，已尽可能考虑基本安全标准和ISO/IEC指南，以符合医用电气设备或医用电气系统与患者、操作员和周围环境的特殊关系。

The format of the third edition has been aligned with the basic requirements of Part 2 of the ISO/IEC Directives. All the sections except Section 1 of the second edition have been converted into major clauses. This change was implemented because sections are no longer allowed under the drafting rules and the new numbering system will allow future changes to modify a clause without affecting the number of other parts of the standard.
第三版的格式符合ISO/IEC指令第2部分的基本要求。除第二版第1节外，所有章节都已改为主要条款。实施这一更改是因为起草规则不再允许章节，新的编号系统将允许将来的更改在不影响本标准其他部分编号的情况下修改条款。

The normative references have been moved from Appendix L of the second edition to Clause 2. Informative references are listed in the Bibliography.
规范性引用文件已从第二版附录L移至第2条。参考文献在参考书目中列出。

The definitions in Clause 3 have been rearranged into a single alphabetical listing as organizing the definitions by category was becoming increasingly difficult and the result less intuitive. The index has been expanded to identify each page where a term is used in the body of the standard. A number of new defined terms have been introduced in support of new or expanded requirements.
由于按类别组织定义变得越来越困难，结果也越来越不直观，第3条中的定义被重新排列成一个字母表。索引已经展开，以标识标准正文中使用术语的每个页面。为了支持新的或扩展的需求，引入了一些新的定义术语。

A general requirement for a RISK MANAGEMENT PROCESS has been introduced in 4.2.
风险管理过程的一般要求已在4.2中介绍。

Clause 8 has been extensively restructured to bring together in one clause the requirements relating to electrical safety. The requirements in Clause 8 have been reviewed against the safety requirements for information technology (IT) equipment in IEC 60950-1 and harmonized where appropriate given the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings. 对第8条进行了广泛的重组，将有关电气安全的要求集中在一条中。根据IEC 60950-1中信息技术（IT）设备的安全要求，对第8条中的要求进行了审查，并根据医用电气设备与患者、操作员和周围环境的特殊关系，在适当情况下进行了协调。

Clause 9 on protection against MECHANICAL HAZARDS has been substantially revised to deal with a wide range of the HAZARDS that ME EQUIPMENT could pose to the OPERATOR or PATIENT. Requirements relating to the mechanical strength of the ME EQUIPMENT when subjected to the stresses caused by pushing, impact, dropping, and rough handling are in 15.3. 有关机械危险防护的第9条已作了实质性修订，以处理医用电气设备可能对操作员或患者造成的各种危害。医用电气设备在受到推挤、冲击、跌落和粗暴搬运引起的应力时的机械强度要求见15.3。

The standard now deals with USABILITY in 12.2 as opposed to “user or human errors.” 该标准现在处理12.2中的可用性，而不是“用户或人为错误”

Section six of the second edition on protection against the HAZARDS of ignition of flammable anaesthetic mixtures has been moved to a normative annex. While this annex was originally intended to be informative because the use of such anaesthetics is rare, comments from National Committees indicated that some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications.

第二版关于防止易燃麻醉剂混合物着火危险的第六节已移至规范性附录。虽然本附件的初衷是提供信息，因为此类麻醉剂的使用很少，但来自国家委员会的意见表明，一些制造商可能仍希望为此类应用提供医用电气设备。

The surface temperature limit in 11.1.2.2 for APPLIED PARTS that are in contact with the PATIENT for 10 min or more has been increased from 41 °C to 43 °C. However, the MANUFACTURER is to disclose in the ACCOMPANYING DOCUMENTS if the surface temperature of an APPLIED PART exceeds 41 °C. 11.1.2.2中关于与患者接触10分钟或更长时间的应用部件的表面温度限制已从41°C增加到43°C。

但是，如果应用部件的表面温度超过41°C，制造商应在随附文件中披露。

The requirements of IEC 60601-1-4 [14] for PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS, as IEC 60601-1-4[14]对可编程电气医疗系统的要求，如

referred to in 52.1 of the second edition, have been incorporated into the body of this standard in a new Clause 14.

已将第二版52.1中所述内容纳入本标准正文的第14条。

The requirements of IEC 60601-1-1 [13] for ME SYSTEMS have been incorporated into the body of this standard in a new Clause 16.

IEC 60601-1-1[13]对医用电气系统的要求已纳入本标准正文的新第16条中。

A.4 Rationale for particular clauses and subclauses 特定条款和子条款的理由

The following are rationales for specific clauses and subclause in this standard, with clause and subclause numbers parallel to those in the body of the document. 以下是本标准中具体条款和子条款的基本原理，条款和子条款编号与文件正文中的数字平行。

Subclause 1.1 – Scope

第1.1款-范围

The scope of this standard is established by the reference to the definitions of ME EQUIPMENT and ME SYSTEMS. This is to clearly define the scope of this standard as compared with requirements for other types of electrical equipment.

本标准的范围通过参考医用电气设备和医用电气系统的定义确定。与其他类型电气设备的要求相比，这是为了清楚地定义本标准的范围。

Laboratory equipment within the scope of IEC 61010-1 [22] is not covered by this standard except when a MANUFACTURER incorporates such laboratory equipment into an ME SYSTEM. 本标准不包括IEC 61010-1[22]范围内的实验室设备，除非制造商将此类实验室设备并入医用电气系统。

This standard does not apply to active implantable medical devices covered by the ISO 14708-1 [31] except where the ISO 14708-1 requires compliance with IEC 60601-1. 本标准不适用于ISO 14708-1[31]涵盖的有源植入式医疗器械，除非ISO 14708-1要求符合IEC 60601-1。

This standard does not apply to any other electrical equipment unless it falls under the definition of ME EQUIPMENT or ME SYSTEMS.

本标准不适用于任何其他电气设备，除非属于医用电气设备或医用电气系统的定义。

Subclause 1.3 – Collateral standards

第1.3款-附属标准

Collateral standards are a vehicle developed by Technical Committee 62 as a way of extending the general standard. Collateral standards fall into two categories: 附属标准是由技术委员会62开发的一种工具，用于扩展通用标准。抵押品标准分为两类：

- standards that address additional BASIC SAFETY and ESSENTIAL PERFORMANCE requirements that are common to a subgroup of ME EQUIPMENT. For example, Subcommittee 62B developed IEC 60601-1-3 to provide general requirements for protection against ionizing radiation in medical diagnostic X-ray equipment in order that the dose equivalent to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable; or 基本安全要求和通用设备的基本要求。例如，小组委员会62B制定了IEC 60601-1-3，以提供医用诊断X射线设备中电离辐射防护的一般要求，以便将患者、操作员和其他工作人员的剂量当量保持在合理可行的最低水平；或
- standards that address additional BASIC SAFETY or ESSENTIAL PERFORMANCE requirements that deal with characteristic of ME EQUIPMENT or ME SYSTEMS that are not fully covered by the general standard. At the time of publication, three collateral standards in this category have been published by Subcommittee 62A: EMC (IEC 60601-1-2), Usability (IEC 60601-1-6) and Alarm systems (IEC 60601-1-8). 处理通用标准未完全涵盖的医用电气设备或医用电气系统特性的附加基本安全或基本性能要求的标准。在出版时，62A小组委员会已经发布了这一类别的三个并行标准：EMC（IEC 60601-1-2）、可用性（IEC 60601-1-6）和警报系统（IEC 60601-1-8）。

The editions of IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6 and IEC 60601-1-8 existing at the time of publication of this third edition of the general standard were all developed in relation to the second edition of the general standard (IEC 60601-1:1988). It is intended that revised editions of these collateral standards, relating specifically to this third edition, will be developed and published as soon as possible. As stated in 1.3, these will become normative at the date of their publication and shall apply together with this standard. 本通用标准第三版出版时存在的IEC 60601-1-2、IEC 60601-1-3、IEC 60601-1-6和IEC 60601-1-8的版本均与通用标准第二版（IEC 60601-1:1988）相关。这些附属标准的修订版，特别是与第三版有关的修订版，将尽快制定并出版。如1.3所述，这些标准将在发布之日成为规范性文件，并与本标准一起适用。

Until such new editions of these collateral standards are published, users of this standard should apply the existing editions as far as possible when they are relevant to the 在这些附属标准的新版本发布之前，本标准的用户应尽可能使用与本标准相关的现有版本

ME EQUIPMENT or ME SYSTEM concerned. However some requirements of these collateral standards might not be compatible with this standard.
医用电气设备或医用电气系统。然而，这些附属标准的某些要求可能与本标准不兼容。

The requirements from two of the collateral standards developed for the second edition of IEC 60601-1 have been incorporated into the body of this standard. They are:
为第二版IEC 60601-1制定的两个附带标准的要求已纳入本标准正文。他们是：

- IEC 60601-1-1:2000, Medical electrical equipment – General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-1:2000，医用电气设备-安全的一般要求-附带标准：医用电气系统的安全要求
- IEC 60601-1-4:1996, Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems and its Amendment 1 (1999).
IEC 60601-1-4:1996，医用电气设备—第1部分：安全通用要求—4。并行标准：可编程电子医疗系统及其修改件1（1999年）。

While both standards will remain active until all the particular standards based on the second edition of IEC 60601-1 have been aligned with this standard, they are not applicable when applying this standard.
尽管这两个标准将保持有效，直到基于第二版IEC 60601-1的所有特定标准与本标准保持一致，但在应用本标准时，它们不适用。

Additional collateral standards can be published from time to time as needs are identified. While those standards will not be mentioned in this standard, they still establish general requirements that need to be considered when applicable. Readers are encouraged to consult the registers of currently valid International Standards maintained by their national standards body to see what applicable collateral standards have been published.
如有需要，可不时发布其他抵押品标准。虽然这些标准将不会在本标准中提及，但它们仍然确定了在适用时需要考虑的一般要求。我们鼓励读者查阅其国家标准机构保存的现行有效国际标准的登记册，以了解已经发布了哪些适用的附属标准。

Subclause	1.4	–	Particular	standards
第1.4款-特殊标准				
A	particular	standard	can	specify:
特定标准可规定：				
– clauses or subclauses of this standard that apply without amendment;				
本标准中未经修改而适用的条款或子条款；				
– clauses or subclauses (or parts of them) of this standard that do not apply;				
本标准中不适用的条款或子条款（或其部分）；				
– clauses or subclauses (or parts of them) of this standard that are replaced by clauses or subclauses in the particular standard; or				
被特定标准中的条款或子条款取代的本标准的条款或子条款（或其中的一部分）；或				
– additional clauses or subclauses.				
附加条款。				
A particular standard can contain:				
特定标准可包含：				
a) requirements that result in an increase of BASIC SAFETY or ESSENTIAL PERFORMANCE;				
增加基本安全或基本性能的要求；				
b) requirements that can be less stringent than the requirements in this standard, if the latter cannot be maintained because of, for example, the power output of ME EQUIPMENT;				
如果由于医用电气设备的功率输出等原因而无法维持本标准中的要求，则可不严格于本标准中的要求；				
c)	requirements	concerning	performance,	reliability, interfaces, etc.;

- 性能、可靠性、接口等要求。；
- d) accuracy of working data;
工作数据的准确性；或
- e) extension and limitation of environmental conditions.
环境条件的扩展和限制。

Clause 2 – Normative references
第2条-规范性引用文件

This clause provides a list of the documents cited in other normative parts of this standard in such a way as to make them indispensable for the application of the document. However, conformance with the documents in this list is required only to the extent that they are referenced in a normative requirement in this standard. For example, if a reference is made to a specific clause, subclause, table or figure, then the user of this standard is only required to conform to the requirements in that clause, subclause, table or figure in order to satisfy the requirement in this standard. 本条提供了本标准其他规范性部分中引用的文件清单，以使其对本文件的应用必不可少。但是，仅当本标准的规范性要求中引用了这些文件时，才要求与本清单中的文件一致。例如，如果引用了某一特定的条款、子条款、表格或图形，则本标准的使用者只需符合该条款、子条款、表格或图形中的要求，以满足本标准的要求。

Undated references are made only to a complete document or to a major part thereof and only if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of this standard. For example, an undated reference is made to IEC 60529 because it is intended that the MANUFACTURER will always use the latest edition of that standard when assigning IP Codes to ENCLOSURES. 凡是不注日期的引用文件仅对完整文件或其主要部分进行引用，并且只有在被接受的情况下，才有可能将引用文件的所有未来更改用于本标准的目的。例如，参考IEC 60529时未注明日期，因为制造商打算在为外壳分配IP代码时始终使用该标准的最新版本。

²¹⁾ There exists a consolidated edition 1.1 (2000) including IEC 60601-1-4 (1996) and its Amendment 1 (1999).
有一个合并版本1.1（2000），包括IEC 60601-1-4（1996）及其修正案1（1999）。

Undated references are understood to include all amendments to and revisions of the referenced document.
不注日期的引用文件应包括对引用文件的所有修改和修订。

Dated references are made when the requirements of a particular edition are to be used to satisfy a requirement of this standard. Subsequent amendments to, or revisions of, dated references will need to be incorporated by amendment of this standard. For example, a dated reference is made to IEC 60825-1 because relevant parts of that standard are applied to light emitting diodes (LEDs) and IEC/TC 76 was in the early stages of developing a third edition of IEC 60825-1 and was considering removing the requirements for LEDs.
当使用特定版本的要求来满足本标准的要求时，应注明日期的参考文件。凡是注日期的引用文件的后续修改件或修订件都需要通过对本标准的修改件进行合并。例如，引用IEC 60825-1的日期是因为该标准的相关部分适用于发光二极管（LED），而IEC/TC 76处于制定第三版IEC 60825-1的早期阶段，并正在考虑取消对LED的要求。

References to specific clauses, subclauses, tables and figures of another document are always dated.
对另一份文件中具体条款、子条款、表格和图表的引用总是注明日期的。

Clause3- Terminology and definitions
第3条-术语和定义

This clause contains definitions for terms that are necessary for the understanding of the requirements in this standard. Many of these terms are inherited from the second edition. However, a number of terms have been added during the course of developing new or modified requirements. Where possible, existing definitions in other standards have been copied or adapted.
本条包含理解本标准要求所需术语的定义。这些术语中有许多是从第二版继承而来的。然而，在开发新的或修改过的需求的过程中，增加了一些术语。在可能的情况下，已复制或改编了其他标准中的现有定义。

Except when used to support other defined terms, a definition is only provided if the term is used more than once in the text of the standard.
除非在标准中定义的术语比标准定义的术语多用一次。

Defined terms are printed in SMALL CAPITALS to assist the reader in identifying them in the body of the standard. When normal case is used, the words have their normal English meaning. The committee made an effort to avoid using the same word both as a defined term and in its normal English meaning. At times this has not been possible. For example, the word “procedure” is used as a defined term in Start-up PROCEDURE, specifically meaning a “specific way to perform an activity” of starting up the ME EQUIPMENT or ME SYSTEM. It is also used in the definition of PATIENT according to its general English meaning, i.e. “Living being (person or animal) undergoing a medical, surgical or dental procedure.”
定义的术语用小号大写印刷，以帮助读者在标准正文中识别它们。当使用正常大小写时，这些词就有了正常的英语意义。委员会努力避免使用同一个词作为一个定义的术语和它的正常英语含义。有时这是不可能的。例如，“程序”一词用作启动程序中的定义术语，具体指启动医用电气设备或医用电气系统的“执行活动的特定方式”。它也用于定义病人，根据它的一般英语含义，即“正在接受医疗、外科或牙科手术的活着的人或动物。”

Subclause3.8- APPLIED PART
第8.3款-适用

Parts that contact PATIENTS can present greater HAZARDS than other parts of the ENCLOSURE, and these APPLIED PARTS are therefore subject to more stringent requirements, for example, for temperature limits and (according to classification B/BF/CF) for LEAKAGE CURRENT.
与患者接触的部件可能比外壳的其他部件产生更大的危害，因此这些应用部件受到更严格的要求，例如温度限制和（根据B/BF/CF分类）泄漏电流要求。

NOTE Some other ACCESSIBLE PARTS of the ENCLOSURES of ME EQUIPMENT are

subject to tests that are more demanding than those for ENCLOSURES of other kinds of equipment, because the PATIENT can touch them, or the OPERATOR can touch them and the PATIENT simultaneously.

注：医用电气设备外壳的一些其他可触及部件需要进行比其他类型设备外壳更高的测试，因为患者可以触摸它们，或者操作员可以同时触摸它们和患者。

In order to determine which requirements apply, it is necessary to distinguish between
为了确定哪些需求适用，有必要区分

APPLIED PARTS and parts that are simply considered as the ENCLOSURE.
应用部件和仅被视为外壳的部件。

Thus,

typically:

因此，通常：

- an infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT;
红外线治疗灯没有应用部分，因为它不需要与患者直接接触；
- the only part of an X-ray table that is an APPLIED PART is the top on which the PATIENT lies;
X光检查床的唯一应用部分是病人躺在上面；
- likewise, in an MRI scanner, the only APPLIED PART is the table supporting the PATIENT.
同样，在核磁共振扫描仪中，唯一应用的部分是支撑病人的桌子。

However, a part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT can reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR. 然而，无意中接触到失去知觉、麻醉或丧失行为能力的患者的部件可能与必须接触患者的应用部件具有相同的风险。另一方面，一个活跃的病人可以接触到的部位对病人来说可能不会比给操作者带来更多的风险。

The definition in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties. 本标准第一版和第二版中的定义未能解决这一问题。第二版的第二修正案扩大了定义的范围，包括可以与病人接触的部分，但新的定义继续造成困难。

In this edition, subclause 4.6 requires the RISK MANAGEMENT PROCESS to identify which parts, other than APPLIED PARTS, are subject to the same requirements as APPLIED PARTS. These can include parts of non-ME EQUIPMENT in an ME SYSTEM.
在本版本中, 子条款4.6要求风险管理过程, 以确定除应用部件外的哪些部件与应用部件符合相同的要求。这些可包括医用电气系统中非医用电气设备的部件。

Particular standards should specifically identify the APPLIED PART(S) in particular types of
特殊标准应特别确定特定类型的应用部件
ME EQUIPMENT.
医用电气设备。

In order to assess which parts are APPLIED PARTS and what are the PATIENT CONNECTIONS, the following PROCESS is employed in the order shown.
为了评估哪些部件是应用部件以及哪些是患者连接, 按照所示顺序采用以下过程。

- a) Determine whether the ME EQUIPMENT has an APPLIED PART, and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).
确定医用电气设备是否有应用部件, 如果有, 确定应用部件的范围 (这些决定基于非电气方面的考虑)。
- b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S).
如果没有应用部件, 则没有患者连接。
- c) If there is an APPLIED PART, there can be one or more PATIENT CONNECTION(S). Even if the APPLIED PART has no accessible conductive parts, foil applied in accordance with 8.7.4.7 is regarded as one PATIENT CONNECTION.
如果有应用部件, 则可以有一个或多个患者连接。即使应用部件没有可触及的导电部件, 按照8.7.4.7的要求施加的箔材也被视为一个病人连接。
- d) Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not separated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.
如果应用部分的导电部分不与患者直接接触, 但没有分离, 并且电流可以通过该部分流入或流出患者, 则应将其视为单个患者连接。

NOTE Relevant separation requirements are those that relate to MEANS OF PATIENT PROTECTION.
注: 相关隔离要求是指与患者保护措施相关的要求。

An APPLIED PART can include one or more functions. Each function can include one or more PATIENT CONNECTIONS. A PATIENT CONNECTION can be an electrode that is intended to carry current; or the electrical connection can be incidental to the purpose, for example with an intra-vascular fluid line or a PATIENT support.
应用部件可以包括一个或多个功能。每个功能可以包括一个或多个患者连接。患者连接可以是用于承载电流的电极; 或者电连接可以是附带的, 例如与血管内流体管线或患者支架连接。

See also the rationale for 3.78.
另见3.78的基本原理。

Figure A.1 to Figure A.7 (inclusive) provide examples of the way in which APPLIED PARTS and PATIENT CONNECTIONS are identified in order to apply the requirements for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT in various ME EQUIPMENT and ME SYSTEMS.
图A.1至图A.7 (包括图A.1) 提供了应用部件和患者连接的识别方法示例, 以便在各种医用电气设备和医用电气系统中应用对患者泄漏电流和患者辅助电流的要求。

Figure A.1 and Figure A.2 shows an ECG monitor that includes the ECG monitor, the PATIENT

图A.1和图A.2所示为ECG监护仪，包括ECG监护仪、患者 cable, PATIENT leads and the ECG electrodes. In Figure A.1 and Figure A.2: 电缆、病人导联和心电图电极。在图A.1和图A.2中：

- The APPLIED PART includes the electrodes and those parts of the PATIENT leads or PATIENT cable that need to physically contact the PATIENT in NORMAL USE.
应用部分包括电极和病人导线或病人的那些部分
正常使用时需要与患者身体接触的电缆。
- Application of RISK MANAGEMENT might identify other parts of the PATIENT lead or PATIENT cable that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
风险管理的应用可能会识别患者导线或患者电缆的其他部分，因为它们可能会接触到患者，因此必须将其视为应用部件。
- The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.
病人连接由心电图电极组成，它们都是应用部分相同功能的一部分。

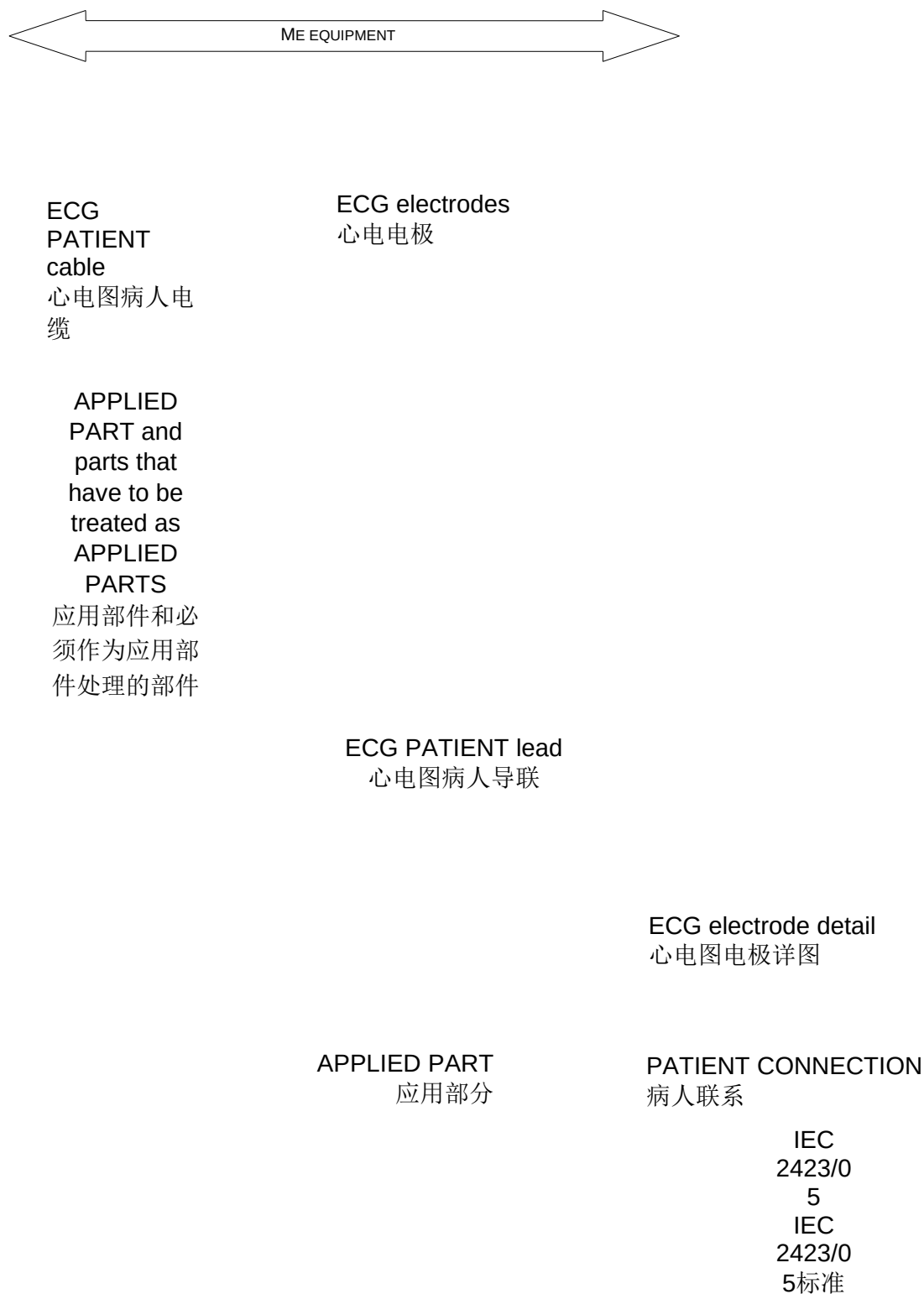


Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS
图A.1–医用电气设备、应用部件和患者连接的标识
in an ECG monitor
在心电图监护仪上

Figure A.2 shows the required F-TYPE APPLIED PART insulation. The parts within the dotted line are the PATIENT circuit.
图A.2显示了所需的F-TYPE应用部件绝缘。虚线内的部分是病人电路。

In Figure A.2, the required APPLIED PART insulation is:

在图A.2中，所需的应用部件绝缘为：

- one MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the MAINS VOLTAGE;
一种基于电源电压的接地和虚线内部件之间的病人保护方法；
- two MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the voltage carried by these parts; and
接地和虚线内部件之间的两种保护方式，基于这些部件所承载的电压； 以及
- two MEANS OF PATIENT PROTECTION between live parts (including mains) and the parts within the dotted line.
带电部件（包括电源）和虚线内部件之间的两种保护方式。

ECG
PATIENT
cable
心电图病人电
缆

ECG electrodes
心电电极

APPLIED
PART and
parts that
have to be
treated as
APPLIED
PARTS
应用部件和必
须作为应用部
件处理的部件

ECG PATIENT lead
心电图病人导联

ECG monitor
心电图监护仪

IEC 2424/05
IEC 2424/05标准

Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART
图A.2–F-TYPE应用部件的绝缘示例
with the insulation incorporated in the ME EQUIPMENT
在医用电气设备中加入绝缘材料

Figure A.3 shows an F-TYPE APPLIED PART with the insulation incorporated in a transducer. The parts within the dotted line are the PATIENT circuit. There are parts outside the dotted line that are subject to the requirements for APPLIED PARTS as determined through the RISK MANAGEMENT PROCESS.
图A.3显示了一个F型应用部件，其绝缘层包含在传感器中。虚线内的部分是病人电路。虚线以外的部分，根据风险管理流程确定的应用部件要求。

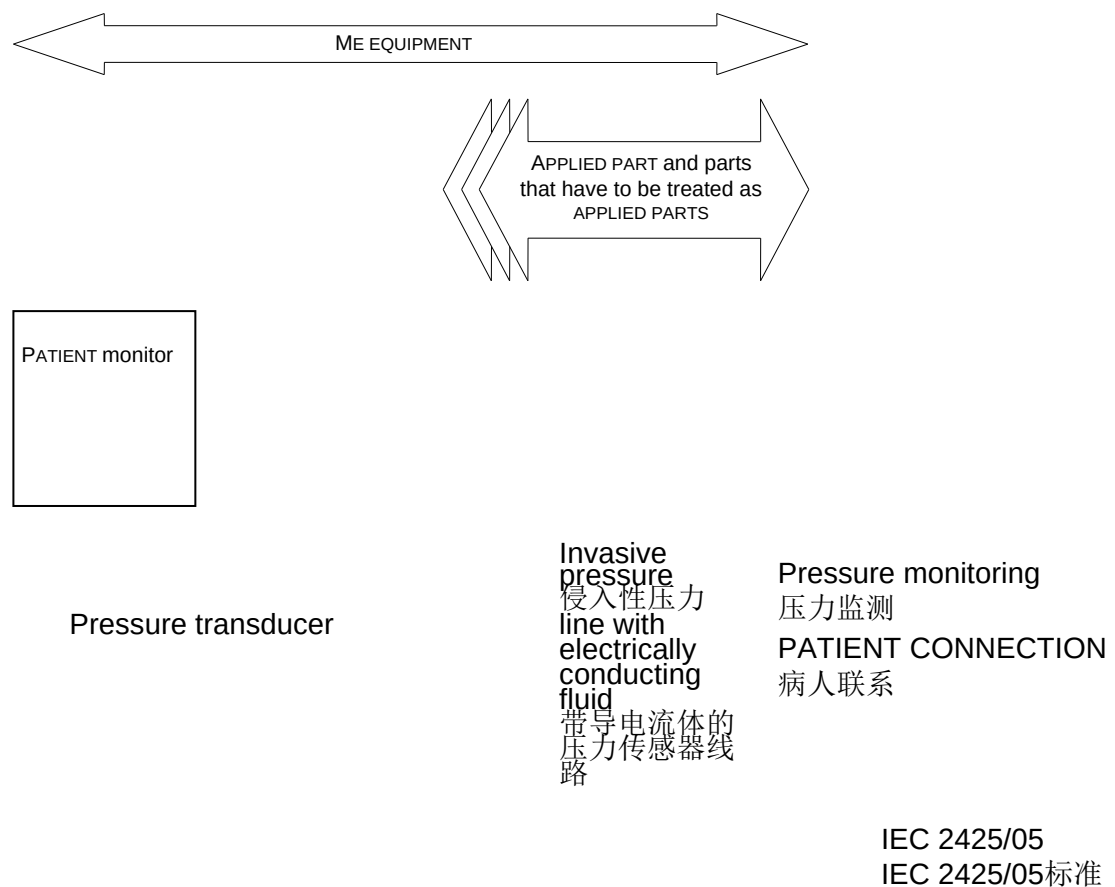


Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS
图A.3—医用电气设备、应用部件和患者连接的标识
in a PATIENT monitor with invasive pressure monitoring facility
在有创性压力监测设备的病人监护仪中

Figure A.4 shows a PATIENT monitor with ECG and invasive pressure monitoring facilities. In this example:

图A.4显示了带有ECG和有创压力监测设备的病人监护仪。在本例中：

- The ME EQUIPMENT includes the ECG monitor; the ECG PATIENT cable, the PATIENT leads and its their electrodes; and the pressure transducer and its fluid filled line.
医用电气设备包括心电图监护仪、心电图病人电缆、病人导联及其电极、压力传感器及其充液管线。
- The APPLIED PART(s) include the ECG electrodes and those parts of the PATIENT cable and PATIENT leads that need to physically contact the PATIENT in NORMAL USE; and the fluid filled pressure monitoring line.
应用部分包括ECG电极、正常使用时需要与患者身体接触的患者电缆和患者导线部分；以及充液压力监测线。
- Application of RISK MANAGEMENT might identify other parts of the ECG PATIENT cable, the PATIENT leads or the pressure transducer that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
风险管理的应用可能会识别ECG患者电缆、患者导线或压力传感器的其他部分，因为它们可能会接触到患者，因此必须将它们视为应用部件。
- The ECG PATIENT CONNECTIONS consist of the ECG electrodes.
ECG患者连接由ECG电极组成。
- The pressure monitoring PATIENT CONNECTION consists of the electrically conducting fluid in the pressure line. For the measurement of PATIENT LEAKAGE CURRENT and

PATIENT AUXILIARY CURRENT, an electrode is placed in the electrically conducting fluid and treated as a single PATIENT CONNECTION. 压力监测病人连接由压力管道中的导电流体组成。为了测量病人漏电流和病人辅助电流，在导电液体中放置一个电极，并将其当作一个病人连接。

- If the PATIENT CONNECTIONS associated with the ECG function are not electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as two functions of the same APPLIED PART. 如果与ECG功能相关联的患者连接未与与压力监测功能相关的患者连接电分离，则这些连接被视为同一应用部分的两个功能。
- If the PATIENT CONNECTIONS associated with the ECG function are electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as separate APPLIED PARTS. 如果与ECG功能相关的患者连接与与压力监测功能相关的患者连接电分离，则这些连接被视为单独的应用部件。

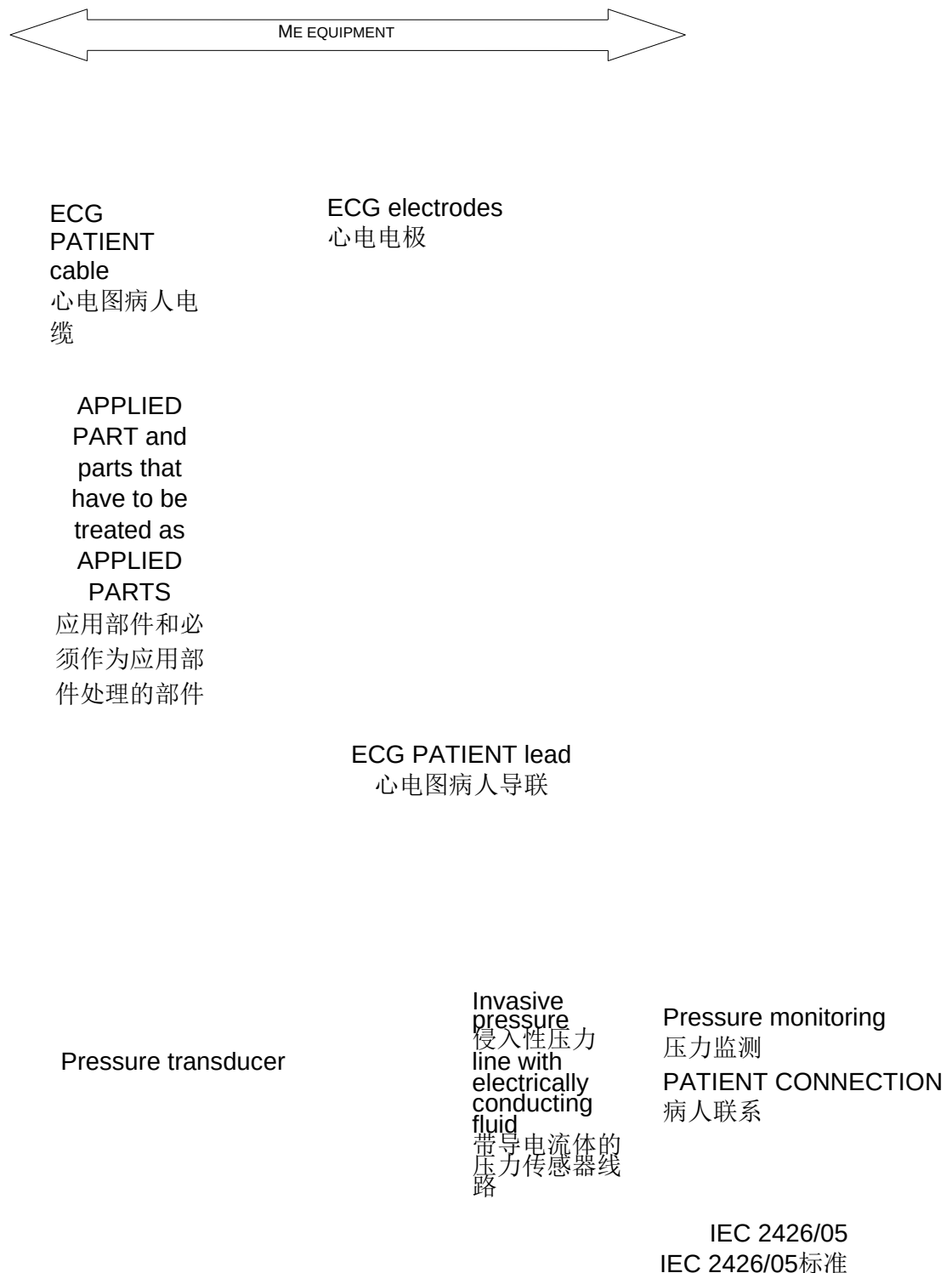


Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS

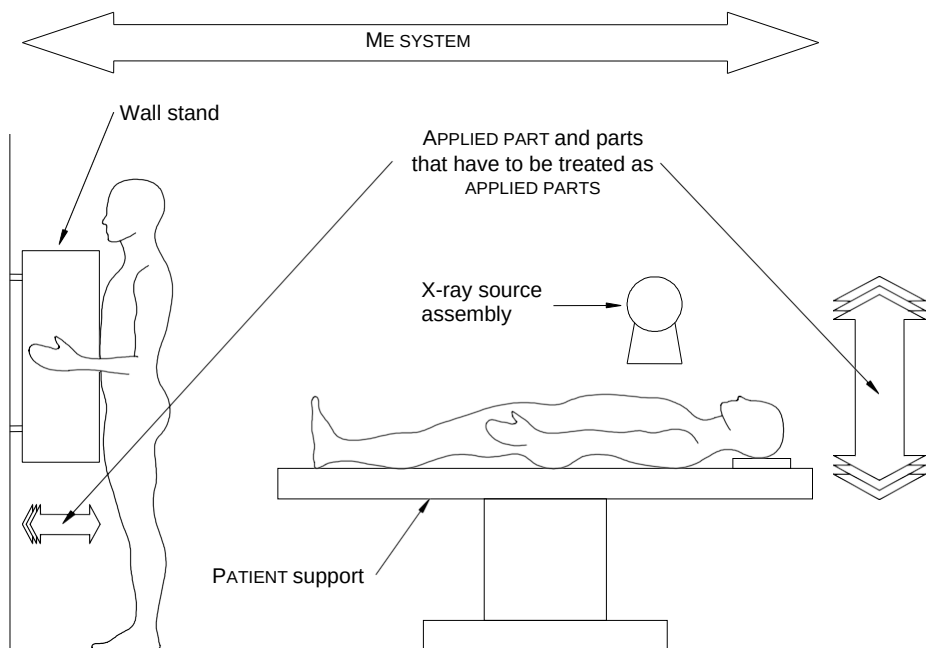
图A.4—医用电气设备、应用部件和患者连接的标识
 in a multifunction PATIENT monitor with invasive pressure monitoring facilities
 在一个多功能病人监护仪和有创压力监测设备

Figure A.5 shows an X-ray ME SYSTEM in which:
 图A.5所示为X光ME系统，其中：

- The ME SYSTEM includes the X-ray tube source assembly, the X-ray table and the wall stand, which are all items of ME EQUIPMENT. Other parts of the ME SYSTEM such as the X-ray generator and OPERATOR console are not shown.

医用电气系统包括X射线管源组件、X射线桌和壁挂架，它们都是医用电气设备的组成部分。医用电气系统的其他部分，如X射线发生器和操作员控制台没有显示。

- The APPLIED PART(s) include the top of the table and the front of the wall stand, as these parts need to physically contact the PATIENT in NORMAL USE.
应用部分包括桌面和壁式支架的前部，因为这些部件在正常使用时需要与患者身体接触。
- The application of RISK MANAGEMENT might identify some parts of the tube assembly and some other parts of the table and the wall stand have as having to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
风险管理的应用可能会将管组件的某些部分以及检查床和壁挂架的其他部分视为应用部件，因为它们可能会接触到患者。
- The PATIENT CONNECTIONS consist of the conductive parts of these APPLIED PARTS that electrically contact the PATIENT.
患者连接由这些与患者电接触的应用部件的导电部件组成。
- The MANUFACTURER can specify that the table and the wall stand are different functions of the same APPLIED PART.
制造商可以指定桌子和壁挂架是同一应用部件的不同功能。
- Alternatively, the MANUFACTURER can specify that the table and the wall stand are different
或者，制造商可以指定桌子和墙支架不同
APPLIED PARTS.
应用部件。



IEC 2427/05
 IEC 2427/05标准

Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS
 图A.5-应用部件和患者连接的识别
 in an X-ray ME SYSTEM
 在X光ME系统中

Figure A.6 shows a transcutaneous electronic nerve stimulator (TENS) that is intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm. In this case:
 图A.6所示为一个经皮电子神经刺激器（TENS），该刺激器拟佩戴在患者的腰带上，并与应用于患者上臂的电极相连。在这种情况下：

- The ME EQUIPMENT includes the TENS stimulator, the electrode cable and the electrodes.
 医用电气设备包括TENS刺激器、电极电缆和电极。
- The APPLIED PART includes the electrodes and those parts of the electrode leads that physically need to contact the PATIENT in NORMAL USE.
 所述应用部分包括电极和在正常使用中身体上需要与患者接触的电极引线部分。
- The application of RISK MANAGEMENT might identify that the case of the stimulator and its belt clip also have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
 风险管理的应用可能会确定刺激器及其皮带夹的情况也必须作为应用部件来处理，因为它们可能会接触到患者。
- The PATIENT CONNECTIONS consist of the electrodes, which are all part of the same function of this APPLIED PART.
 病人连接由电极组成，它们都是这个应用部分相同功能的一部分。

Skin electrodes
 皮肤电极

APPLIED PART
 and parts that
 have to be treated
 as APPLIED

PARTS

应用部件和必须作
为应用部件处理的
部件

IEC 2428/05

IEC 2428/05标准

Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT'S

图A.6—拟在患者身上佩戴的经皮电子神经刺激器（TENS）中识别医用电气设备、应用部件和患者连接

belt and connected to electrodes applied to the PATIENT'S upper arm
并连接到病人上臂的电极上

Figure A.7 shows an ECG processing ME EQUIPMENT / ME SYSTEM in which:

图A.7所示为ECG处理ME设备/ME系统，其中：

- The ME SYSTEM includes the ECG module, PATIENT cable, PATIENT leads and electrodes, and the personal computer and any of its ACCESSORIES (not shown).
ME系统包括ECG模块、患者电缆、患者导线和电极、个人计算机及其任何附件（未显示）。
- The MANUFACTURER can choose to specify one of the following situations:
制造商可以选择指定以下情况之一：
 - The ECG module and its PATIENT cable, PATIENT leads and electrodes are an item of ME EQUIPMENT; and the personal computer is not an item of ME EQUIPMENT. This would be an ME SYSTEM.
心电模块及其病人电缆、病人导联和电极是医用电气设备的一项；个人计算机不是医用电气设备的一项。这将是一个ME系统。
 - The ECG module and its PATIENT cable, PATIENT leads and electrodes are one item of ME EQUIPMENT; and the personal computer is a separate item of ME EQUIPMENT. This would also be an ME SYSTEM.
ECG模块及其病人电缆、病人导联和电极是医用电气设备的一项；个人计算机是医用电气设备的一个单独项目。这也是一个ME系统。
 - The ECG module and its PATIENT cable, PATIENT leads and electrodes together with the personal computer is a single item of ME EQUIPMENT and not an ME SYSTEM.
ECG模块及其病人电缆、病人导联和电极以及个人计算机是一个单一的医用电气设备，而不是医用电气系统。
- The APPLIED PART includes the electrodes and those parts of the PATIENT cable or, PATIENT leads that need to physically contact the PATIENT in NORMAL USE.
应用部分包括电极和病人电缆的那些部分
leads that need to physically contact the PATIENT in NORMAL USE.
正常使用时需要与患者身体接触的导线。
- Application of RISK MANAGEMENT might identify other parts of the PATIENT cable or, PATIENT leads have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
风险管理的应用可能会识别患者电缆的其他部分，或者，由于患者导线与患者接触的可能性，必须将患者导线视为应用部件。
- The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.
病人连接由心电图电极组成，它们都是应用部分相同功能的一部分。

ECG electrodes
心电电极

Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module

图A.7—带有ECG模块的个人计算机中的医用电气设备或医用电气系统、应用部件和患者连接的标识

Subclause 4.6 would likely not apply to ACCESSIBLE PARTS of ME EQUIPMENT which are positioned according their INTENDED USE in such a way that the PATIENT could touch them only by a deliberate movement. This is based on the assumption that a PATIENT could react to a negative stimulus. Further, such PATIENTS are likely to have contact with non-ME EQUIPMENT such as bedside lights, personal computers, radios, etc.
子条款4.6可能不适用于医用电气设备的可触及部件，这些部件按照其预期用途进行定位，使得患者只能通过故意的动作接触到它们。这是基于这样一个假设，即患者可能会对负面刺激做出反应。此外，此类患者可能会接触非医用电气设备，如床头灯、个人电脑、收音机等。

Subclause 3.9 – BASIC INSULATION

第3.9款-基本绝缘

This definition does not include insulation used exclusively for functional purposes.
此定义不包括专门用于功能目的的绝缘。

Subclause 3.10 – BASIC SAFETY

第3.10款-基本安全

BASIC SAFETY relates to a device not harming the PATIENT resulting in HARM incidental to its operation.

基本安全指的是一种不会对病人造成伤害的装置，这种装置在操作过程中不会造成伤害。

BASIC SAFETY is often a passive form of protection (such as radiation shielding or electrical grounding).

基本安全通常是一种被动的保护形式（如辐射屏蔽或电气接地）。

ESSENTIAL PERFORMANCE generally relates to ME EQUIPMENT or ME SYSTEMS operating as intended without creating a HAZARD. A failure of ESSENTIAL PERFORMANCE can be either a lack of performance (such as life supporting performance) or incorrect performance (such as delivering an incorrect dose to the PATIENT). 基本性能通常与医用电气设备或医用电气系统按预期运行而不产生危害有关。基本表现的失败可以是缺乏表现（如维持生命的表现），也可以是不正确的表现（如给病人服用不正确的剂量）。

In general, BASIC SAFETY relates to product properties that are not device specific and ESSENTIAL PERFORMANCE relates to a class of products (such as a defibrillators being able to deliver the correct electrical shock). 一般来说，基本安全与产品特性有关，而这些特性与设备无关，基本性能与一类产品有关（例如除颤器能够发出正确的电击）。

While the terms BASIC SAFETY and ESSENTIAL PERFORMANCE are generally considered to be mutually exclusive, there are some HAZARDS that may relate to both BASIC SAFETY and ESSENTIAL PERFORMANCE concurrently. 虽然术语“基本安全”和“基本性能”通常被认为是互斥的，但也存在一些可能同时涉及基本安全和基本性能的危险。

Subclause
第3.15款-清晰易读

3.15

—

CLEARLY

LEGIBLE

Vision or visual acuity can be tested by reading a Snellen eye chart at a distance of 6 m. Near vision can be tested using a Jaeger test card. By examining a large number of people, doctors have decided what a “normal” human being should be able to see at various distances. That is the description of normal vision.

视力或视视力可以通过在6米远的地方阅读斯内伦眼图来测试。近视力可以使用Jaeger测试卡进行测试。通过对大量的人进行检查，医生们已经决定了一个“正常”的人应该能够在不同的距离上看到什么。这是对正常视力的描述。

Subclause 3.17 — COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS
第3.17款-具有高完整性特征的部件

The concept of high-integrity refers only to specific characteristics of the component. These characteristics are relied upon to ensure safety of the product. Such a COMPONENT WITH HIGH- INTEGRITY CHARACTERISTICS should be identified in the ACCOMPANYING DOCUMENTS by the MANUFACTURER (e.g. for maintenance). See also the rationale for 4.9.

高完整性的概念仅指组件的特定特性。这些特性是用来确保产品安全的。制造商应在随附文件中确定具有高完整性特征的此类部件（例如用于维护）。另见4.9的基本原理。

Subclause
第3.18款-连续运行

3.18

—

CONTINUOUS

OPERATION

While the terms CONTINUOUS OPERATION or non-CONTINUOUS OPERATION are used with regard to the ME EQUIPMENT, parts of the ME EQUIPMENT can be RATED differently. For example, an electrosurgical generator might be RATED for CONTINUOUS OPERATION while the APPLIED PART is RATED for non-CONTINUOUS OPERATION. 当术语“连续运行”或“非连续运行”用于医用电气设备时，医用电气设备的各部分可采用不同的额定值。例如，电外科发电机的额定值可能是连续运行，而应用部分的额定值是非连续运行。

Subclause 3.20
第3.20款-防除颤应用部分

—

DEFIBRILLATION-PROOF

APPLIED

PART

A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators complying with IEC 60601-2-4 [15]. Higher voltage defibrillators could damage DEFIBRILLATION-PROOF APPLIED PARTS.
防除颤应用部件仅受符合IEC 60601-2-4[15]的除颤器放电的保护。高电压除颤器可能损坏防除颤应用部件。

Subclause 3.21 – DETACHABLE POWER SUPPLY CORD
第3.21款-可拆卸电源线
Cord sets are covered by IEC 60320-1.
IEC 60320-1涵盖了电线组件。

Subclause 3.22 – DIRECT CARDIAC APPLICATION
第3.22款-直接心脏应用
A distinction is made between use of APPLIED PARTS that might come in direct contact with the PATIENT'S heart and all other circumstances of contact with the PATIENT. Ventricular fibrillation can be caused by a much smaller current flowing through a small contact area where a wire or catheter makes direct contact with the heart than a current flowing through any other point of contact on or in the PATIENT'S body.
对可能直接接触患者心脏的应用部件的使用和与患者接触的所有其他情况进行了区分。心室颤动可能是由于流经一个金属丝或导管直接接触心脏的小接触区的电流比流经病人身体上或身体内任何其他接触点的电流小得多。

Subclause 3.23 – DOUBLE INSULATION
第3.23款-双重绝缘
BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately. Where multiple layers of insulation cannot be tested separately, the insulation system is considered as REINFORCED INSULATION.
必要时，可单独测试基本绝缘和辅助绝缘。如果多层绝缘不能单独测试，则绝缘系统被视为加强绝缘。

Subclause 3.24 - DUTY CYCLE
第3.24款-占空比

The terms “on time” and “off time” are considered to include “bursts” of operation and deactivation as well as CONTINUOUS OPERATION.
术语“on time”和“off time”被认为包括操作和失活以及连续操作的“突发”。

Subclause 3.26 - ENCLOSURE
第3.26款-附件

The ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.
医用电气设备或医用电气设备部件的外壳包括所有可触及部件、旋钮、把手、电缆、连接器等。这包括其他独立部件之间外部连接的任何可触及部件。

Subclause 3.27 - ESSENTIAL PERFORMAMNCE
第3.27款-基本性能

It has long been recognized that ME EQUIPMENT or an ME SYSTEM that does not perform properly could result in unacceptable RISK for PATIENTS, OPERATORS, or others. All features or functions that must perform properly to prevent HARM to the PATIENT, OPERATOR or others are important, but not every feature or function of ME EQUIPMENT is ESSENTIAL PERFORMANCE. When a failure to perform would result in unacceptable RISK for the PATIENT, OPERATOR or others, then those features or functions are, for the purposes of this standard, seen as ESSENTIAL PERFORMANCE. Hence the concept of "safety" has been broadened from the BASIC SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters.
人们早就认识到，医用电气设备或医用电气系统如果不能正常工作，可能会给患者、操作员或其他人带来不可接受的风险。所有必须正确执行以防止对患者、操作员或其他人造成伤害的特性或功能都很重要，但并非医用电气设备的每个特性或功能都是必不可少的性能。如果未能执行将导致患者、操作员或其他人无法接受的风险，则在本标准中，这些特征或功能被视为基本性能。因此，“安全”的概念已从本标准第一版和第二版中的基本安全考虑扩大到包括基本性能问题。

Assessment of this RISK is made on the assumption that the performance aspect in question has been lost or degraded, and takes account of the probability that HARM would then occur (which in some instances could be 100 %) and the SEVERITY of that HARM. Application of the RISK MANAGEMENT PROCESS then ensures that the probability of loss of the performance aspect is low enough to make the RESIDUAL RISK acceptable.
对该风险的评估是在假设相关性能方面已经丢失或降低的情况下进行的，并考虑到随后发生损害的概率（在某些情况下可能是100%）和损害的严重性。然后应用风险管理过程，确保性能方面的损失概率足够低，以使剩余风险可接受。

A problem with ESSENTIAL PERFORMANCE exists when the feature or function in question is either absent or its characteristics are degraded to a point that the ME EQUIPMENT or ME SYSTEM is no longer suitable for its INTENDED USE.
当相关特征或功能缺失或其特性退化到医用电气设备或医用电气系统不再适合其预期用途时，存在基本性能问题。

In order to achieve its INTENDED USE, the ME EQUIPMENT or ME SYSTEM needs to perform within certain limits. These limits are usually specified by the MANUFACTURER but could be specified by this standard, a collateral standard or a particular standard in the IEC 60601 family.
为了达到预期用途，医用电气设备或医用电气系统需要在一定范围内工作。这些限值通常由制造商规定，但也可由本标准、附带标准或IEC 60601系列中的特定标准规定。

Examples of ESSENTIAL PERFORMANCE are:
基本性能示例如下：

- accuracy of a life-supporting function or correct administration of a drug by a syringe pump where inaccuracy/incorrect administration would cause an unacceptable RISK to the PATIENT;
维持生命功能的准确性或通过注射泵正确给药，其中不准确/不正确的给药会给患者带来不可接受的风险；
- the ability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator where the failure to recover could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT;
心电图机/监护仪从除颤器放电的影响中恢复的能力，在这种情况下，无法恢复可能导致医务人员做出不正确的反应，从而给患者带来不可接受的风险；
- correct operation of an ALARM SYSTEM in an intensive care or operating room monitoring system where an incorrect/missing ALARM SIGNAL could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT;
重症监护室或手术室监控系统中警报系统的正确操作，其中错误/缺失的警报信号可能导致医务人员做出不正确的响应，从而给患者带来不可接受的风险；或
- correct output of diagnostic information from ME EQUIPMENT that is likely to be relied upon to determine treatment, where incorrect information could lead to an inappropriate treatment that would present an unacceptable RISK to the PATIENT.
医用电气设备诊断信息的正确输出，可能会依赖这些信息来确定治疗方案，不正确的信息可能导致不适当的治疗，从而给患者带来不可接受的风险。

ESSENTIAL PERFORMANCE is identified without taking into account the probability of occurrence of factors that could result in a loss of functionality. These factors are taken into account in the RISK MANAGEMENT PROCESS.
基本性能确定不考虑可能导致功能丧失的因素的发生概率。在风险管理过程中考虑到这些因素。

For purposes of this standard, performance related to BASIC SAFETY aspects of the ME EQUIPMENT, such as the performance of BASIC INSULATION, is not considered to be ESSENTIAL PERFORMANCE.
在本标准中，与医用电气设备基本安全方面有关的性能，如基本绝缘性能，不被视为基本性能。

Particular and collateral standards in the IEC 60601 family are expected to identify specific IEC 60601系列中的特殊标准和附属标准将识别特定的 ESSENTIAL PERFORMANCE.
基本性能。

Subclause 3.33 – FUNCTIONAL CONNECTION

第3.33款-功能连接

The defined term FUNCTIONAL CONNECTION is used to facilitate the definition of an ME SYSTEM. The FUNCTIONAL CONNECTION is a coupling between items of an ME SYSTEM, including the possibility of supplying power. 定义的术语功能连接用于帮助定义医用电气系统。功能连接是医用电气系统各部件之间的耦合，包括供电的可能性。

The phrase “or otherwise” could include mechanical, optical or wireless connections for example. 例如，短语“或其他”可以包括机械、光学或无线连接。

Subclause 3.35 – FUNCTIONAL EARTH TERMINAL

第3.35款-功能性接地端子

In ME EQUIPMENT, functional earth connections can be made by means of a FUNCTIONAL EARTH TERMINAL that is accessible to the OPERATOR. Alternatively this standard also allows a functional earth connection for CLASS II ME EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts to which this conductor is connected cannot be ACCESSIBLE PARTS (see 8.6.9), and have to be insulated from ACCESSIBLE PARTS.

在医用电气设备中，功能性接地连接可通过操作员可接近的功能性接地端子进行。或者，本标准还允许通过电源线中的绿色和黄色导线为II类医用电气设备提供功能性接地连接。在这种情况下，与该导线连接的部件不能是可触及部件（见8.6.9），必须与可触及部件绝缘。

Subclause 3.38 – HARM

第3.38款-损害

The definition of HARM is based on the definition in ISO 14971 modified to include animals. This change was made since the scope of the IEC 60601-1 includes the safety of animals.

伤害的定义基于ISO 14971中的定义，修改后包括动物。这一变化是因为IEC 60601-1的范围包括动物的安全。

Subclause 3.40 – HAZARDOUS SITUATION

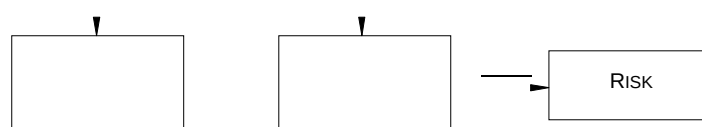
第3.40款-危险情况

As used in this standard, a HAZARD cannot result in HARM until such time as a sequence of events or other circumstances (including NORMAL USE) lead to a HAZARDOUS SITUATION. As a result of the RISK MANAGEMENT PROCESS, the related RISK acceptability can be assessed by estimating both SEVERITY and probability of occurrence of the HARM that could result from this HAZARDOUS SITUATION (see Figure A.8 adapted from the draft text of the 2nd edition of the ISO 14971).

如本标准所用，在一系列事件或其他情况（包括正常使用）导致危险情况之前，危害不会导致损害。作为风险管理过程的结果，相关的风险可接受性可以通过估计这种危险情况可能造成的危害的严重性和发生概率来评估（见图a.8，改编自ISO 14971第2版的草案文本）。

Exposure (P1)

暴露（P1）



NOTE P1 is the probability of a HAZARDOUS SITUATION occurring.
注P1是发生危险情况的概率。

P2 is the probability of a HAZARDOUS SITUATION leading to a HARM.
P2是危险情况导致伤害的概率。

Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events,
图A.8——危害关系、事件顺序的图示，
HAZARDOUS SITUATION and HARM
危险情况和危害

Subclause

3.44

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INTENDED

USE

第3.44款-预期用途

ISO 14971:2000 defined the compound term INTENDED USE/INTENDED PURPOSE because, at the time that version was being developed, there was no consensus on which term to use. The European Medical Device Directive uses “intended purpose,” whereas the United States regulations use “intended use.” Both terms have essentially the same definition. After some year of experience with applying ISO 14971, it has generally been accepted that the combined term is unwieldy and a consensus has emerged to use the shorter term “intended use.” The second edition of ISO 14971 (in preparation) is expected to use “intended use” as the preferred term with “intended purpose” being an “admitted term.” To avoid being out of step with the future edition of ISO 14971, this standard has adopted the shorter defined term INTENDED USE. The definition itself is identical to that in ISO 14971:2000 and to the definition that is expected to be in the second edition of ISO 14971. 在2000年版中，ISO/1471中的术语被定义为“一致目的”，因为该术语在2000年被定义为“复合物”。欧洲医疗器械指令使用“预期用途”，而美国法规使用“预期用途”。这两个术语的定义基本相同。在应用ISO 14971一年的经验之后，人们普遍认为组合术语不实用，并且一致同意使用较短的术语“预期用途”。ISO 14971第二版（编制中）将使用“预期用途”作为首选术语，“预期用途”是指“认可术语”。为避免与ISO 14971的未来版本不一致，本标准采用了定义较短的术语“预期用途”。定义本身与ISO 14971:2000中的定义以及ISO 14971第二版中预期的定义相同。

Subclause

3.49

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MAINS

PART

第3.49款-电源部分

A definition of MAINS PART is needed to identify the parts to which certain requirements apply. The definition given in the first and second editions of this standard depended on another defined term, “conductive connection.” During the development of this edition, a difficulty with the definition of “conductive connection” became apparent and the requirements were revised so the defined term was no longer needed. This necessitated a new definition of MAINS PART focussing on the MEANS OF PROTECTION that separate the MAINS PART from other parts. 需要对电源部件进行定义，以确定某些要求适用的部件。本标准第一版和第二版中给出的定义依赖于另一个定义术语“导电连接”。在本版本的开发过程中，“导电连接”的定义出现了明显的困难，并且对要求进行了修订，因此不再需要定义的术语。这就需要对电源部分进行新的定义，重点放在将电源部分与其他部分分开的保护方法上。

Subclause

3.50

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MAINS

PLUG

第3.50款-电源插头

A definition of MAINS PLUG is needed to identify the plug to which certain requirements apply. The words “mains plug” without a definition would also cover other connectors within ME EQUIPMENT that carry MAINS VOLTAGE. 需要对电源插头进行定义，以确定适用于特定要求的插头。没有定义的“电源插头”也包括医用电气设备内携带电源电压的其他连接器。

Subclause

3.56

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MAXIMUM

MAINS

VOLTAGE

第3.56款-最大电源电压

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown but it is assumed to be related to the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used. See also the rationale for 8.5.3. 本标准的一些要求和试验与来自外部电源的意外电压连接到患者或医用电气设备的某些部分的可能性有关。这种电压的实际大小是未知的，但假定它与医用电气设备使用位置的电源电压有关。另见8.5.3的基本原理。

In the early stages of preparing this edition, a defined term “reference supply voltage” was introduced to avoid repetition of extensive wording. During the review of the National Committees’ comments on an early draft, it became apparent that there was some confusion between the defined term “reference supply voltage” and the undefined term “reference voltage” which was used in relation to the requirements for dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES. 在编写本版本的早期阶段，引入了一个定义的术语“参考电源电压”，以避免重复大量的措辞。在审查国

家委员会对早期草案的意见时，很明显，在定义的术语“参考电源电压”和未定义的术语“参考电压”之间存在一些混淆，后者用于电介质强度、爬电距离和空气间隙的要求。

In order to clarify the requirements, the term “reference supply voltage” has been replaced by MAXIMUM MAINS VOLTAGE and “reference voltage” has been replaced by the defined terms WORKING VOLTAGE and PEAK WORKING VOLTAGE. 为了澄清要求，术语“参考电源电压”已被最大电源电压取代，“参考电压”已被定义的术语工作电压和峰值工作电压取代。

Subclause 3.57 – MAXIMUM PERMISSIBLE WORKING PRESSURE
第3.57款-最大允许工作压力

The MAXIMUM PERMISSIBLE WORKING PRESSURE is decided by a competent person, taking into account the original design specification, the manufacturer's rating, the current condition of the vessel and the circumstances of use. 最大允许工作压力由合格人员决定，并考虑原始设计规范、制造商额定值、容器当前状况和使用环境。

In some countries, the figure could be reduced from time to time. 在一些国家，这一数字可能会不时减少。

Subclause3.58–MEANSOFPROTECTION

第3.58款-保护手段

One guiding principle in the development of the third edition of this standard was to make it less prescriptive than the second edition, especially Clauses 17 and 20 of the second edition. The concept of MEANS OF PROTECTION was conceived as a generic one that could cover a number of things such as PROTECTIVE EARTH CONNECTIONS, BASIC INSULATION, SUPPLEMENTARY

本标准第三版制定过程中的一个指导原则是使其规定性低于第二版，尤其是第二版第17和第20条。保护手段的概念被认为是一个通用的概念，可以涵盖许多东西，如保护接地连接、基本绝缘、补充

INSULATION, impedances, etc; and that might also be expanded to include other things which serve in the same capacity but have not yet been envisaged or are not yet practical. This concept, with the general requirement for ME EQUIPMENT to have two MEANS OF PROTECTION, fitted in well with the single fault philosophy, which all agreed was to be retained in the third edition. It enables a consistent approach to carry through a design effort without getting bogged down in the wordy prescriptive subclauses.

绝缘、阻抗等；也可以扩大到包括其他相同容量但尚未设想或不实用的东西。这一概念，一般要求医用电气设备有两种保护手段，与单一故障原理很好地吻合，所有人都同意在第三版中保留。它使一致的方法能够执行设计工作，而不会陷入冗长的规定性子条款中。

The concept also fitted in well when it was decided to differentiate protection of PATIENTS from protection of OPERATORS.
当决定区分保护病人和保护操作者时，这一概念也很适合。

Some National Committee comments during the development of this edition suggested that the concept could be extended to apply to protection against HAZARDS other than electric shock. However it was decided that such a change would not be justified by the benefits. 国家委员会在编写本版本期间的一些评论建议，这一概念可以扩展到适用于电击以外的危险防护。不过，会议决定，这样的改变不会以好处为理由。

Subclause3.59–MEANSOFPATIENTPROTECTION

第3.59款-患者保护方法

See the rationale for 8.5.1.

见8.5.1的基本原理。

Subclause3.60–MEANSOFOPERATORPROTECTION

第3.60款-操作员保护方法

See the rationale for 8.5.1.

见8.5.1的基本原理。

Subclause3.63–MEDICALELECTRICALEQUIPMENT

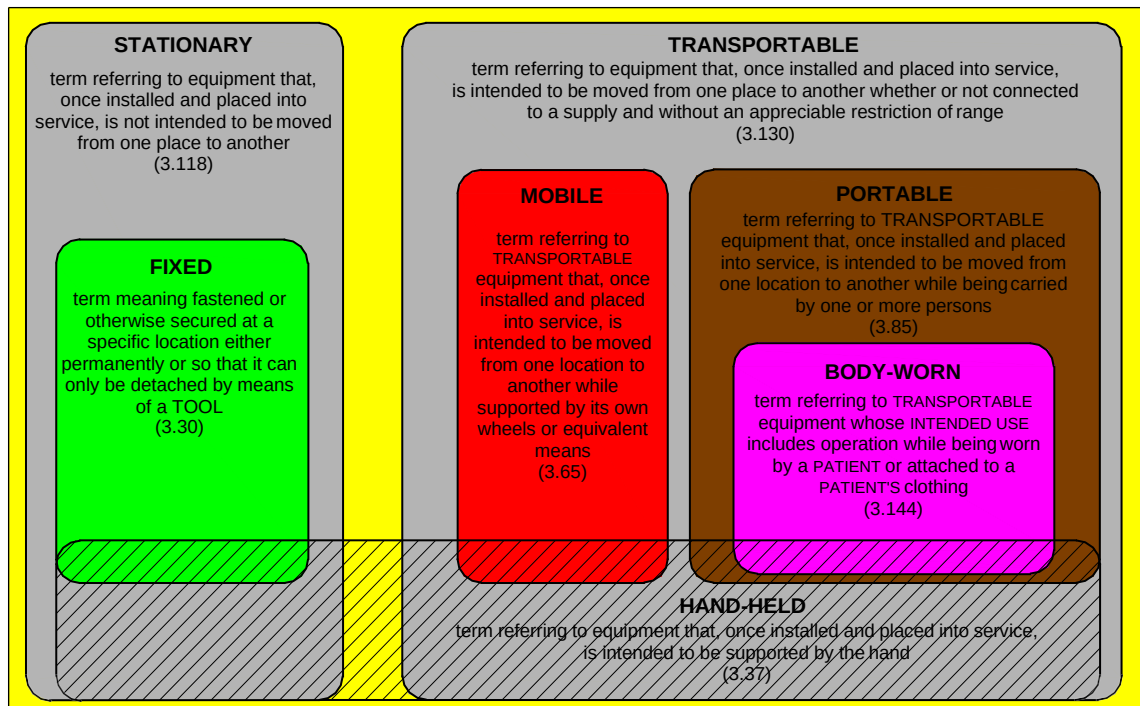
第3.63款-医用电气设备

The present definition of ME EQUIPMENT excludes multiple connections to the same particular SUPPLY MAINS, but does not exclude different connectors to different particular SUPPLY MAINS. However, connection to more than one of different SUPPLY MAINS at the same time should be avoided. While it might be possible to design equipment with provision to be connected simultaneously to two different SUPPLY MAINS in an electrically safe manner, the particular HAZARDS HAZARDOUS SITUATIONS that might arise have not been identified in this standard. 医用电气设备的当前定义不包括与同一特定电源干线的多个连接，但不排除连接到不同特定电源干线的不同连接器。但是，应避免同时连接多个不同的电源干线。虽然设计设备时可能会以电气安全的方式同时连接到两个不同的电源干线上，但本标准并未确定可能出现的特殊危险和危险情况。

This standard applies several terms to describe ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts. They are FIXED (3.30), STATIONARY (3.118), TRANSPORTABLE (3.130), MOBILE (3.65), PORTABLE (3.85), HAND-HELD (3.37) and BODY-WORN (3.144). To help in

本标准适用于多个术语来描述医用电气设备、附件和医用电气设备部件。它们分别是固定式（3.30）、固定式（3.118）、可移动式（3.130）、移动式（3.65）、便携式（3.85）、手持（3.37）和穿戴式（3.144）。帮助

understanding the relationship of these terms, the chart in Figure A.20 was developed. 为了理解这些术语之间的关系，绘制了图A.20中的图表。



IEC 1422/12
 IEC 1422/12标准

Figure A.20 – Relationship of the terms used to describe equipment,
图A.20–用于描述设备的术语之间的关系，
ACCESSORIES or equipment

parts Subclause 3.64 – MEDICAL ELECTRICAL SYSTEM

附件或设备零件第3.64款-医疗电气系统

It is common practice for MANUFACTURERS, RESPONSIBLE ORGANISATIONS and OPERATORS to connect ME EQUIPMENT and other medical or non-medical equipment to MULTIPLE SOCKET- OUTLETS. The inclusion of such arrangements within the definition of ME SYSTEM brings them within the scope of this standard and thus allows appropriate requirements to be specified for BASIC SAFETY and ESSENTIAL PERFORMANCE. 制造商、责任机构和操作员通常将医用电气设备和和其他医疗或非医疗设备连接到多个插座。在医用电气系统的定义中包含此类装置，使其处于本标准的范围内，从而允许对基本安全和基本性能规定适当的要求。

To minimize the impairment of the safety level of this standard, the connection of a MULTIPLE SOCKET-OUTLET to the SUPPLY MAINS is subject to certain conditions. Subclause 16.9.2.1 requires that MULTIPLE SOCKET-OUTLETS are constructed to comply with the requirements from this standard applying to ME EQUIPMENT. 为尽量减少对本标准安全水平的损害，将多个插座连接到电源干线上要遵守一定的条件。子条款16.9.2.1要求多个插座的构造符合本标准中适用于医用电气设备的要求。

Subclause 3.66 – MODEL OR TYPE REFERENCE
 第3.66款-型号或型号参考

The MODEL OR TYPE REFERENCE is intended to establish the relationship of the ME EQUIPMENT to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of ME EQUIPMENT. It is also important for identifying of ME EQUIPMENT or ACCESSORIES in case of a safety alert or other required field action.

型号或型号参考旨在建立医用电气设备与商业和技术出版物、随附文件以及医用电气设备可分离部件之间的关系。在出现安全警报或其他要求的现场行动时，识别医用电气设备或附件也很重要。

Subclause 3.67 – MULTIPLE SOCKET-OUTLET

第3.67款-多个插座

The definition is derived from IEC 60884-1.

该定义源自IEC 60884-1。

In the second edition of IEC 60601-1-1 [13], there were definitions for multiple portable socket-outlet and auxiliary mains socket-outlet. In this edition, these definitions have been merged. 在IEC 60601-1-1[13]第二版中，有多个便携式插座和辅助电源插座的定义。在本版中，这些定义已合并。

A single socket-outlet forming part of an equipment is also considered a MULTIPLE SOCKET-OUTLET.

构成设备一部分的单个插座也被视为多个插座。

MULTIPLE SOCKET-OUTLETS are sometimes necessary and offer advantages and disadvantages, which have to be investigated in order to establish a balance. MULTIPLE SOCKET-OUTLETS might be necessary for the following reasons:
多个插座有时是必要的, 并提供优点和缺点, 为了建立一个平衡, 必须对其进行调查。由于以下原因, 可能需要多个插座:

- to minimize the number of POWER SUPPLY CORDS lying on the floor;
尽量减少地板上的电源线数量;
- to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED mains socket-outlets;
在固定电源插座数量不足的情况下, 允许使用进行适当治疗或诊断所需的所有设备;
- to improve mobility by having all equipment on one trolley;
将所有设备放在一个手推车上, 以提高机动性;
- to reduce potential differences within the protective earth wiring to below those that occur in some FIXED installations.
将保护接地线路内的电位差降低到某些固定装置中出现的电位差以下。

The use of MULTIPLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

应尽量避免使用多个插座, 原因如下:

- combined EARTH LEAKAGE CURRENTS could result in:
综合接地漏电电流可能导致:
 - excessive EARTH LEAKAGE CURRENT in NORMAL CONDITION,
正常情况下接地漏电电流过大,
 - excessive TOUCH CURRENT in the SINGLE FAULT CONDITION of the broken PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET supply cable;
多插座供电电缆的保护接地导体断裂的单一故障情况下的接触电流过大;
- availability of the SUPPLY MAINS depends on the reliability of a single FIXED mains socket-outlet;
供电电源的可用性取决于单个固定电源插座的可靠性;
- a complete interruption of electrical supply is possible and might require a long set-up time to reactivate the complete ME SYSTEM;
电源完全中断是可能的, 可能需要较长的设置时间才能重新启动整个医用电气系统;
- only one PROTECTIVE EARTH CONNECTION to the electrical installation is provided; this is less reliable than when each part of the ME SYSTEM is directly earthed;
仅提供一个与电气装置的保护接地连接; 这比医用电气系统的每个部分直接接地时更不可靠;
- the protective earth resistance is increased.
保护接地电阻增大。

The optimum solution includes installing an adequate number of FIXED mains socket-outlets according to appropriate installation rules.

最佳解决方案包括根据适当的安装规则安装足够数量的固定电源插座。

Subclause 3.68 – NETWORK/DATA COUPLING

第3.68款-网络/数据耦合

The definition of NETWORK/DATA COUPLING has been written so as not to be restricted to any particular technology, such as electronic transmission along wires. The definition allows for wireless electromagnetic transmission, infra-red, optical, etc., as well as any future technology.
网络/数据耦合的定义是为了不局限于任何特定技术, 例如沿导线的电子传输。这个定义允许无线电磁传输、红外线、光学等, 以及任何未来的技术。

Subclause 3.73 – OPERATOR

第3.73款-操作员

The OPERATOR is defined as the person who handles the equipment, which could be
操作员被定义为操作设备的人员，可以是

ME EQUIPMENT or any item of equipment in the context of an ME SYSTEM. This person could be:
医用电气设备或医用电气系统中的任何设备。此人可以是：

- a health care professional using the equipment with a PATIENT,
一个医护人员在病人身上使用设备，
- either a PATIENT or a layperson assisting a PATIENT in a home-care environment,
在家庭护理环境中帮助患者的患者或外行人员，
- a person who is using the equipment to compensate or alleviate the effects of disease,
injury or disability, or
使用设备补偿或减轻疾病、伤害或残疾影响的人员，或
- the person that installs, assembles, maintains or repairs the equipment.
安装、装配、维护或修理设备的人。

People who install, assemble, maintain or repair the equipment are also referred to in this standard as
SERVICE PERSONNEL.

在本标准中，安装、组装、维护或修理设备的人员也被称为维修人员。

Many requirements in this standard are constructed so that SERVICE PERSONNEL experience the same RESIDUAL RISK as the person who uses the equipment for its INTENDED USE. However, SERVICE PERSONNEL, who are often engineers or engineering technicians, are expected to have certain competencies and to take account of the technical description. Other OPERATORS are expected to have different competencies and to follow the instructions for use. Therefore, this standard presumes in certain circumstances that the safety of SERVICE PERSONNEL depends partly on their knowledge and training to take appropriate precautions when gaining access to hazardous parts. The other OPERATORS are presumed to be competent to use the
本标准中的许多要求都是为了使维修人员和使用设备达到预期用途的人员一样，经历同样的残余风险。然而，服务人员，通常是工程师或工程技术人员，应具备一定的能力，并考虑到技术说明。其他操作员应具备不同的能力，并遵循使用说明。因此，本标准假定在某些情况下，维修人员的安全部分取决于他们在接触危险部件时采取适当预防措施的知识 and 培训。假定其他操作员有能力使用

ME EQUIPMENT or ME SYSTEM but are not necessarily competent to avoid RISKS that can arise during servicing.
医用电气设备或医用电气系统，但不一定能够避免在维修过程中可能出现的风险。

Subclause 3.75 – OXYGEN RICH ENVIRONMENT
第3.75款-富氧环境

At a 25 % oxygen concentration, the increase in the burning rate of a paper strip is only moderate (30 %) (per NFPA 99 [42]). In NFPA 99, 23,5 % is defined to be oxygen-enriched atmosphere that requires protective measures, but it allows this value also for oxygen chambers at pressures of more than 200 kPa. NASA allows concentrations of 25,9 % in its space shuttles (NFPA 53 [41]). UL 2601-1 [44] uses 25 % as threshold value. A sample of epoxy circuit board material burns incompletely at 20,9 % and 25,9 % (burning length of 3 cm and 8,3 cm) but completely at 30 % according to Rimanosky, E.M. et al., ASTM STP 1267 [36].
在25%的氧气浓度下，纸带燃烧速度的增加只是适度的（30%）（根据NFPA 99[42]）。在NFPA 99中，23.5%被定义为需要保护措施的富氧大气，但它也允许在压力超过200 kPa的氧气室中使用该值。美国宇航局航天飞机的NFPA浓度为25.53%。UL 2601-1[44]使用25%作为阈值。根据Rimanosky, E.M.等人，ASTM STP 1267[36]，环氧电路板材料样品在20,9%和25,9%（燃烧长度为3 cm和8,3 cm）时不完全燃烧，但在30%时完全燃烧。

When first considering the relationship between flame rate and the amount of oxygen, it would seem reasonable that the flame rate would be proportional to the total locally available amount of oxygen, which is given by the partial pressure. However, experience shows that this is only true to a degree. Figures C-1.2.2(a) and (b) in NFPA 53:1999 and Figure
当首先考虑火焰速度和氧气量之间的关系时，似乎合理的做法是，火焰速率与局部总可用氧气量成正比，这是由分压得出的。然而，经验表明，这在一定程度上是正确的。NFPA 53:1999中的图C-1.2.2（a）和（b）以及图

A.3.3.14.4 in NFPA 99:2002 show that for paper strips the increase of flame rate with oxygen concentration at a set absolute pressure is stronger than the increase of flame rate with absolute pressure at a set concentration. For the borderline “complete combustion” to “incomplete combustion” the oxygen concentration seems to come to the same number (14 %) at high pressures, independent of the absolute (and partial) pressure. Therefore, to be on the safe side, two numbers are given in the definition. The concentration limit makes sure that for smaller ambient pressures than one atmosphere the danger does not increase. The partial pressure limit makes sure that for higher pressures (e.g. in oxygen chambers) the situation is safe.
A、NFPA 99:2002中的3.3.14.4表明，对于纸带，在设定的绝对压力下，火焰速率随氧气浓度的增加而增加，而在设定浓度下，随绝对压力而增加的火焰速率更大。对于“完全燃烧”到“不完全燃烧”的边界，氧浓度在高压下似乎达到相同的数值（14%），与绝对（和分）压力无关。因此，为了安全起见，定义中给出了两个数字。浓度限值确保在小于一个大气压的环境压力下，危险不会增加。分压限制可确保较高压力（如氧气室）的情况是安全的。

Subclause 3.77 – PATIENT AUXILIARY CURRENT
第3.77款-患者辅助电流

PATIENT AUXILIARY CURRENT is a current that is necessary for:
患者辅助电流是指：

- the ME EQUIPMENT to perform its function, e.g. electrical impedance imaging, monitoring of respiration by impedance changes;
执行其功能的医用电气设备，如电阻抗成像、通过阻抗变化监测呼吸；
- monitoring the correct operation of the ME EQUIPMENT, e.g. contact impedance of electrodes with the PATIENT;
监控医用电气设备的正确操作，例如电极与患者的接触阻抗；
- the functioning of the ME EQUIPMENT;
医用电气设备的功能；

or that is incidental to the functioning of the ME EQUIPMENT. An example is the bias current of an amplifier for physiological signals.
或者是医用电气设备工作时附带的。例如生理信号放大器的偏置电流。

PATIENT AUXILIARY CURRENT could have a function, but not a physiological function, or it could have no function.
病人辅助电流可能有功能，但不是生理功能，也可能没有功能。

Subclause 3.78 – PATIENT CONNECTION
第3.78款-病人联系

One of the HAZARDS associated with the application of PATIENT CONNECTIONS is the fact that LEAKAGE CURRENT can flow through the PATIENT via the PATIENT CONNECTIONS. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.
与患者连接应用相关的危险之一是，泄漏电流可以通过患者连接流过患者。在正常条件下和各种故障条件下，对这些电流的大小有特殊的限制。

NOTE The current that flows through the PATIENT between various PATIENT CONNECTIONS is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT that flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.
注意在不同的病人连接之间流过病人的电流称为病人辅助电流。通过病人流到地上的漏电流称为病人漏电流。

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current could flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT could flow into an earthed PATIENT.
患者连接的定义旨在确保识别应用部分的每个单独部分，其中电流可以作为患者辅助电流流动，并且患者泄漏电流可以从该部分流入接地患者。

In some cases it will be necessary to carry out PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements to determine which parts of the APPLIED PARTS are individual PATIENT CONNECTIONS.
对病人个别部位的电流进行测量是必要的。

PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART that come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps that do not comply with the relevant dielectric strength tests or AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS. See also the rationale for 3.8. 患者的连接并不总是可以接触到的。应用部件的任何导电部件与患者发生电气接触，或仅通过不符合本标准中规定的相关介电强度试验或空气间隙和爬电距离要求的绝缘或气隙阻止其接触的任何导电部件均为患者连接。另见3.8的基本原理。

Examples include the following.

示例包括以下内容。

- A table top supporting a PATIENT is an APPLIED PART. Sheets do not provide adequate insulation and the conductive parts of the table top would therefore be classified as PATIENT CONNECTIONS. 支撑患者的桌面是应用部件。床单不能提供足够的绝缘性，因此桌面的导电部分将被归类为患者连接。
- The administration set or needle of an infusion controller is an APPLIED PART. Conductive parts of the controller separated from the (potentially conducting) fluid column by inadequate insulation would be PATIENT CONNECTIONS. 输液控制器的给药装置或针头是应用部件。控制器的导电部分因绝缘不足而与（可能导电的）液柱分离，应为患者连接。

Where an APPLIED PART has a surface of insulating material, 8.7.4.7 d) specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

如果应用部件具有绝缘材料表面，8.7.4.7 d) 规定使用箔或盐水进行试验。这就被视为与病人的联系。

Subclause 3.79 – PATIENT ENVIRONMENT

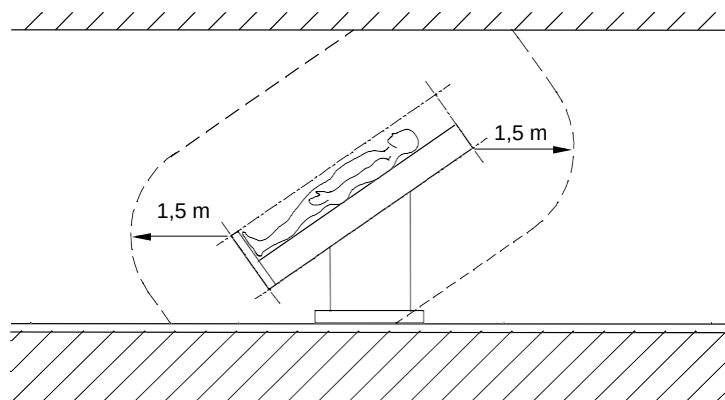
第3.79款-患者环境

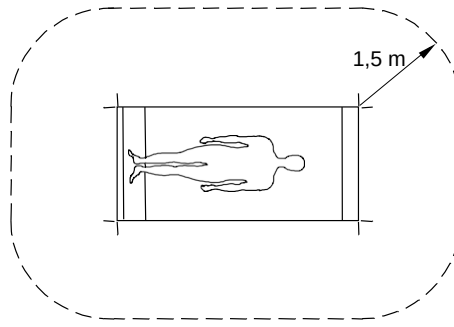
It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure

本标准很难定义诊断、监测或治疗发生的容积的尺寸。图中给出了患者环境的尺寸

A.9 have been justified in practice.

A、9在实践中是合理的。





IEC 2431/05
IEC 2431/05标准

NOTE The dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

注意图中的尺寸显示了自由环境中患者环境的最小范围。

Figure A.9 – Example of PATIENT ENVIRONMENT
图A.9—患者环境示例

Subclause 3.81 – PEAK WORKING VOLTAGE

第3.81款-峰值工作电压

This definition was taken from IEC 60950-1:20012005, subclause 1.2.9.7 1.2.9.8. Use of this term along with the defined term WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56. 该定义摘自IEC 60950-1:20012005第1.2.9.7款1.2.9.8。将该术语与定义的工作电压一道使用，应使已熟悉该标准的人员更容易理解IEC 60950-1中包含的绝缘协调要求。另见3.56的基本原理。

Subclause 3.99 – REINFORCED INSULATION

第3.99款-加强绝缘

The term “insulation system” does not imply that the insulation has to be one homogeneous piece. It could comprise several layers that cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

术语“绝缘系统”并不意味着绝缘必须是一个均匀的部件。它可以包括几层，不能作为补充或基本绝缘单独测试。

Subclause 3.110 – SECONDARY CIRCUIT

次级电路-110

This definition is based on the definition of the same term in IEC 60950-1:20012005, subclause 1.2.8.4 1.2.8.5 and identifies circuits that are subject to lower transient overvoltages than the MAINS PART and therefore have lower values for dielectric strength test voltages and AIR CLEARANCES. 该定义基于IEC 60950-1:20012005第1.2.8.4款1.2.8.5款中同一术语的定义，并确定了承受比电源部分更低的瞬态过电压的电路，因此具有更低的介电强度试验电压和空气间隙值。

Subclause 3.112 – SEPARATION DEVICE

第3.112款-分离装置

Assembly of equipment into an ME SYSTEM could involve connections that transfer power or signals. In both cases, the same separation requirements are needed.

将设备装配到医用电气系统中可能涉及传输功率或信号的连接。在这两种情况下，需要相同的分离要求。

Subclause 3.115 – SIGNAL INPUT/OUTPUT PART

第3.115款-信号输入/输出部分

If a SIGNAL INPUT/OUTPUT PART carries electrical signals, or if it carries non-electrical signals but nevertheless introduces a conductive connection to the other equipment (e.g. through an optical fibre cable with a metal sheath), appropriate separation from other circuits can be necessary to satisfy the requirements of this standard. Alternatively a SIGNAL INPUT/OUTPUT PART could have no conductive connections, in which case it will automatically satisfy the requirements for electrical BASIC SAFETY.

如果信号输入/输出部分携带电信号，或者如果它携带非电信号，但仍然引入了与其他设备的导电连接（例如，通过带有金属护套的光缆），则需要与其他电路进行适当的分离，以满足本标准的要求。或者，信号输入/输出部分可以没有导电连接，在这种情况下，它将自动满足电气基本安全的要求。

Subclause 3.120 – SUPPLY MAINS

第3.120款-供电干线

An external d.c. power source (e.g. in an ambulance) is considered as a SUPPLY MAINS. ME EQUIPMENT specified for connection to such a power source has to satisfy all requirements for mains powered ME EQUIPMENT. In the past, some ME EQUIPMENT specified for such a power source has had a direct connection between the ENCLOSURE and one side of the supply, presumed to be at earth potential. In the event of interruption of the connection to this side of the supply, the ENCLOSURE of such ME EQUIPMENT assumes the supply potential and would therefore exceed the specified limit for TOUCH CURRENT. The first and second editions of this standard were intended to exclude such an arrangement, but this was not always understood by users of the standard. This rationale has been added to clarify the requirement. 外部直流电源（如救护车）被视为电源。指定用于连接此类电源的医用电气设备必须满足市电医用电气

设备的所有要求。在过去，为此类电源指定的一些医用电气设备在外壳和电源一侧之间有直接连接，假定处于接地电位。如果与该侧电源的连接中断，此类医用电气设备的外壳将承担供电电位，因此将超过规定的接触电流限值。本标准的第一版和第二版旨在排除此类安排，但本标准的用户并不总是理解这一点。添加此基本原理是为了澄清要求。

Subclause 3.132 – TYPE B APPLIED PART
第3.132款——B类应用部件

TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of
B型应用部件为所有类型的患者提供最低程度的保护
APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.
应用部分和不适合直接心脏应用。

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART could be:
B型应用部件的患者连接可以是：

- PROTECTIVELY EARTHED;
保护接地；
- connected to earth but not PROTECTIVELY EARTHED; or
接地但未保护接地；或
- floating, but not isolated from earth to the degree that would be required for a TYPE BF APPLIED PART.
浮动的，但不与地面隔离到BF型应用部件所需的程度。

Subclause3.133—TYPEBFAPPLIEDPART

第3.133款——BF型应用部件

TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This is achieved by isolating the PATIENT CONNECTIONS from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event that an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTIONS and earth. However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

BF型应用部件比B型应用部件提供更高程度的患者保护。这是通过将患者连接与医用电气设备的接地部件和其他可触及部件隔离来实现的，从而限制了当来自外部电源的意外电压连接到患者时流过患者的电流大小，从而应用于病人与大地的连接。然而，BF型应用部件不适合直接心脏应用。

Subclause3.134—TYPECFAPPLIEDPART

第3.134款——CF型应用部件

TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This is achieved by increased isolation of the PATIENT CONNECTION from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION insofar as PATIENT LEAKAGE CURRENT is concerned, though they could be unsuitable in other respects, such as sterility or biocompatibility.

CF型应用部件提供最高程度的患者保护。这是通过增加患者连接与医用电气设备接地部件和其他可触及部件的隔离来实现的，从而进一步限制通过患者的可能电流大小。就患者漏电流而言，CF型应用部件适用于直接心脏应用，但在其他方面，如无菌性或生物相容性可能不适用。

Subclause3.139—WORKINGVOLTAGE

第3.139款-工作电压

This definition is taken from IEC 60950-1:20012005, subclause 1.2.9.6. Use of this term along with the defined term PEAK WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56.

该定义摘自IEC 60950-1:20012005第1.2.9.6款。从IEC 601标准中定义的电压协调术语应更容易理解。另见3.56的基本原理。

Subclause4.1—Conditions for application to ME EQUIPMENT or ME SYSTEMS

第4.1款-医用电气设备或医用电气系统应用条件

The condition for application of RISK MANAGEMENT to ME EQUIPMENT and ME SYSTEMS includes reasonable reasonably foreseeable misuse. The MANUFACTURER identifies foreseeable misuse as part of the RISK ANAYLSIS (see ISO 14971:2000, subclause 4.2). This identification could include the results of a USABILITY ENGINEERING PROCESS.

医用电气设备和医用电气系统应用风险管理的条件包括合理可预见的误用。制造商将可预见的误用确定为风险分析的一部分（见ISO 14971:2000，第4.2款）。这种识别可以包括可用性工程过程的结果。

Subclause4.2—RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

第4.2款-医用电气设备或医用电气系统的风险管理流程

A change introduced in the third edition of this standard is that, in specifying minimum BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, provision is made for assessing the adequacy of the design PROCESS where this provides an appropriate alternative to the application of laboratory

testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies). Application of this principle leads to the introduction of a general requirement to carry out elements of a RISK MANAGEMENT PROCESS as part of demonstrating compliance with this standard. 本标准第三版中引入的变更是，在规定最低基本安全和基本性能要求时，对设计过程的充分性进行了评估，这为使用特定的合格/不合格标准的实验室试验提供了适当的替代方案，（例如，评估新技术的安全性）。这一原则的应用导致引入一个一般要求，以执行风险管理过程的要素，作为证明遵守本标准的一部分。

The MANUFACTURER is responsible for ensuring that the design and construction of the ME EQUIPMENT renders it suitable for its INTENDED PURPOSE USE and that any RISKS that are associated with its use are acceptable when weighed against the benefits. ISO 14971 specifies a PROCEDURE for the MANUFACTURER to identify HAZARDS associated with the ME EQUIPMENT or ME SYSTEM and its ACCESSORIES, to estimate and evaluate the RISKS associated with those HAZARDS, and to control those RISKS, and to monitor the effectiveness of that control. 制造商应负责确保医用电气设备的设计和结构使其适合其预期用途，并确保与使用相关的任何风险在权衡效益时是可接受的。ISO 14971规定了制造商识别与医用电气设备或医用电气系统及其附件相关的危险，评估和评估与这些危险相关的风险，控制这些风险，并监控控制的有效性的程序。

The scope of this standard is confined to type examination of ME EQUIPMENT and ME SYSTEMS; it does not extend to lifecycle monitoring. For this reason, the monitoring of production and post-production information and the planning thereof, as required by ISO 14971:2007, is excluded from the RISK MANAGEMENT PROCESS described in this standard. The requirement in ISO 14971:2007 for periodic review of the suitability of the RISK MANAGEMENT PROCESS is also excluded. 本标准的范围仅限于医用电气设备和医用电气系统的型式检验；不适用于生命周期监测。因此，根据ISO 14971:2007的要求，生产和生产后信息的监控及其规划不在本标准所述的风险管理过程中。ISO 14971:2007中关于风险管理过程适用性的定期评审要求也不包括在内。

Compliance with the clauses of this standard that contains specific, verifiable requirements is presumed to reduce the associated RISK(S) to an acceptable level. 遵守本标准中包含具体、可验证要求的条款，可将相关风险降低至可接受水平。

The MANUFACTURER of ME SYSTEMS should make this determination on a system level. The MANUFACTURER should assess RISKS resulting from the fact that individual system components have been integrated into one system. This assessment should include all aspects of the information exchanged between the system components. Even when these components are non-ME ELECTRICAL components, the potential RISK related to the integration of these components into the ME SYSTEM need to be considered. Further requirements for the integration of non-medical equipment into an ME SYSTEM are described in Clause 16. It gives the requirements for an ME SYSTEM and how RISKS associated with non-ME EQUIPMENT are addressed. 医用电气系统的制造商应在系统级别上做出此决定。制造商应评估因单个系统组件已集成到一个系统中而产生的风险。该评估应包括系统组件之间交换信息的所有方面。即使这些部件是非医用电气部件，也需要考虑将这些部件集成到医用电气系统中的潜在风险。有关将非医疗设备集成到医用电气系统中的更多要求，请参见第16条。它给出了医用电气系统的要求，以及如何解决与非医用电气设备相关的风险。

It should be noted that compliance with ISO 14971 does not require that the MANUFACTURER 应注意，符合ISO 14971并不要求制造商 have a formal quality system in place. 建立正式的质量体系。

This RISK MANAGEMENT PROCESS results in a set of RECORDS and other documents: the RISK MANAGEMENT FILE. Compliance of the RISK MANAGEMENT PROCESS is checked by inspection of the RISK MANAGEMENT FILE. 这个风险管理过程产生了一套记录和其他文件：风险管理文件。通过检查风险管理文件来检查风险管理过程的合规性。

In all cases, the MANUFACTURER is to be considered the expert on the device being developed and on the HAZARDS associated with its use. 在所有情况下，制造商应被视为正在开发的设备及其使用相关危险的专家。

Where compliance tests are by inspection or review of the RISK MANAGEMENT FILE, only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. MANUFACTURER'S calculations or test results, or the determination of RISK acceptability. 如果合规性测试是通过检查或审查风险管理文件，则只需审查风险管理文件的相关部分，例如制造商的计算或测试结果，或风险可接受性的确定。

Some requirements of this standard use the term unacceptable RISK, other requirements use the term HAZARDOUS SITUATION. All unacceptable RISKS result from a HAZARDOUS SITUATION, not all HAZARDOUS SITUATIONS result in an unacceptable RISK.

本标准的某些要求使用术语“不可接受的风险”，其他要求使用术语“危险情况”。所有不可接受的风险都源于危险情况，并非所有的危险情况都会导致不可接受的风险。

In deciding which term phrase to use in a requirement the following rule has been used. 在决定在需求中使用哪个术语短语时，使用了以下规则。

- Unacceptable RISK is used when the MANUFACTURER has to, or is permitted to, make a judgment about the acceptability of the RISK. This judgement needs to be supported by an appropriate rationale such as experience, historical data, etc. 当制造商必须或被允许对风险的可接受性作出判断时，使用不可接受风险。这种判断需要有适当的理由支持，如经验、历史数据等。
- HAZARDOUS SITUATION is used when the possibility of HARM determines whether certain requirements apply. In these cases the only determination a MANUFACTURER has to make is whether or not a HAZARDOUS SITUATION exists; this determination is made regardless of the RISK resulting from that HAZARDOUS SITUATION. 当危害的可能性决定了某些要求是否适用时，使用危险情况。在这些情况下，制造商唯一要做的就是确定是否存在危险情况；无论危险情况导致的风险如何，都要进行这种确定。
- The term HAZARD is used when the HAZARD is not necessarily exposed. 当危险不一定暴露在外时，使用“危险”一词。

- The phrase “no unacceptable RISK” is used when the MANUFACTURER has to, or is permitted to, make a judgement about the acceptability of the RISK. This judgement is to be supported by an appropriate rationale such as experience, historical data, etc. 当“风险是不可接受的”这句话时，制造商可以用“风险不可接受”。这种判断要有适当的理由支持，如经验、历史数据等。
- The phrase “no HAZARDOUS SITUATION” is used when the MANUFACTURER has to demonstrate (e.g. by technical drawing or technical description) that there is no exposure to a HAZARD or no possibility of HARM can develop. In these cases the only determination a MANUFACTURER has to make is whether or not a HAZARDOUS SITUATION exists; this determination is made regardless of the acceptability of the RISK that could develop from that HAZARDOUS SITUATION. 当制造商必须证明（例如通过技术图纸或技术说明）没有暴露于危险中或不会产生危害的可能性时，使用“无危险情况”。在这些情况下，制造商必须做出的唯一决定是是否存在危险情况；无论从该危险情况中可能产生的风险的可接受性如何，都要作出这一决定。
- The phrase “no HAZARD” is never used.
“无危险”一词从未使用过。

The following provides guidance on how to use several elements of the RISK MANAGEMENT PROCESS as defined in ISO 14971 within the context of IEC 60601-1. 以下提供了如何在IEC 60601-1范围内使用ISO 14971中定义的风险管理过程的几个要素的指南。

- INTENDED USE: The INTENDED USE is determined at the highest level of the ME EQUIPMENT or ME SYSTEM and should be used in identifying HAZARDS or HAZARDOUS SITUATIONS related to the use of the ME EQUIPMENT or ME SYSTEM. The INTENDED USE is not (or very rarely) used in the evaluation of specific components. Further, the INTENDED USE is the primary input when determining what aspects of the clinical functions of the ME EQUIPMENT or ME SYSTEM constitute ESSENTIAL PERFORMANCE as required by 4.3. 预期用途：在医用电气设备或医用电气系统的最高级别确定预期用途，并应用于识别与医用电气设备或医用电气系统使用相关的危险或危险情况。预期用途不用于（或很少）评估特定组件。此外，当确定医用电气设备或医用电气系统的临床功能的哪些方面构成4.3要求的基本性能时，预期用途是主要输入。
- HAZARD identification: This standard and ISO 14971 require identification of all HAZARDS 危险识别：本标准和ISO 14971要求识别所有危险 and HAZARDOUS SITUATIONS associated with the ME EQUIPMENT or ME SYSTEM, regardless of 以及与医用电气设备或医用电气系统相关的危险情况，无论

whether they are identified in an international safety standard or not (see 4.2.2, Note 1, and 4.2.3.2). This holds for NORMAL USE, reasonably foreseeable misuse and SINGLE FAULT CONDITIONS. However, when HAZARDS or HAZARDOUS SITUATIONS identified in this standard cannot occur for the specific ME EQUIPMENT or ME SYSTEM, the HAZARD identification would be performed only to document that the corresponding requirements of this standard do not apply. In this case, further RISK ASSESSMENT or VERIFICATION of compliance is not required. When a requirement does apply, no HAZARD identification is necessary (because the standard has already done so). For example, no HAZARD of electric shock arises in ME EQUIPMENT having no voltages capable of producing LEAKAGE CURRENTS that exceed the applicable limits as specified in 8.4.2 c). 是否在国际安全标准中进行了识别（见4.2.2注1和4.2.3.2）。这适用于正常使用、合理可预见的误用和单一故障情况。但是，当特定医用电气设备或医用电气系统不能出现本标准中确定的危险或危险情况时，危险识别仅用于证明本标准的相应要求不适用。在这种情况下，不需要进一步的风险评估或合规性验证。当某项要求确实适用时，无需进行危害识别（因为标准已经这样做了）。例如，如果医用电气设备的电压不能产生超过8.4.2 c)中规定的适用限值的漏电流，则不会产生电击危险。

- RISK EVALUATION: RISK is evaluated at two points in the RISK MANAGEMENT PROCESS— before and then again after implementation of RISK CONTROL measures. Evaluation before implementation of RISK CONTROL measures is applicable to the requirements of this standard only in order to demonstrate that the associated RISK is acceptable without applying a requirement. However, when this standard requires that RISKS related to a specific requirement remain acceptable or that no unacceptable RISK occurs in relation to a specific requirement, compliance is checked by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS related to this requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER'S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable based on the MANUFACTURER'S criteria for acceptability of RISK. The effectiveness of the RISK CONTROL measures is evaluated in accordance with subclause 6.3 of ISO 14971:2007. 风险评估：在风险管理过程中，在实施风险控制措施之前和之后对风险进行评估。实施风险控制措施前的评估仅适用于本标准的要求，以证明相关风险可接受，无需应用要求。然而，当本标准要求与特定要求相关的风险保持可接受或不存在与特定要求相关的不可接受风险时，通过检查风险管理文件中与该要求相关的危害或危险情况以及客观证据（例如。根据制造商的计算、分析或试验结果），根据制造商的风险可接受性标准判断相应的风险是可接受的。风险控制措施的有效性根据ISO 14971:2007第6.3款进行评估。
- RISK reduction: When a requirement of this standard requires implementation of specific RISK CONTROL measures to assure that the associated RISK is acceptable, compliance is checked by either of the following: 风险降低：当本标准的要求要求实施特定的风险控制措施以确保相关风险可接受时，可通过以下任一方式检查合规性：
 - by assuring that the specific measures have been implemented, in which case no RISK MANAGEMENT and no evaluation of RESIDUAL RISK are required because the RISKS are assumed to be reduced to an acceptable level by the presence of the specific measures (meeting the objective requirements of this standard), or 通过确保已实施具体措施，在这种情况下，不需要进行风险管理和评估残余风险，因为假设通过采取特定措施（满足本标准的客观要求）将风险降低到可接受的水平，或
 - by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS identified in the requirement in absence of the measures specified by the requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER'S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable. 通过检查风险管理文件，以确定在没有要求规定的措施的情况下，要求中确定的危险或危险情况，以及客观证据（例如，通过制造商的计算、分析或试验结果）判断相应的风险是可接受的。

Subclauses 7.2.2 for detachable components and 7.2.17 for protective packaging are examples where special markings are required unless no unacceptable RISKS occur. So, either the markings must be provided or the RISKS in absence of those markings must be evaluated and judged acceptable. Another example is 15.4.1 a), for the design and construction of connector plugs.

可拆卸部件的第7.2.2款和保护性包装的第7.2.17款是要求特殊标记的例子，除非没有出现不可接受的风险。因此，要么必须提供标记，要么必须评估没有这些标记的风险，并判断其可接受。另一个例子是15.4.1 a)，用于连接器插头的设计和构造。

- RISK/benefit analysis: A RISK/benefit analysis according to subclause 6.5 of ISO 14971:2007 is only required when the RESIDUAL RISK associated with a specific HAZARD or HAZARDOUS SITUATION remains unacceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan and further RISK CONTROL is not practicable. Such RISK/benefit analyses are not required when the RESIDUAL RISKS are judged acceptable or when the ME EQUIPMENT or ME SYSTEM complies with specific requirements of this standard. Subclause 11.1.2 is one of the few examples where a RISK/benefit analysis is required when temperature limits are exceeded to achieve a clinical purpose (see Table 24, footnote b).
风险/收益分析：仅当与特定危害或危险情况相关的残余风险使用风险管理计划中记录的风险可接受性标准仍然不可接受时，才需要根据ISO 14971:2007第6.5款进行风险/效益分析，而进一步的风险控制则不需要可行的。当剩余风险被判定为可接受或医用电气设备或医用电气系统符合本标准的具体要求时，不需要进行此类风险/效益分析。第11.1.2款是为数不多的几个例子之一，当超过温度限制以达到临床目的时，需要进行风险/效益分析（见表24，脚注b）。

Subclause 4.3 – ESSENTIAL PERFORMANCE

第4.3款-基本性能

The concept of “safety” has been broadened from the BASIC SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title from “Safety of medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance”.

“安全”的概念已从本标准第一版和第二版中的基本安全考虑扩大到包括基本性能问题（例如生理监测设备的准确性）。这一原则的应用导致标题从第二版的“医用电气设备的安全，第1部分：安全的一般要求”改为“医用电气设备，第1部分：基本安全和基本性能的一般要求”。

For an explanation of ESSENTIAL PERFORMANCE, see the rationale for 3.27. 有关基本性能的说明，请参见3.27的基本原理。

During the initial RISK ANALYSIS, the MANUFACTURER identifies the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM that is necessary for achieving the INTENDED USE. The MANUFACTURER also identifies other qualitative and quantitative characteristics that could affect the safety of the ME EQUIPMENT or ME SYSTEM. 在初始风险分析期间，制造商确定医用电气设备或医用电气系统实现预期用途所必需的临床功能性能。制造商还确定了可能影响医用电气设备或医用电气系统安全性的其他定性和定量特征。

The performance limits specified by the MANUFACTURER could be anywhere within the full range of intended performance in NORMAL CONDITION and SINGLE FAULT CONDITION, to no performance. 制造商规定的性能限值可在正常条件下和单一故障条件下的预期性能范围内的任何位置，直至无性能。

The MANUFACTURER then determines if the loss or failure to perform within specified limits would result in a RISK to the PATIENT. The estimate is often made with the assumption that the performance aspect in question has been lost or degraded beyond the specified limits (i.e. P1 in Figure A.8 is 100 %). The MANUFACTURER takes into account the probability of a HAZARDOUS SITUATION leading to HARM (P2 in Figure A.8) as well as the SEVERITY of that HARM. In some instances P2 could also be 100 %, in which case the RISK estimate is based entirely on the SEVERITY of the HARM. When considering the RISK associated with a level of degraded performance, which might include full loss, the analysis should include expected measures as prescribed in the ACCOMPANYING DOCUMENTS, which might return some or all performance after a delay including service to the ME EQUIPMENT or ME SYSTEM, or a return of some or all of the PATIENT'S medical care with back-up medical care measures. 然后，制造商确定损失或未能在规定范围内执行操作是否会对患者造成风险。估计通常是假设所讨论的性能方面已经丢失或退化到超过规定的限度（即图A.8中的P1为100%）。制造商考虑危险情况导致伤害的可能性（图a.8中的P2）以及危害的严重程度。在某些情况下，P2也可能是100%，在这种情况下，风险估计完全基于危害的严重程度。当考虑与性能降级水平相关的风险时（可能包括全部损失），分析应包括随附文件中规定的预期措施，这些措施可能在延迟后恢复部分或全部性能，包括医用电气设备或医用电气系统的服务，或者患者的部分或全部医疗护理和备用医疗措施的返回。

The MANUFACTURER then evaluates the RISK using their established RISK acceptance criteria. If the RISK is unacceptable, then the identified performance is ESSENTIAL PERFORMANCE because RISK reduction is required to achieve an acceptable level of RESIDUAL RISK.

然后，制造商使用他们建立的风险接受标准来评估风险。如果风险是不可接受的，那么所识别的性能就是基本性能，因为需要降低风险以达到可接受的残余风险水平。

Once the ESSENTIAL PERFORMANCE is identified, the MANUFACTURER puts in place RISK CONTROL measures that are appropriate to reduce the RISK to an acceptable level. When conducting the RISK CONTROL option analysis, the MANUFACTURER is to follow the priority order listed in ISO 14971, namely:

一旦确定了基本性能，制造商应采取适当的风险控制措施，将风险降低到可接受的水平。在进行风险控制选项分析时，制造商应遵循ISO 14971中列出的优先顺序，即：

- a) **inherent safety by design;**
设计固有安全性；
- b) **protective measures;**
防护措施；
- c) **information for safety.**
安全信息。

The RISK CONTROL measures selected need to be reasonably practicable and consistent with the generally accepted technology. For example, it might be possible to build a critical care ventilator that will continue to function in the presence of a single component failure, but, given the generally accepted technology, this is not practicable. Therefore, the MANUFACTURER might rely on a protective measure, such as an ALARM SYSTEM, to alert the OPERATOR of the failure so the OPERATOR can take appropriate and timely action to prevent the onset of HARM. The ALARM SIGNAL coupled with required OPERATOR training might be adequate RISK CONTROL measures to reduce the RISK arising from the loss or degradation of the identified performance to an appropriate level, i.e. the RESIDUAL RISK is acceptable. These RISK CONTROL measures can be integral with the consideration of ESSENTIAL PERFORMANCE.

所选择的风险控制措施必须合理可行，并与公认的技术相一致。例如，有可能建造一个重症监护呼吸机，在单一部件故障的情况下继续工作，但是，鉴于普遍接受的技术，这是不可行的。因此，制造商可以依靠一种保护措施，例如警报系统，来提醒操作员故障，以便操作员能够采取适当和及时的措施来防止危害的发生。警报信号加上所需的操作员培训可能是适当的风险控制措施，以将所识别性能的损失或退化降低到适当的水平，即剩余风险是可接受的。这些风险控制措施可以与基本绩效的考虑结合起来。

Of course, the RISK CONTROL measure has to be sufficiently independent such that the condition that causes the loss or degradation of the identified performance does not compromise the effectiveness of the RISK CONTROL measure. This is consistent with the two MEANS OF PROTECTION philosophy employed in the IEC 60601 series. For example, an ALARM SYSTEM intended to alert the OPERATOR that the SUPPLY MAINS has been interrupted could not depend on the SUPPLY MAINS as the sole source of its power. A back-up battery could be used to power the ALARM SYSTEM if the SUPPLY MAINS is interrupted.

当然，风险控制措施必须具有足够的独立性，以确保导致已识别性能损失或退化的条件不会损害风险控制措施的有效性。这与IEC 60601系列中采用的两种保护原理相一致。例如，旨在提醒操作员电源中断的报警系统不能依赖于电源作为其唯一的电源。如果电源中断，可使用备用电池为报警系统供电。

In RISK CONTROL, timing is everything. If there is insufficient time from the onset of the event (interruption of the SUPPLY MAINS) for the OPERATOR to register that an ALARM CONDITION has occurred and take appropriate action to prevent the onset of HARM, then the ALARM SYSTEM alone would not be an effective RISK CONTROL measure. A back-up power source to keep the ME EQUIPMENT operating for a period of time sufficient for the OPERATOR to take the necessary corrective action could also be required. 在风险控制中，时机决定一切。如果从事件发生（供电干线中断）起，操作员没有足够的时间来登记警报情况已经发生，并采取适当的措施来防止危害的发生，那么仅使用报警系统并不是一种有效的风险控制措施。还可能需要一个备用电源，使医用电气设备运行一段时间，以便操作员采取必要的纠正措施。

As with all aspects of the RISK MANAGEMENT PROCESS, the identification of ESSENTIAL PERFORMANCE can be iterative. The MANUFACTURER might have to revisit the process of determining what the ESSENTIAL PERFORMANCE is during the lifecycle of the ME EQUIPMENT or ME SYSTEM. 与风险管理过程的所有方面一样，基本性能的识别可以是迭代的。在医用电气设备或医用电气系统的生命周期内，制造商可能必须重新审视确定其基本性能的过程。

See also the rationale for
另见3.27的基本原理。

3.27.

Subclause 4.4— EXPECTED SERVICE LIFE
第4.4款-预期使用寿命

LIFE

The EXPECTED SERVICE LIFE is the time period during which the ME EQUIPMENT or ME SYSTEM is expected to remain suitable for its INTENDED USE. It is also the period when all RISK CONTROL measures need to remain effective to ensure that RISKS remain acceptable. 预期使用寿命是指医用电气设备或医用电气系统预期保持适合其预期用途的时间段。这也是所有风险控制措施需要保持有效以确保风险保持可接受的时期。

The EXPECTED SERVICE LIFE needs to be determined by the MANUFACTURER, as part of the RISK MANAGEMENT PROCESS, as a precondition for assessing compliance with many requirements of this standard, such as 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2 and 11.6.6. 作为风险管理过程的一部分，制造商需要确定预期使用寿命，作为评估是否符合本标准许多要求的前提条件，如4.5、4.7、7.1.3、8.6.3、9.8.2和11.6.6。

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER should provide information to allow the RESPONSIBLE ORGANIZATION to assess when the ME EQUIPMENT is approaching the end of its life. Such information should include the EXPECTED SERVICE LIFE as determined by the MANUFACTURER (e.g. in terms of years of service or number of uses) but could also include tests to be performed as part of preventive maintenance, or other criteria to allow the RESPONSIBLE ORGANIZATION to make an appropriate determination. The need for such information and the appropriate way to present it should be addressed as part of the RISK MANAGEMENT PROCESS.

在随附文件中，制造商应提供相关信息，以便责任机构在医用电气设备接近使用寿命时进行评估。此类信息应包括制造商确定的预期使用寿命（例如，根据使用年限或使用次数），但也可以包括作为预防性维护一部分进行的试验，或其他标准，以便责任组织做出适当的决定。作为风险管理过程的一部分，应解决对此类信息的需求和适当的呈现方式。

In defining the EXPECTED SERVICE LIFE, the MANUFACTURER should assume that the RESPONSIBLE ORGANIZATION will follow the MANUFACTURER'S instructions for routine maintenance. See 7.9.2.13.

在确定预期使用寿命时，制造商应假定负责组织将按照制造商的说明进行日常维护。见 7.9.2.13。

Subclause 4.5 – Equivalent safety for ME EQUIPMENT or ME SYSTEMS Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS
第4.5款-医用电气设备或医用电气系统的等效安全医用电气设备或医用电气系统的替代风险控制措施或试验方法

This subclause allows alternative means of achieving equivalent safety to be used safety to those means specified in this standard. This is important as it permits a MANUFACTURER to use innovative solutions that might be safer or are safe and can have other benefits, e.g. lower cost or performance better manufacturability.

本款允许采用与本标准中规定的方法相同的安全性替代方法。这一点很重要，因为它允许制造商使用更安全或更安全的创新解决方案，并具有其他好处，例如更低的成本或性能更好的可制造性。

Because it is often difficult to ascertain a sense of RISK acceptability for an individual RISK CONTROL measure or test method, the MANUFACTURER is permitted to use scientific data, clinical opinion, or comparative studies on a case-by-case basis to establish that the RESIDUAL RISK from applying an alternative remains acceptable.

由于通常很难确定单个风险控制措施或试验方法的风险可接受性，制造商可根据具体情况使用科学数据、临床意见或比较研究，以确定采用替代方案的剩余风险仍然可以接受。

Documentation in the RISK MANAGEMENT FILE should show that the RESIDUAL RISK achieved using the alternative means is remains acceptable because it is equal to or less than the RESIDUAL RISK achieved by applying the requirements of this standard and is comparable to this standard. Comparative studies should take into account scientific studies referenced in this standard and applicable to the alternative means. 风险管理文件中的文件应表明，使用替代方法实现的剩余风险仍然是可接受的，因为它等于或小于通过应用本标准要求而获得的剩余风险，并且与本标准具有可比性。比较研究应考虑本标准中引用并适用于替代方法的科学研究。

If the RESIDUAL RISK is greater than the RESIDUAL RISK achieved by applying the requirements of this standard, the ME EQUIPMENT or ME SYSTEM cannot be regarded as complying with this standard, even if the RESIDUAL RISK is fully justified by other considerations such as the clinical benefit to the PATIENT. 如果剩余风险大于通过应用本标准的要求所达到的剩余风险，则医用电气设备或医用电气系统不能被视为符合本标准，即使剩余风险完全由其他考虑因素（如对患者的临床益处）来证明。

Subclause 4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT 第4.6款-与患者接触的医用电气设备或医用电气系统部件

A part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT could reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR. 无意中与失去知觉、麻醉或丧失能力的患者接触的部件可能与必须接触患者的应用部件具有相同的风险。另一方面，一个活跃的病人可以接触到的部位，对病人来说可能不会比给操作者带来更多的风险。

The definition of APPLIED PART in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

本标准第一版和第二版中应用部分的定义未能解决这一问题。第二版的第二修正案扩大了定义的范围，包括可以与病人接触的部分，但新的定义继续造成困难。

Since this standard now requires a RISK MANAGEMENT PROCESS to be followed, it is appropriate to use this PROCESS to establish whether such parts should be subject to the requirements for APPLIED PARTS or not. 由于本标准现在要求遵循一个风险管理流程，因此使用该流程来确定此类零件是否符合应用零件的要求。

The exclusion of marking requirements reflects the majority view of the National Committees that responded to an enquiry on the subject during the development of this edition. It would be confusing to OPERATORS if parts that are not intended to be APPLIED PARTS were marked like APPLIED PARTS.

排除标记要求反映了国家委员会的多数意见，这些委员会在本版本的编制过程中对这一主题的询问作出了回应。如果不是应用部件的部件被标记为应用部件，则会使操作员感到困惑。

Parts identified as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases, these parts might need to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS in order to provide an appropriate level of safety. 被确定为需要遵守应用部件要求的部件（标记除外）通常比应用部件接触患者的频率要低，因此与大地电隔离的好处会更少。然而，在某些情况下，这些零件可能需要满足BF型应用零件或CF型应用零件的要求，以提供适当的安全等级。

Subclause 4.7 – SINGLE FAULT CONDITION for ME EQUIPMENT 第4.7款-医用电气设备的单一故障条件

The requirement that ME EQUIPMENT is SINGLE FAULT SAFE effectively puts a lower limit

on the probability of occurrence of HARM from a HAZARD. If this probability is achieved then the RISK of the HAZARD is acceptable. In all cases where this discussion refers to the SEVERITY or probability of a particular HAZARD, it is intended to refer to the probability or SEVERITY of the HARM resulting from that HAZARD. 医用电气设备是单一故障安全的要求有效地降低了危险造成伤害的概率。如果达到该概率，则危险的风险是可接受的。在所有情况下，本讨论涉及特定危害的严重性或可能性，其目的是指由该危害造成危害的可能性或严重性。

SINGLE FAULT SAFE is a concept that flows from the single fault philosophy described in IEC/TR 60513 [12]. SINGLE FAULT SAFE is a characteristic of ME EQUIPMENT that assures BASIC SAFETY during its EXPECTED SERVICE LIFE. For a high SEVERITY HARM, application of a RISK MANAGEMENT PROCESS can conclude that the single fault concept does not achieve an acceptable RISK. 单一故障安全是一个源自IEC/TR 60513[12]中所述单一故障原理的概念。单一故障安全是医用电气设备的一个特点，它确保了在其预期使用寿命内的基本安全。对于严重程度较高的危害，应用风险管理过程可以得出结论，单一故障概念无法实现可接受的风险。

The probability of simultaneous occurrence of two single faults is considered small enough to be negligible, provided that:
两个单一故障同时发生的概率被认为是小到可以忽略不计的，前提是：

- a) a single fault causes operation of a protective device (e.g. a fuse, OVER-CURRENT RELEASE, safety catch, etc.) that prevents occurrence of a HAZARD, or
单一故障导致保护装置（如保险丝、过电流脱扣器、安全锁扣等）的运行，以防止危险发生，或
- b) a single fault is discovered by an unmistakable and clearly discernible signal that becomes obvious to the OPERATOR, or
一个单一的故障是由一个明确的、清晰的信号发现的，该信号对操作员来说是显而易见的，或者

- c) a single fault is discovered and remedied by periodic inspection and maintenance that is prescribed in the instructions for use. There is a finite probability that a second fault can arise before the next scheduled inspection and maintenance cycle. As with case a) above, for the probability of this double fault condition to be negligible, the probability of each fault has to be low. This means that the frequency of inspection and maintenance has to be high compared to the expected probability of occurrence of the fault. The longer the time that one SINGLE FAULT CONDITION remains present before being detected and rectified, the greater the probability that a second fault will arise. Therefore, the MANUFACTURER might need to explicitly consider the detection time in relation to the occurrence of a possible second fault as part of RISK ANALYSIS.
- 通过使用说明书中规定的定期检查和维修来发现和修复单个故障。在下一个预定的检查和维修周期之前，第二个故障出现的可能性是有限的。与上述情况a)一样，为了使这种双重故障的概率可以忽略不计，每个故障的概率必须很低。这意味着，与故障发生的预期概率相比，检查和维修的频率必须很高。一个单一故障状态在被检测和纠正之前保持的时间越长，出现第二个故障的概率就越大。因此，作为风险分析的一部分，制造商可能需要明确考虑与可能发生的第二次故障相关的检测时间。

Non-exclusive examples of the categories a) to c) are:

类别a)至c)的非排他性示例包括：

- REINFORCED or DOUBLE INSULATION;
加强或双重绝缘；
- CLASS I ME EQUIPMENT in case of a fault in BASIC INSULATION;
基本绝缘发生故障时的I类医用电气设备；
- abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;
显示异常，冗余吊线缺陷，导致过度噪音或摩擦；
- deterioration of a flexible PROTECTIVE EARTH CONDUCTOR that is moved in NORMAL USE.
在正常使用中移动的柔性保护接地导体的劣化。

Subclause 4.8 – Components of ME EQUIPMENT

第4.8款-医用电气设备部件

Resistors bridging a MEANS OF PROTECTION

电阻桥接保护方法

A resistor or group of series connected resistors (two or more), can bridge one or two MEANS OF PROTECTION (MOOP or MOPP), providing the following is observed:

一个电阻器或一组串联电阻器（两个或多个）可以桥接一个或两个保护装置（MOOP或MOPP），前提是遵守以下条件：

- the resistor or group of resistors has a voltage rating twice the value of the WORKING VOLTAGE across the MEANS OF PROTECTION;
电阻器或电阻器组的额定电压是保护装置工作电压值的两倍；
- the resistor or group of resistors can withstand dielectric strength tests according to 8.8.3 and considering the expected transient voltages that the component(s) will be subjected to during NORMAL USE over the EXPECTED SERVICE LIFE;
电阻器或电阻器组能够承受8.8.3规定的介电强度试验，并考虑到部件在预期使用寿命内正常使用期间将承受的预期瞬态电压；
- the resistor or group of resistors has a power rating twice that expected in NORMAL USE;
电阻器或电阻器组的额定功率是正常使用时预期的两倍；
- the resistor or group of resistors have a resistance value such that TOUCH CURRENT, PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT requirements are not exceeded;
所述电阻器或电阻器组具有一个电阻值，使得不超过触摸电流、患者漏电流和患者辅助电

流要求；

- the resistor or group of resistors have a construction that maintains the MOP separation requirements for CREEPAGE DISTANCE and AIR CLEARANCE (For a series group, separation at each component is additive making up the required separation.); 电阻器或电阻器组的结构保持了对爬电距离和空气间隙的MOP分离要求（对于串联组，每个组件的分离是附加的，构成所需的分离）；
- the resistor or group of resistors are constructed such that their inductance is low; 电阻器或电阻器组的构造使其电感较低；
- the resistor or group of resistors have a construction that cannot fail short-circuit; and 电阻器或电阻器组具有不会发生短路故障的结构；以及
- when using a group of resistors they all need have the same resistance value and the voltage and power doubling requirement applies also to each component based on the expected WORKING VOLTAGE across that resistor in NORMAL USE. 当使用一组电阻器时，它们都需要具有相同的电阻值，并且电压和功率倍增要求也适用于每个元件，这是基于正常使用时电阻器的预期工作电压。

Subclause 4.9 – Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT

第4.9款-医用电气设备中高完整性部件的使用

The first step to determine a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS is to conduct a RISK ANALYSIS to find those characteristics that are required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE. Having done this, the appropriate component can be selected. Reference can be made to IEC component standards as part of the determination of the characteristics required. 确定具有高完整性特征的部件的第一步是进行风险分析，以找出维持基本安全或基本性能所需的特征。完成此操作后，可以选择适当的组件。在确定所需特性时，可参考IEC部件标准。

TYPE TESTS of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are only part of the required determination of suitability. Since a particular COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS has to function as intended or a HAZARD is likely to occur, additional considerations include as appropriate: 具有高完整性特征的部件的型式试验只是确定适用性所需的一部分。由于具有高完整性特征的特定部件必须按预期功能运行或可能发生危险，因此附加考虑因素包括：

- continuous surveillance as part of the manufacturing PROCESS and also after assembly into the end product; 作为制造过程的一部分，以及组装成最终产品后的持续监督；
- particular characteristics of the device concerned; 有关装置的特殊特性；

- lottesting;
批量测试;
- calibration;
校准;
- control of manufacturing defects;
制造缺陷的控制;
- maintenance;
维护;
- EXPECTED SERVICE LIFE of equipment;
设备的预期使用寿命;
- use of relevant component standards;
相关部件标准的使用;
- failure mode characteristics;
故障模式特性;
- environmental conditions;
环境条件;
- anticipated misuse of equipment;
预期的设备误用;
- interaction with other equipment.
与其他设备的交互。

Subclause4.10–Power supply
第4.10款-电源

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 5 % of the peak value of the ideal waveform.
如果有有关波形的任何瞬时值与理想波形在同一时刻的瞬时值相差不超过理想波形峰值的±5%，则认为交流电压为正弦电压。

A polyphase voltage system is considered to be symmetrical if neither the magnitude of its negative sequence components nor the magnitude of its zero sequence components exceeds 2 % of the magnitude of its positive sequence components.
如果多相电压系统的负序分量和零序分量的幅值均不超过其正序分量幅值的2%，则认为多相电压系统是对称的。

A polyphase supply system is considered to be symmetrical if, when supplied from a symmetrical voltage system, the resulting current system is symmetrical. That is, the magnitude of neither the negative sequence current components nor the zero sequence current components exceeds 5 % of the magnitude of the positive sequence current components.
如果从对称电压系统供电时，产生的电流系统是对称的，则认为多相供电系统是对称的。也就是说，负序电流分量和零序电流分量的幅值都不超过正序电流分量幅值的5%。

Clause5–General requirements for testing ME EQUIPMENT
第5条-医用电气设备测试的一般要求

In ME EQUIPMENT there could be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of ME EQUIPMENT.
医用电气设备中可能有许多绝缘件、部件（电气和机械）和结构特征，其中故障不会对患者、操作员或周围环境造成危害，即使会导致医用电气设备性能恶化或失效。

Subclause5.1–TYPE TESTS

第5.1款-型式试验

The RISK MANAGEMENT PROCESS identifies the RISK CONTROL measures that are necessary to ensure that the ME EQUIPMENT is safe.
风险管理过程确定了确保医用电气设备安全所需的风险控制措施。

Unless otherwise specified in this standard, tests should not be repeated. This applies particularly to the dielectric strength tests, which are performed only at the MANUFACTURER'S site or in test laboratories.

除非本标准另有规定，否则不得重复试验。这尤其适用于仅在制造商现场或试验实验室进行的介电强度试验。

In order to ensure that every individually produced item of ME EQUIPMENT conforms to this standard, the MANUFACTURER or installer should carry out such measures during manufacture or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.
为了确保医用电气设备的每个单独生产的项目符合本标准，制造商或安装人员应在制造或安装装配过程中采取措施，以确保每个项目满足所有要求，即使在制造或安装过程中未对其进行完全单独测试。

Such measures could take the form of:
这些措施可以采取以下形式：

- a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety;
与安全相关的生产方法（确保良好的生产产量和稳定的质量）；
- b) production tests (routine tests) performed on every produced item;
对每个生产项目进行的生产试验（常规试验）；
- c) production tests performed on a production sample where results would justify a sufficient confidence level.
在生产样品上进行的生产试验，结果证明有足够的置信水平。

Production tests need not be identical with TYPE TESTS, but can be adapted to manufacturing conditions and possibly invoking less RISK for the quality of the insulation or other characteristics important for BASIC SAFETY and ESSENTIAL PERFORMANCE.
生产试验不必与型式试验相同，但可以适应制造条件，并且可能对绝缘质量或其他对基本安全和基本性能重要的特性的风险较小。

Production tests would, of course, be restricted to settings (possibly derived from TYPE TESTS) that would provoke the worst case situation.

当然，生产测试将被限制在可能引发最坏情况的设置（可能来自类型测试）。

Depending upon the nature of ME EQUIPMENT, production methods or tests could concern critical insulation of the MAINS PART, of the PATIENT CONNECTIONS and the insulation or the separation between these parts.

根据医用电气设备的性质，生产方法或测试可能涉及电源部分的关键绝缘、患者连接以及这些部件之间的绝缘或分离。

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

建议的测试参数可以是泄漏电流和介电强度。

When applicable, the continuity of protective earthing can be a major test parameter.

适用时，保护接地的连续性可作为主要试验参数。

Guidance on general testing procedures that can be used with this standard is given in IEC/TR 62354

IEC 624标准中给出的试验指南可用于本标准

This standard uses several terms to describe fault conditions that could be encountered. They are:
本标准使用了几个术语来描述可能遇到的故障条件。他们是：

SINGLE

FAULT

CONDITION

单一故障条件

The SINGLE FAULT CONDITION is defined in 3.116 to describe those conditions where “a single means for reducing a RISK is defective” or “a single abnormal condition is present”. Possible SINGLE FAULT CONDITIONS are listed in this standard and can affect verifiable values like CREEPAGE DISTANCES, protective earth path impedances, LEAKAGE CURRENTS, etc.

3.116中定义了单一故障条件，以描述“降低风险的单一方法存在缺陷”或“存在单一异常情况”的情况。本标准列出了可能的单一故障条件，并可能影响可验证的值，如爬电距离、保护接地路径阻抗、泄漏电流等。

Faults

not

leading

to

a

SINGLE

FAULT

CONDITION

不导致单一故障状态的故障

Compared with SINGLE FAULT CONDITIONS, this standard does not have verifiable requirements for faults not leading to a SINGLE FAULT CONDITION. This means this standard does not give guidance how reliable it is that faults can be prevented.
与单一故障条件相比，本标准对不导致单一故障条件的故障没有可验证的要求。这意味着，本标准并未给出故障预防的可靠性指南。

Combination

of

simultaneous

independent

faults

同时独立故障组合

Because there are no reliable verifiable requirements defined in this standard for the prevention of faults, all possible simultaneous faults should be considered in accordance with 4.7.
根据本标准第7.4条的要求，所有可能的故障都应被视为可靠的预防，因为本标准中没有可验证的故障。

Where a SINGLE FAULT CONDITION remains undetected (e.g. bridging of one MEANS OF OPERATOR PROTECTION), further simultaneous faults should be considered in

accordance with 4.7.
如果一个单一的故障条件仍未被检测到（例如，一种操作员保护手段的桥接），则应根据4.7考虑进一步的故障。

NOTE For additional guidance, see IEC 60513:1994.
注：更多指南见IEC 60513:1994。

The worst cases of simultaneous faults are those which lead to most dangerous results. The wording of the standard is used to avoid conducting all possible simultaneous fault tests, because many of them could be covered by worst case testing.
同时发生故障的最坏情况是那些导致最危险结果的情况。本标准的措辞是为了避免进行所有可能同时进行的故障测试，因为其中许多测试可能包含在最坏情况测试中。

Subclause 5.2 – Number of samples
第5.2款-样品数量

The TYPE TEST sample or samples need to be representative of the units intended for the
型式试验样品必须代表拟用于
RESPONSIBLE ORGANIZATION.
责任组织。

Subclause 5.7 – Humidity preconditioning treatment
第5.7款-湿度预处理

According to IEC 60529, the ENCLOSURE of ME EQUIPMENT that is RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could result in a HAZARD.
根据IEC 60529，额定IPX8的医用电气设备外壳在规定的条件下，可防止大量水进入可能导致危险的地方。

The test condition as well as the acceptable amount and location of water are to be defined in particular standards. If no ingress of water is tolerated (sealed ENCLOSURES) the application of the humidity preconditioning treatment is inappropriate. 试验条件以及可接受的水量和位置将在特定标准中规定。如果不允许进水（密封外壳），则不应进行湿度预处理。

Parts sensitive to humidity, normally used in controlled environments and which do not influence safety BASIC SAFETY and ESSENTIAL PERFORMANCE, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc. 对湿度敏感的部件，通常在受控环境中使用，且不影响安全性、基本安全性和基本性能，无需进行本试验。例如：计算机系统的高密度存储介质、磁盘和磁带机等。

To prevent condensation when ME EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet should be equal to or slightly lower than the temperature of the ME EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20 °C to +32 °C and then “stabilized” at the initial value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

为防止医用电气设备放置在湿度柜内时发生冷凝，湿度柜的温度应等于或略低于医用电气设备引入时的温度。为避免机柜外房间空气温度稳定系统的需要，在处理过程中，机柜空气温度在+20℃~+32℃范围内与外界空气温度相适应，然后“稳定”在初始值。虽然试验箱温度对湿度吸收程度的影响已被认识到，但人们认为试验结果的再现性并未受到实质性的损害，而且成本降低效果显著。

Subclause 5.9 – Determination of APPLIED PARTS and ACCESSIBLE PARTS

第5.9款-应用部件和可触及部件的确定

Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with: 除特殊情况外，如患者支架和水床，请与医用电气设备接触

应该用以下材料制成：

- one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm x 20 cm (or less if the total ME EQUIPMENT is smaller);
一方面，用10 cm x 20 cm的金属箔模拟泄漏电流测量（如果整个医用电气设备较小，则为更小）；
- one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;
一个手指，在自然位置笔直或弯曲，由带有挡板的试验指模拟；
- an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.
一种可以向外拉的边缘或狭缝，允许手指随后进入，由测试钩和测试手指的组合来模拟。

Subclause 5.9.2.1 – Test finger

第5.9.2.1款-试验指

An ACCESS COVER is a part of the ENCLOSURE that can be removed in order to allow access to parts of electrical equipment for purposes of adjustment, inspection, replacement or repair. It is presumed that parts that can be removed without the use of a TOOL are intended to be replaced by any OPERATOR, not only by SERVICE PERSONNEL, even if this is not described in the instructions for use. OPERATORS other than SERVICE PERSONNEL might not be as well trained or experienced in good safety practices as SERVICE PERSONNEL. Therefore, extra safety precautions are needed to prevent accidental contact with hazardous voltages. That is why parts such as lamps, fuses, and fuseholders that can be removed without the use of a TOOL are to be removed before determining which parts inside the ACCESS COVER are to be considered ACCESSIBLE PARTS. 检修盖是外壳的一部分，可以拆下，以便接近电气设备的零件，以便进行调整、检查、更换或修理。假定不使用工具即可拆卸的零件应由任何操作员更换，而不仅仅由维修人员更换，即使使用说明中没有说明。服务人员以外的操作员可能没有服务人员那样训练有素或经验丰富。因此，需要额外的安全预防措施，以防止意外接触危险电压。这就是为什么在确定检修盖内的哪些零件被视为可触及零件之前，必须

先拆下不使用工具即可拆下的零件，如灯、保险丝和保险丝座。

Fuseholders where the fuselink is held in a cap that can be removed without use of a TOOL are a special concern. If the fuselink does not come out when the cap is removed, the OPERATOR could be inclined to try to remove it by gripping the end of the fuselink with the fingers. The OPERATOR could try to insert a new fuselink into the fuseholder without first inserting it in the cap. Both cases can be considered reasonably foreseeable misuse. This should be taken into consideration with assessing what parts are accessible.

保险丝座是一个特殊的问题，它将机身固定在一个可以不用工具就可以取下的盖子中。如果在取下盖子时机身墨水没有出来，操作员可能会倾向于用手指抓住机身墨水的末端来试图取下它。操作员可以尝试将新的fuselink插入保险丝盒，而不必先将其插入盖子。这两种情况都可以被认为是可以合理预见的滥用。在评估哪些部件可接近时，应考虑到这一点。

The reader is referred to IEC 60127-6 [7] for more information on fuseholders.
有关熔断器的更多信息，请参阅IEC 60127-6[7]。

Clause 6 – Classification of ME EQUIPMENT and ME SYSTEMS
第6条-医用电气设备和医用电气系统的分类

ME EQUIPMENT can have a multiple classification.
医用电气设备可以有多种分类。

Subclause 6.2 – Protection against electric shock

第6.2款-电击防护

The term “Class III equipment” is used in some other standards to identify equipment that is powered from a safety extra-low voltage (SELV) mains supply system. The term Class III equipment is not formally used in this standard. The BASIC SAFETY of Class III equipment is critically dependent on the installation and on other Class III equipment connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for ME EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons, this standard does not recognize Class III construction. 术语“III级设备”在其他一些标准中用于识别由安全特低电压（SELV）电源系统供电的设备。本标准中未正式使用术语III类设备。第三类设备的基本安全性主要取决于安装和与之相连的其他三类设备。这些因素超出了操作员的控制范围，这对于医用电气设备来说是不可接受的。另外，限制电压不足以保证病人的安全。基于这些原因，本标准不承认三级结构。

Subclause 6.3 – Protection against harmful ingress of water or particulate matter

第6.3款-防止有害水或颗粒物进入

It should be noted that compliance with the requirements of this standard automatically allows MANUFACTURERS to rate ME EQUIPMENT as IP2X because the requirements of IEC 60529 for this rating are the same as the accessibility requirements (see 5.9). 应注意的是，符合本标准要求自动允许制造商将医用电气设备评定为IP2X，因为IEC 60529对该等级的要求与可及性要求相同（见5.9）。

Subclause 6.6 – Mode of operation

第6.6款-操作模式

CONTINUOUS OPERATION and non-CONTINUOUS OPERATION cover the range of operating modes of virtually all equipment. ME EQUIPMENT that remains plugged into the SUPPLY MAINS continuously but is operated intermittently should be RATED for non-CONTINUOUS OPERATION, have the appropriate indication of on/off times in the ACCOMPANYING DOCUMENTS and markings on the ME EQUIPMENT (see 7.2.11). 连续运行和非连续运行涵盖了几乎所有设备的运行模式范围。持续接通电源但间歇运行的医用电气设备应额定为非连续运行，并在随附文件和医用电气设备上的标记中适当指示开/关时间（见7.2.11）。

Subclause 7.1.1 – USABILITY of the identification, marking and documents

第7.1.1款-标识、标记和文件的可用性

For ME EQUIPMENT to be well designed, its markings and ACCOMPANYING DOCUMENTS should be clear, consistent, and help to reduce potential use error. Thus, markings and ACCOMPANYING DOCUMENTS should undergo the same rigorous evaluation as other OPERATOR-ME EQUIPMENT interface elements. 为使医用电气设备设计良好，其标记和随附文件应清晰、一致，并有助于减少潜在的使用错误。因此，标记和随附文件应接受与其他操作员-医用电气设备接口元素相同的严格评估。

Subclause 7.1.2 – Legibility of markings

第7.1.2款-标记的易读性

Markings on ME EQUIPMENT are expected to be CLEARLY LEGIBLE by an OPERATOR over the range of normal illumination levels where the ME EQUIPMENT is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design [51]: 医用电气设备上的标记应在医用电气设备通常操作的正常照明度范围内，由操作人员清晰地辨认出来。本试验中使用的水平源于以下推荐的室内照明设计照明度[51]:

- 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;
建议在仅偶尔执行视觉任务的工作空间使用100 lx至200 lx;

- 500 lx to 1000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;
对于小尺寸的视觉任务或阅读中等笔迹的视觉任务，建议使用500 lx至1000 lx;
- 1 000 lx to 2 000 lx is recommended for visual tasks of low contrast or very small size: e.g. reading handwriting in hard-pencil on poor-quality paper.
对于低对比度或非常小尺寸的视觉任务，建议使用1000 lx到2000 lx的分辨率：例如，在劣质纸张上用硬铅笔阅读手写体。

If markings are not legible to the OPERATOR under the expected conditions of use, there would be an unacceptable RISK.
如果在预期使用条件下，操作员看不清标记，则存在不可接受的风险。

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are expressed as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. $\log \text{MAR} = \log(6/6) = 0$ for normal vision.
最小分辨角（MAR）是在长期使用的Snellen标尺的基础上发展起来的一种视力测量方法。这些值表示为最小分辨率角的对数。Log-MAR可以根据Snellen量表计算，即对于正常视力， $\text{Log-MAR} = \text{Log}(6/6) = 0$ 。

The Jaeger test card is used for determining near vision. N6 corresponds to reading at a distance of 0,87 m from the face.
Jaeger测试卡用于确定近视力。N6对应于距离工作面0.87 m处的读数。

An ambient light level of 500 lx is recommended for conducting the visual acuity examination.
建议使用500 lx的环境光照进行视力检查。

If a recommended minimum font size is to be considered, then a readable font size is a function of reading distance and the resulting visual angle of the marking image presented to the retina of the eye. Calculations of visual angle in minutes of arc are found in ANSI/AAMI HE-75:2009 subclause 6.2.2.6.5, Table 6.2. Using a minimal acceptable visual angle of 12 minutes of arc, a font size of 9 would be recommended for a reading distance of one meter and a font size of 6 for a typical reading distance of 0,7 m.
如果要考虑推荐的最小字体大小，那么可读字体大小是阅读距离和呈现在眼睛视网膜上的标记图像的最终视角的函数。ANSI/AAMI HE-75:2009第6.2.2.6.5款表6.2中给出了以弧分为单位的视角计算。如果最小可接受视角为12弧分，建议阅读距离为1米时字体大小为9，典型阅读距离为0.7米时，字体大小为6。

Subclause 7.1.3 – Durability of markings
第7.1.3款-标记耐久性

The rubbing test is performed with distilled water, methylated spirits ethanol 96 % and isopropyl alcohol.
使用蒸馏水、96%甲基化乙醇和异丙醇进行摩擦试验。

Ethanol 96% is defined in the European Pharmacopoeia as a reagent in the following terms: C₂H₆O (MW 46.07).
96%乙醇在欧洲药典中定义为以下术语的试剂：C₂H₆O（MW 46.07）。

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C₃H₈O (MW 60.1).
异丙醇在欧洲药典中定义为以下术语的试剂：C₃H₈O（MW 60.1）。

Subclause 7.2.2 – Identification
第7.2.2款-识别

This subclause is intended to apply to any detachable component when misidentification could present a HAZARD result in a HAZARDOUS SITUATION. For examples, normal consumables would probably need to be identified, but a cosmetic cover would not need to be identified.
当错误识别可能导致危险情况时，本款适用于任何可拆卸部件。例如，一般的消耗品可能需要识别，但化妆品封面不需要识别。

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it might not denote the exact construction, including the applied components and materials. If this is required, The MODEL OR TYPE REFERENCE can be is supplemented by a serial number or lot or batch identifier. The serial number or lot or batch identifier can be used for other purposes such as providing traceability in case the MANUFACTURER needs to take a corrective action.
虽然模型或类型引用通常表示某种性能规范，但它可能并不表示确切的结构，包括应用的组件和材料。如果需要，型号或类型参考可以由序列号或批次或批次标识符补充。序列号或批次或批次标识符可用于其他目的，如在制造商需要采取纠正措施时提供可追溯性。

Indication of a manufacturing series only might not be sufficient if local requirements require individual identification.
如果当地要求要求单独标识，则仅显示制造系列可能不够。

It is characteristic of software that different versions can run on a PEMS. The identification of the software will often be on the user interface, although this might not be possible e.g. where the software does not have a user interface. Identification of the software could need special tools. For this reason, the requirement permits the identification to be only available to designated people. PEMS上可以运行不同版本的软件是软件的特点。软件可能没有用户界面的标识。识别软件可能需要特殊工具。由于这个原因，要求只允许指定人员使用标识。

Subclause 7.2.3 – Consult ACCOMPANYING DOCUMENTS
第7.2.3款-查阅随附文件

It is not intended in every case when the instructions for use contain warnings, that the ME EQUIPMENT be marked with IEC 60878 Safety 01 ISO 7010-M002 (see Table D.2, safety sign 10). Too many warnings and unnecessary warnings are counterproductive. Only when the MANUFACTURER, as a RISK CONTROL measure for a specific RISK, decides to mark the

ME EQUIPMENT to instruct the OPERATOR to read the instructions for use, should safety sign IEC 60878 Safety 01 ISO 7010-M002 be used. 当使用说明书中包含警告信息时，医用电气设备不应标上IEC 60878安全01 ISO 7010-M002（见表D.2，安全标志10）。过多的警告和不必要的警告会适得其反。只有当制造商作为特定风险的风险控制措施，决定标记医用电气设备以指示操作员阅读使用说明时，才应使用安全标志IEC 60878安全01 ISO 7010-M002。

Subclause	7.2.4	—	ACCESSORIES
第7.2.4款-附件			

RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to identify ACCESSORIES in order to know which ones can be used without impairing BASIC SAFETY or ESSENTIAL PERFORMANCE. A MODEL OR TYPE REFERENCE alone is not sufficient, because different MANUFACTURERS might use the same number. The name marked on the ACCESSORY could be that of the ME EQUIPMENT MANUFACTURER or a different name.

负责的组织 and 操作员需要能够识别配件，以便知道哪些配件可以在不损害基本安全或基本性能的情况下使用。仅凭型号或类型引用是不够的，因为不同的制造商可能使用相同的编号。附件上标记的名称可以是医用电气设备制造商的名称，也可以是其他名称。

Subclause 7.2.10 – APPLIED PARTS
第7.2.10款-应用部分

According to the second edition of this standard, the marking could be either on the APPLIED PART itself or adjacent to the connection point. Neither location is satisfactory in all cases.
根据本标准第二版，标记可以在应用部件上，也可以在连接点附近。在任何情况下，位置都不令人满意。

Where a conductor that is not separated from PATIENT CONNECTIONS extends up to the point inside ME EQUIPMENT where an isolation barrier exists, a TYPE BF or TYPE CF marking on the APPLIED PART itself could mislead the RESPONSIBLE ORGANIZATION or the OPERATOR into believing that isolation is built into the APPLIED PART itself. If, on the other hand, the classification depends on the particular APPLIED PART in use, a single marking on the connection point would be inaccurate and multiple marking would be confusing.
如果未与患者连接分离的导线延伸到医用电气设备内部存在隔离屏障的点，则应用部件上的BF或CF型标记可能会误导责任机构或操作员，使其相信隔离已内置在应用部件中。另一方面，如果分类取决于使用中的特定应用部件，则连接点上的单个标记将不准确，多个标记将混淆。

For DEFIBRILLATION-PROOF APPLIED PARTS, if protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, a warning to the OPERATOR is necessary because there are can be non-obvious HAZARDS HAZARDOUS SITUATIONS if the wrong cable is used. HAZARDS These HAZARDOUS SITUATIONS can include decreasing the defibrillation energy delivered to the PATIENT, damage to the ME EQUIPMENT with consequent loss of ESSENTIAL PERFORMANCE, or electric shock to the OPERATOR or other persons.
对于防除颤应用部件，如果部分患者电缆中存在心脏除颤器放电影响的保护，则有必要向操作员发出警告，因为如果使用错误的电缆，可能会出现不明显的危险情况。危险这些危险情况可能包括降低输送给患者的除颤能量，损坏医用电气设备，导致基本性能损失，或对操作员或其他人员造成电击。

Subclause	7.2.12	–	Fuses
第7.2.12款-保险丝			
Examples of marking for fuses complying with IEC 60127-1 are:			
符合IEC 60127-1的保险丝标记示例如下：			
– T 315L, 250V		315L,	250V
– T 315mAL, 250V		315mAL,	250V
– F 1,25小时, 250伏		1,25H,	250V
– F 1,25AH, 250V		1,25AH,	250V

The operating speed can be marked by the letter or colour codes in IEC 60127-1, which are as follows:
运行速度可以用IEC 60127-1中的字母或颜色代码标记，如下所示：

– very quick acting:	FF,	or	black
快速反应：			
– quick acting:	F,	or	red
速效：			
– medium time lag:	M,	or	yellow
中等时间延迟：			

- time lag: T, or blue
时间延迟：T或蓝色
- long time lag: TT, or grey
长时间滞后：TT或灰色

Subclause 7.2.21 – Mass of MOBILE ME EQUIPMENT
第7.2.21款-移动式医用电气设备的质量

MOBILE ME EQUIPMENT is intended to be transported from one location to another by its own wheels or equivalent means. For safety, it is important that the OPERATOR be aware of the total mass of the ME EQUIPMENT with its SAFE WORKING LOAD installed. This is important when moving the ME EQUIPMENT, and, for heavy ME EQUIPMENT, understanding any limitations on locations where the ME EQUIPMENT can be taken. The ME EQUIPMENT can have bins, shelves or drawers that might have their own maximum loading requirements. The marking on the ME EQUIPMENT needs to be sufficiently separate and distinct from any markings on the bins, shelves or draws to avoid confusing the OPERATOR as to what the marking applies. 从一个或另一个相同的方式从一个或另一个移动设备。为了安全起见，操作员必须了解医用电气设备在安装了安全工作负载的情况下的总质量。移动医用电气设备时，这一点很重要，对于重型医用电气设备，了解医用电气设备所在位置的任何限制。医用电气设备可以有箱子、架子或抽屉，它们可能有自己的最大装载要求。医用电气设备上的标记需要与垃圾箱、货架或图纸上的任何标记充分分离和区分，以避免操作员混淆标记的应用。

Subclause 7.3.2 – HIGH VOLTAGE parts
第7.3.2款-高压部件

HIGH VOLTAGE parts present a significant electric shock HAZARD to SERVICE PERSONNEL and others who could be required to work inside the ME EQUIPMENT while it is energized. Because the parts are inside the ENCLOSURE, the RISK is perceived to be substantially less than that for HIGH VOTAGE TERMINAL DEVICES located on the outside of the ME EQUIPMENT. Therefore, the “dangerous voltage” symbol (IEC 60417-5036) (DB:2002-10) (see Table D.1, symbol 24) is permitted as a marking to alert SERVICE PERSONNEL and others to the potential presence of these dangerous voltages. The MANUFACTURER is permitted to use a safety sign 3 ISO 7010- W012 (see Table D.3, safety sign 3). The RISK MANAGEMENT PROCESS could determine that the 高压部件对维修人员和其他可能需要在医用电气设备通电时在其内部工作的人员造成严重的触电危险。由于零件在外壳内，因此风险被认为大大低于位于医用电气设备外部的高压终端设备。因此，允许使用“危险电压”符号（IEC 60417-5036）（DB:2002-10）（见表D.1，符号24）作为标记，提醒维修人员和其他人员注意这些危险电压的潜在存在。允许制造商使用安全标志3 ISO 7010-W012（见表D.3，安全标志3）。风险管理过程可以确定

safety sign is the most appropriate choice if the personnel exposed to the HAZARD have minimal training or might otherwise be unaware that HIGH VOLTAGE is present.
如果最合适的选择是暴露在高电压下的人员，则可能不知道是否存在安全隐患。

Subclause 7.3.4 – Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

第7.3.4款-熔断器、热断路器和过电流脱扣器

See the rationale for 7.2.12.

见7.2.12的基本原理。

Subclause 7.3.5 – PROTECTIVE EARTH TERMINALS

第7.3.5款-保护接地端子

This standard does not require marking of terminals for internal PROTECTIVE EARTH CONNECTIONS, but does not preclude it.

本标准不要求对内部保护接地连接的端子进行标记，但并不排除此要求。

Subclause 7.4.1 – Power switches

第7.4.1款-电源开关

If a marking is used for a toggle-type switch, the symbols for "on" () and "off" () [symbols 12 and 13 from Table D.1] should be used to indicate its ON and OFF positions.
如果标记用于拨动式开关，则应使用符号“开”（ ）和“关”（[表D.1中的符号12和13]来指示其开关位置。

For a push-button type switch, the appropriate marking will depend on the type of switch. For a push button switch with bistable positions, the symbol) [symbol 14 from Table D.1] should be used to indicate that both the ON and OFF positions are stable.
对于按钮式开关，适当的标记取决于开关的类型。对于具有双稳态位置的按钮开关，应使用符号[表D.1中的符号14]来表示接通和断开位置均稳定。

For a push button switch with a momentary ON position, the symbol) [symbol 15 from Table D.1] should be used to indicate that mains power is applied for only as long as the push button is depressed. As soon as the button is released the switch returns to the stable OFF position.
对于具有瞬时开启位置的按钮开关，符号[表D.1中的符号15]应用于指示只要按下按钮，电源才被应用。按钮一松开，开关就回到稳定的关闭位置。

Subclause 7.4.2 – Control devices

第7.4.2款-控制装置

The different positions of switches that control the functionality of the ME EQUIPMENT or a part of the ME EQUIPMENT, but do not control mains power to the ME EQUIPMENT or a part of the ME EQUIPMENT should also be marked in such a way as to clearly indicate the state of the control function. Any appropriate means including figures, letters, indicator lights, etc. can be used. If the marking includes symbols, the symbols for "on" for part of the equipment () and "off" for part of the equipment () [symbols 16 and 17 from Table D.1] can be used to indicate its ON and OFF positions.

控制医用电气设备或医用电气设备一部分功能，但不控制医用电气设备或医用电气设备一部分的电源的开关的不同位置也应进行标记，以便清楚地指示控制功能的状态。可以使用任何适当的方法，包括数字、字母、指示灯等。如果标记包括符号，则部分设备的“开”和部分设备的“关”（[表D.1中的符号16和17]可用于指示其打开和关闭位置。

A switch or switch position by means of which the ME EQUIPMENT or part of the ME EQUIPMENT is switched on in order to bring it into the "stand-by" condition can be indicated by the stand-by symbol) [symbol 29 from Table D.1]. This symbol is required by IEC 60950-1 to indicate the stand-by mode of the information technology equipment covered by that standard.
一个开关或开关位置，通过该开关或开关位置，医用电气设备或医用电气设备的一部分被打开，以使其进入“备用”状态，可通过备用符号来表示。[表D.1中的符号29]。IEC 60950-1要求该符号表示该标准所涵盖的信息技术设备的待机模式。

Subclause 7.8 – Indicator lights and controls

第7.8款-指示灯和控制装置

For colours of indicator lights see also IEC 60073 [5].

有关指示灯的颜色，另请参见IEC 60073[5]。

Colour alone should not be used to convey important information. A redundant means of conveying information such as shape, location, sound or marking is recommended. 不应仅使用颜色来传达重要信息。建议使用冗余的方式来传达信息，如形状、位置、声音或标记。

Subclause 7.9.1 – General

第7.9.1款-概述

It is important that ME EQUIPMENT or an ME SYSTEM is not unintentionally used in an application for which it is not intended by its MANUFACTURER. 医用电气设备或医用电气系统不得无意中用于其制造商不打算使用的应用中，这一点很重要。

The USABILITY ENGINEERING PROCESS requires the MANUFACTURER to develop an applications specification that includes the intended environments of use. The MANUFACTURER is required to supply a summary of this specification in the ACCOMPANYING DOCUMENTS. See 12.2.

可用性工程过程要求制造商制定一个包括预期使用环境的应用规范。要求制造商在随附文件中提供本规范的摘要。见12.2。

Subclause 7.9.2.1 – General

第7.9.2.1款-概述

RESPONSIBLE ORGANIZATIONS and OPERATORS frequently deal with many different types of ME EQUIPMENT. Because of the complexity of modern ME EQUIPMENT, the instructions for use are an important part of the ME EQUIPMENT. Some commonality in the structure for the instructions for use could help OPERATORS to find needed material quickly and easily. However, because of the diversity of ME EQUIPMENT covered by this standard, no one format will be equally applicable to all ME EQUIPMENT. Therefore, the MANUFACTURER is encouraged, but not required, to use the sequence of topics in 7.9.2.2 to 7.9.2.16 as an outline when developing the instructions for use.

负责的组织 and 操作员经常处理许多不同类型的医用电气设备。由于现代医用电气设备的复杂性，使用说明书是医用电气设备的重要组成部分。使用说明书结构中的一些共性可以帮助操作员快速、轻松地找到所需的材料。然而，由于本标准所涵盖的医用电气设备的多样性，没有一种格式可以同样适用于所有医用电气设备。因此，鼓励但不要求制造商在制定使用说明时，使用7.9.2.2至7.9.2.16中的主题顺序作为大纲。

When considering if the PATIENT can act as an OPERATOR, the MANUFACTURER needs to take into account that the level of protection provided by this standard for the OPERATOR can be different from that for the PATIENT. For example, acceptable LEAKAGE CURRENT levels and accessible voltages values are higher for the OPERATOR than they are for the PATIENT. Instead of PATIENT LEAKAGE CURRENT, TOUCH CURRENT could be applied. Additionally the OPERATOR can have access to voltages up to 42,4 V peak a.c. or 60 V d.c.

在考虑患者是否可以作为操作员时，制造商需要考虑本标准为操作员提供的保护级别可能与为患者提供的保护级别不同。例如，操作员的可接受泄漏电流水平和可接近电压值高于患者。用触摸电流代替病人漏电流。此外，操作员可获得高达42.4 V交流峰值电压或60 V直流电压。

Other conditions to consider include:
其他需要考虑的条件包括：

- Is the ME EQUIPMENT to be used under medical supervision or guidance?
医用电气设备是否在医疗监督或指导下使用？
- What is the health condition of the PATIENT?
病人的健康状况如何？
- What treatment is being provided to the PATIENT?
给病人提供什么治疗？
- Are there special USABILITY considerations (see IEC 60601-1-6)?
是否有特殊的可用性考虑因素（见IEC 60601-1-6）？
- Is the ME EQUIPMENT to be used in the professional healthcare environment, the home healthcare environment (see IEC 60601-1-11) or the emergency medical service environment (see IEC 60601-1-12)?
医用电气设备是否用于专业医疗环境、家庭医疗环境（见IEC 60601-1-11）或紧急医疗服务环境（见IEC 60601-1-12）？
- Does the PATIENT have access to the instructions for use?
患者是否可以使用说明书？
- Is adequate training of the PATIENT as an OPERATOR available?
是否对患者进行了足够的操作员培训？

The problem of languages used in markings and in ACCOMPANYING DOCUMENTS cannot be solved by IEC. Even a requirement that identifications and ACCOMPANYING DOCUMENTS have to be in the national languages cannot be upheld world-wide. IEC无法解决标记和随附文件中使用的语言问题。即使要求身份证明和随附文件必须使用本国语言，也不能在全世界得到支持。

Subclause 7.9.2.2 – Warning and safety notices

第7.9.2.2款-警告和安全通知

For CLASS I ME EQUIPMENT, where operation from either a SUPPLY MAINS or an INTERNAL ELECTRICAL POWER SOURCE is specified, the instructions for use should state that the INTERNAL ELECTRICAL POWER SOURCE is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

对于I类医用电气设备，如果规定从供电干线或内部电源进行操作，则使用说明应说明，如果装置中保护接地导体或保护接地系统的完整性存在疑问，则应使用内部电源。

Subclause 7.9.2.6 – Installation

第7.9.2.6款-安装

The instructions for use can contain a statement saying that the MANUFACTURER, assembler, installer or importer considers himself responsible for the effect on BASIC SAFETY, reliability and performance of the ME EQUIPMENT or ME SYSTEM only if: 使用说明可包含一项声明，说明制造商、装配商、安装商或进口商认为自己应对医用电气设备或医用电气系统的基本安全性、可靠性和性能的影响负责，前提是：

- appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications or repairs;
经过适当培训的人员执行装配操作、扩展、重新调整、修改或修理；
- the electrical installation of the relevant room complies with the appropriate requirements; and
相关房间的电气安装符合适当的要求；以及
- the ME EQUIPMENT or ME SYSTEM is used in accordance with the instructions for use.
根据使用说明使用医用电气设备或医用电气系统。

Subclause 7.9.2.7 – Isolation from the SUPPLY MAINS

第7.9.2.7款-与供电干线隔离

A plug and socket provide suitable means for isolation from the SUPPLY MAINS to satisfy 插头和插座提供与电源干线隔离的适当方式，以满足

8.11.1 a), but they would not be suitable if they were not readily accessible when needed. 如果它们不容易接近，但如果不需要的话。

Subclause7.9.2.19–Uniqueversionidentifier

第7.9.2.19款-唯一版本标识符

MANUFACTURERS frequently issue multiple revisions of the instructions for use. RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to determine if the instructions for use they have are current. This is particularly important when dealing with PEMS software that can be updated in the environment of use. Providing a date of issuance is a widely accepted method for identifying versions of a document. The MANUFACTURER decides what level of detail is appropriate with month and year being common for printed material. However, greater granularity might be required, particularly for material distributed electronically. The MANUFACTURER could include a revision number when appropriate.

制造商经常发布多个版本的使用说明书。负责的组织和操作员需要能够确定他们的使用说明是否是最新的。在处理可在使用环境中更新的PEMS软件时，这一点尤为重要。提供发布日期是一种被广泛接受的确定文件版本的方法。制造商决定印刷材料的月份和年份的详细程度。然而，可能需要更大的粒度，特别是对于电子分发的材料。适当时，制造商可包括修订号。

Subclause7.9.3.1–General

第7.9.3.1款-概述

According to the INTENDED USE of ME EQUIPMENT, the MANUFACTURER should specify the permissible environmental conditions for which a HAZARD is not induced. Environmental conditions such as the following are expected to be considered:

根据医用电气设备的预期用途，制造商应规定不产生危险的允许环境条件。应考虑以下环境条件：

- the effect of humidity;
- the effect of temperature;
- the effect of atmospheric pressure;
- the effect of shock and vibration;
- the effect of ultra-violet radiation.
- the effect of the temperature of the water for water cooled ME EQUIPMENT;
- the effect of pollution.

Accuracy and precision are not possible to define in this standard. These concepts have to be addressed in particular standards.

准确度和精密度在本标准中无法定义。这些概念必须在特定的标准中加以处理。

The values listed below were used in the second edition of IEC 60601-1 to describe the range of environmental conditions over which ME EQUIPMENT was required to be safe.

IEC 60601-1第二版中使用了下列值来描述医用电气设备要求安全的环境条件范围。

- a) an ambient temperature range of + 10 □C to + 40 □C;
环境温度范围为+10℃～+40℃;
 - b) a relative humidity range of 30 % to 75 %;
 - c) an atmospheric pressure range of 70,0 kPa to 106,0 kPa;
 - d) a temperature of the water at the inlet of water-cooled ME EQUIPMENT not higher than 25 □C.
- 水冷式医用电气设备入口处的水温不高于25℃。

These environmental conditions were based on the conditions in buildings without air- conditioning in climates where the ambient temperature occasionally reaches + 40 °C.

这些环境条件是基于没有空调的建筑物在环境温度偶尔达到+40°C时的条件。

In the second edition of IEC 60601-1, the ME EQUIPMENT had to be safe when operated under the above conditions but it only needed to be fully operable under conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS. 在IEC 60601-1第二版中，医用电气设备在上述条件下运行时必须是安全的，但它只需要在制造商在随附文件中规定的条件下完全可操作。

This edition specifies particular environmental conditions for some requirements and tests. Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS. 本版规定了一些要求和试验的特殊环境条件。如果不是这样，医用电气设备必须保持安全，并在制造商在随附文件中规定的环境条件范围内正确运行。

Attention is drawn to the fact that there was always a problem to apply a 40 °C environmental condition to a ME EQUIPMENT in cases where the APPLIED PART needed to operate at temperatures close to the 41 °C limit. 需要注意的是，在应用部件需要在接近41°C极限温度下运行的情况下，将40°C的环境条件应用于医用电气设备始终存在一个问题。

The second edition of IEC 60601-1 specified the following range of environmental conditions for transport and storage of ME EQUIPMENT unless otherwise specified by the MANUFACTURER: IEC 60601-1第二版规定了医用电气设备运输和储存的以下环境条件范围，除非制造商另有规定：

- an ambient temperature range of - 40 °C to + 70 °C;
环境温度范围为-40°C至+70°C;
- a relative humidity range of 10 % to 100 %, including condensation;
相对湿度范围为10%至100%，包括冷凝;
- an atmospheric pressure range of 50 kPa to 106 kPa.
50千帕到106千帕的大气压范围。

Amendment 2 to the second edition replaced the above list with a requirement that the MANUFACTURER state the permissible transport and storage conditions. However, in the absence of other information, the above list can serve as a useful starting point in determining the permissible limits.

第二版修正案2将上述清单替换为要求制造商说明允许的运输和储存条件。然而，在缺乏其他信息的情况下，上述列表可作为确定允许限值的有用起点。

Information on environmental parameters and a limited number of their severities within the range of conditions met by electrotechnical products when being transported, stored, installed and used can be found in the IEC 60721 series [18]. IEC 60721系列[18]中提供了有关环境参数及其在电工产品运输、储存、安装和使用满足的条件范围内的有限数量严重性的信息。

For PERMANENTLY INSTALLED high power ME EQUIPMENT, it might be necessary to control the voltage drop in the customer installation to prevent input voltage getting below the minimum normal voltage due to local conditions. Control can be done by specifying the required apparent impedance of the SUPPLY MAINS.

对于永久安装的大功率医用电气设备，可能有必要控制客户安装中的电压降，以防止输入电压因当地条件而低于最小正常电压。控制可以通过指定所需的电源视在阻抗来完成。

Subclause 7.9.3.4 – Mains isolation
第7.9.3.4款-电源隔离

SERVICE PERSONNEL need to know how to isolate the ME EQUIPMENT from the SUPPLY MAINS. This is not always obvious, particularly if there is a switch in the MAINS PART that does not meet the requirements of 8.11. 维修人员需要知道如何将医用电气设备与电源隔离。这并不总是显而易见的，尤其是当电源部分有一个开关不符合8.11的要求时。

Clause 8 – Protection against electrical HAZARDS from ME EQUIPMENT
第8条-医用电气设备电气危害防护

The fundamental principle for protection against electric shock is that the voltage or current between any accessible surface and any other accessible surface or earth is low enough not to present a HAZARD result in a HAZARDOUS SITUATION, in all relevant circumstances including NORMAL CONDITION and SINGLE FAULT CONDITION. 电击防护的基本原则是，在所有相关情况下，包括正常条件和单一故障条件下，任何可触及表面与任何其他可触及表面或接地之间的电压或电流足够低，不会造成危险情况。

Requirements for achieving protection have been formulated in various ways in IEC basic safety standards, in previous editions of this standard, and in other IEC product standards. 在IEC基本安全标准、本标准以前版本和其他IEC产品标准中，以各种方式制定了实现保护的要求。

In order for the fundamental principle to be satisfied:
为了满足基本原则：

- a) parts that are “live” (as defined in the second edition of this standard) or “hazardous live” (as defined in some other standards, such as IEC 61140 [23] and IEC 61010-1 [22]) have to be inaccessible (but see below regarding problems in identifying what is “live”) and “带电”（定义见本标准第二版）或“危险带电”（如IEC 61140[23]和IEC 61010-1[22]）中定义的部件必须不可接近（但有关识别“带电”的问题，请参见下文）和
- b) ACCESSIBLE PARTS including APPLIED PARTS have to be not “live” / “hazardous live.”
可触及部件（包括应用部件）不得为“带电”/“危险带电”

NOTE The term “live” was defined in the second edition of this standard as, “State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT (specified in Sub-clause 19.3) for the part concerned to flow from that part to earth or from that part to an ACCESSIBLE PART of the same EQUIPMENT.

注：术语“带电”在本标准第二版中定义为“当连接到该部件时，可能导致电流超过允许泄漏电流（第19.3款中规定）的部件的状态，该部件从该部件流向地面或从该部件流向同样的设备。

These two requirements are in principle equivalent but some standards state both of them.
这两个要求在原则上是相等的，但有些标准规定了两者的。

These requirements in turn imply that:
这些要求反过来意味着：

c) ACCESSIBLE PARTS including APPLIED PARTS have to be separated from certain internal live parts: in general two separate MEANS OF PROTECTION are necessary, one to provide separation in NORMAL CONDITION and a second to maintain BASIC SAFETY in SINGLE FAULT CONDITION, and
可触及部件（包括应用部件）必须与某些内部带电部件分开：通常需要两种单独的保护措施，一种在正常情况下提供隔离，另一种在单一故障条件下维持基本安全，以及

d) LEAKAGE CURRENTS (and possibly also voltages and energies) have to be below acceptable limits.

泄漏电流（可能还有电压和能量）必须低于可接受的限值。

Most standards include explicit requirements covering each of these aspects of providing protection. For example the first and second editions of this standard dealt with a) in Clause 16, with b) and d) in Clause 19 and with c) in Clauses 17, 18 and 20.
大多数标准都包括明确的要求，包括提供保护的每一个方面。例如，本标准的第一版和第二版涉及第16条中的a)和第19条中的b)和d)以及第17、18和20条中的c)。

Requirement a) has typically been formulated as a requirement for the provision of ENCLOSURES or barriers to prevent contact with internal hazardous live parts. However it can alternatively be formulated in terms of the determination of which parts are accessible. Anyway the adequacy of ENCLOSURES or barriers is determined by use of the relevant test fingers and probes.
要求a)通常被制定为提供外壳或屏障以防止接触内部危险带电部件的要求。然而，也可以根据确定哪些部件可接近的方式来制定。无论如何，外壳或屏障的充分性是通过使用相关的测试指和探针来确定的。

Application of the above approach to ME EQUIPMENT has presented some difficulties. The limits for voltage and current depend on how, if at all, the part(s) concerned can be connected to a PATIENT, e.g. directly to the heart, directly to other parts of the body, or indirectly via the OPERATOR. This has led to difficulties in identifying which parts are “live” parts.
上述方法在医用电气设备中的应用存在一些困难。如果直接连接到病人身体的其他部位，则取决于心脏的其他部位。这导致了识别哪些部件是“带电”部件的困难。

The definition of “live” in the second edition of this standard refers to the allowable LEAKAGE CURRENT. The definition is therefore difficult to apply to internal parts for which no particular LEAKAGE CURRENT limits are specified.
本标准第二版中“带电”的定义是指允许的泄漏电流。因此，该定义很难适用于未规定特定泄漏电流限值的内部零件。

Certain parts could be regarded as “live” (within the definition of the second edition of this standard) for some purposes and at the same time as not “live” for other purposes. For example an internal part that can source a current of, say, 200 □A has to be separated from all ACCESSIBLE PARTS, including PATIENT CONNECTIONS in NORMAL CONDITION.
某些部件在某些情况下可被视为“带电”（在本标准第二版的定义范围内），同时在其他用途上也可被视为“带电”。例如，可以产生200μA电流的内部部件必须与所有可触及部件分开，包括正常情况下的患者连接。

The separation from PATIENT CONNECTIONS of TYPE CF APPLIED PARTS has to remain effective in SINGLE FAULT CONDITION, because a current of 200 □A from these is not permissible. The same part can however become connected to other ACCESSIBLE PARTS and PATIENT CONNECTIONS in SINGLE FAULT CONDITION.
在单一故障条件下，CF型应用部件与患者连接的分离必须保持有效，因为不允许存在200μA的电流。但是，在单一故障情况下，同一部件可以连接到其他可触及部件和患者连接。

Thus two MEANS OF PROTECTION (DOUBLE INSULATION or REINFORCED INSULATION) would be needed between such a part and the PATIENT CONNECTIONS of TYPE CF APPLIED PARTS, but a single MEANS OF PROTECTION (such as BASIC INSULATION alone) would be acceptable between such a part and other ACCESSIBLE PART.
因此，两种保护方法（双重绝缘或加强绝缘）将是需要的，但在这类部件和CF型应用部件的病人连接之间需要，但是在这种部件和其他可触及的部件之间可以使用单一的保护手段（例如仅使用基本绝缘）。

Furthermore, requirements that specify the necessary separation between parts that are accessible and parts that are “live” do not easily take account of parts that are not “live” but can become “live,” such as the parts of a floating circuit that become “live” when a connection is made to another part of the same circuit.
此外，规定可接近部件和“带电”部件之间的必要隔离的要求不容易考虑到非“带电”但可能变为“带电”的部件，例如，当连接到同一电路的另一部分时，浮动电路中变为“带电”的部件。

Consider, for example, the simple situation shown in Figure A.10.
例如，考虑图A.10所示的简单情况。

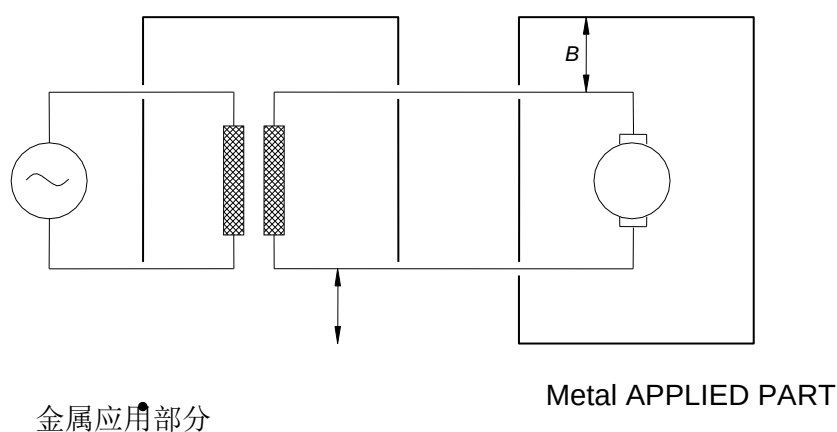


Figure A.10 – Floating circuit
图A.10–浮动电路

The APPLIED PART has a metal ENCLOSURE that is not PROTECTIVELY EARTHED. If there is a direct connection at point A, then the other end of the SECONDARY CIRCUIT is “live,” and even the first edition of this standard would have required DOUBLE INSULATION or REINFORCED INSULATION at point B. 应用部分有一个没有保护性接地的金属外壳。如果在a点直接连接，则二次电路的另一端是“带电”的，即使是本标准的第一版，也要求在B点进行双重绝缘或加强绝缘。

If, instead, there is a direct connection at point B, the first edition would have required only 相反，如果B点有直接连接，第一版只需要 BASIC INSULATION at point A; but this was dealt with in the second edition by adding Subclause A点的基本绝缘；但这在第二版中通过增加子条款来处理 20.2 B-e, which requires DOUBLE INSULATION or REINFORCED INSULATION at point A. 20.2 B-e，要求在A点进行双重绝缘或加强绝缘。

If however there is some insulation at both points A and B, then no part of the SECONDARY CIRCUIT is “live” according to the definition in the second edition, so the second edition of this standard specifies no requirements for that insulation, which can therefore be minimal. The German National Committee of the IEC discovered this problem in 1993, unfortunately just too late for it to be dealt with in the second (and final) amendment to the second edition of this standard. The approach adopted in this edition is intended to overcome this problem. 但是，如果A点和B点都有一些绝缘，那么根据第二版中的定义，二次电路的任何部分都是“带电的”，因此本标准第二版没有规定对该绝缘的要求，因此这一要求可以是最低限度的。IEC德国国家委员会在1993年发现了这一问题，不幸的是，对于本标准第二版的第二次（也是最后一次）修正案来说，已经太晚了。本版采用的方法旨在克服这一问题。

The formulation proposed for the third edition of this standard is to specify:
本标准第三版拟用公式规定：

- 1) how to determine which parts are to be regarded as ACCESSIBLE PARTS (by inspection and where necessary by the use of appropriate test probes and fingers);
如何确定哪些零件被视为可触及零件（通过检查，必要时使用适当的测试探针和手指）；
- 2) the permissible limits for voltage/current/energy in NORMAL CONDITION and relevant SINGLE FAULT CONDITIONS; these limits depend on the possible circumstances of connection to a PATIENT or to an OPERATOR;
正常条件下和相关单一故障条件下的电压/电流/能量允许限值；这些限值取决于与患者或操作员连接的可能情况；
- 3) that NORMAL CONDITION includes short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE or impedance which does not comply with specified requirements for the relevant WORKING VOLTAGE, and open circuit of any earth connection which does not comply with the requirements for PROTECTIVE EARTH CONNECTIONS;
and
正常情况包括不符合相关工作电压规定要求的任何绝缘短路、空气间隙或爬电距离或阻抗，以及不符合保护接地连接要求的任何接地连接开路；以及
- 4) that SINGLE FAULT CONDITIONS include short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE which does comply with specified requirements for the relevant WORKING VOLTAGE, short circuit of any relevant component, and open circuit of any earth connection which does comply with the requirements for PROTECTIVE EARTH CONNECTIONS.
单一故障条件包括符合相关工作电压规定要求的任何绝缘短路、空气间隙或爬电距离、任何相关部件短路以及符合保护接地连接要求的任何接地连接开路。

This approach avoids the need to include explicit separate requirements for particular protective means, as specified in existing IEC standards. Arguably it could avoid even a general requirement for two MEANS OF PROTECTION, as presently specified, but the working group considered that such a requirement is desirable. 这种方法避免了对现有IEC标准中规定的特定保护装置的明确单独要求。可以说，它甚至可以避免目前具体规定的对两种保护手段的一般要求，但工作组认为，这种要求是可取的。

Where requirements from the second edition that used the defined term “live” have been retained, they have been re-phrased so as not to use this term. 如果保留了第二版中使用定义术语“实时”的要求，则应重新措辞，以避免使用该术语。

Generally, protection is obtained by a combination of:
一般来说，保护是通过以下组合获得的：

- limitation of voltage or energy, or protective earthing (see 8.4 and 8.6);
电压或能量限制，或保护接地（见8.4和8.6）；
- enclosing or guarding of energized circuits (see 5.9);
带电电路的封闭或防护（见5.9）；
- insulation of adequate quality and construction (see 8.5).
具有足够质量和结构的绝缘（见8.5）。

The dielectric strength requirements are included to check the quality of the insulation material used at different places in the ME EQUIPMENT.
绝缘强度要求包括在医用电气设备的不同位置检查绝缘材料的质量。

Subclause 8.1 – Fundamental rule of protection against electric shock

Subclause 8.1 a)

第8.1款-电击防护基本规则第8.1 a) 款)

Insulation not complying with 8.8, spacing less than specified in 8.9, etc. are not MEANS OF PROTECTION, but they could influence the voltages or LEAKAGE CURRENTS appearing on ACCESSIBLE PARTS including APPLIED PARTS. Measurements might therefore need to be made with such parts intact or bypassed, whichever is the worse case.
不符合8.8的绝缘、间距小于8.9中规定的绝缘等不属于保护手段，但它们可能会影响可触及部件（包括应用部件）上出现的电压或泄漏电流。因此，可能需要在这些零件完好无损或绕过的情况下进行测量，以最坏的情况为准。

As there are in general no integrity requirements for signal connections, interruption of a functional earth connection has to be considered as a NORMAL CONDITION.
由于信号连接一般没有完整性要求，功能性接地连接中断必须视为正常情况。

Subclause 8.1 b)

第8.1 b) 款

LEAKAGE CURRENTS are not generally measured in the SINGLE FAULT CONDITION of breakdown of BASIC INSULATION in CLASS I EQUIPMENT because either the LEAKAGE CURRENTS in this case flow only during the time before a fuse or OVER-CURRENT RELEASE operates or the use of an isolated power supply limits the LEAKAGE CURRENTS to safe values. Exceptionally, LEAKAGE CURRENTS are measured during short circuiting of BASIC INSULATION in cases where there are doubts concerning the effectiveness of PROTECTIVE EARTH CONNECTIONS inside the ME EQUIPMENT (see 8.6.4 b)).
在I类设备基本绝缘击穿的单一故障条件下，通常不测量泄漏电流，因为在这种情况下，泄漏电流只在保险丝或过电流脱扣器工作之前流动，或者使用隔离电源将泄漏电流限制在安全值内。例外情况下，如果对医用电气设备内部保护接地连接的有效性存在疑问，则在基本绝缘短路期间测量泄漏电流（见8.6.4 b)）。

In certain instances the short-circuit condition is not necessarily the worst case. As an example, an overvoltage device, intended to prevent damage to insulation, could fail in the open-circuit condition thereby no longer rendering its safety function. This could lead to damaged insulation. It is recognized that in most cases in this subclause, the open-circuit condition is superfluous but for select components it was acknowledged that the open-circuit condition is a valid failure mode. Components of ME EQUIPMENT are also addressed in 4.8. 在某些情况下，短路情况不一定是最坏的情况。例如，旨在防止绝缘损坏的过电压装置可能在开路条件下发生故障，从而不再发挥其安全功能。这可能导致绝缘损坏。一般认为，在本款的大多数情况下，开路条件是多余的，但对于选定的部件，则认为开路条件是一种有效的故障模式。医用电气设备的部件也在4.8中进行了说明。

With regard to the presence of the MAXIMUM MAINS VOLTAGE on an unearthed ACCESSIBLE PART 关于未接地可触及部分上存在的最大电源电压 including APPLIED PARTS, see the rationales for 8.5.2.2 and 8.7.4.7 d). 包括应用部件，见8.5.2.2和8.7.4.7 d) 的基本原理。

If ME EQUIPMENT were configured as shown in Figure A.11, interruption of the connection would result in excessive TOUCH CURRENT. This situation is therefore one of the SINGLE FAULT CONDITIONS that should be investigated. 如果医用电气设备的配置如图A.11所示，连接中断将导致接触电流过大。因此，这种情况是应调查的单一故障情况之一。



Figure A.11 – Interruption of a power-carrying conductor
between ME EQUIPMENT parts in separate ENCLOSURES
图A.11-单独外壳中医用电气设备部件之间的载电导体中断

Subclause 8.3 – Classification of APPLIED PARTS 第8.3款-应用部件的分类

Subclause 8.3 a) 第8.3 a) 款

ME EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more TYPE CF APPLIED PARTS could have one or more additional TYPE B APPLIED PARTS or TYPE BF APPLIED PARTS that can be applied simultaneously (see also 7.2.10). 用于直接心脏应用的医用电气设备，具有一个或多个CF型应用部件，可具有一个或多个可同时应用的B型应用部件或BF型应用部件（另见7.2.10）。

Similarly ME EQUIPMENT could have a mixture of TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS. 类似地，医用电气设备可以是B型应用部件和BF型应用部件的混合物。

Subclause 8.3 b) 第8.3 b) 款

Most particular standards developed for kinds of ME EQUIPMENT that have PATIENT electrodes require the APPLIED PARTS to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. For similar kinds of ME EQUIPMENT for which no particular standards are available, it is better to include such a requirement in this standard than to allow such APPLIED PARTS to be TYPE B APPLIED PARTS. The TYPE B APPLIED PART classification is mainly used, in practice, for PATIENT supporting ME EQUIPMENT such as X-ray tables, not for PATIENT electrodes. 为具有病人电极的医用电气设备制定的大多数特殊标准要求应用部件为BF型应用部件或CF型应用部件。对于没有特定标准的类似医用电气设备，最好在本标准中包含此类要求，而不是允许此类应用部件为B型应用部件。B类应用零件分类在实践中主要用于支持医用电气设备（如X射线检查床），而不是用于患者电极。

Subclause 8.3 d)

第8.3 d) 款

Parts identified according to 4.6 as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases the RISK MANAGEMENT PROCESS could identify a need for such parts to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. This requirement reflects the majority view of the National Committees that responded to an inquiry on this subject during the preparation of this edition. 根据4.6确定的需要符合应用部件要求的部件（标记除外）通常比应用部件接触患者的频率低，因此与接地电气隔离的益处较小。然而，在某些情况下，风险管理过程可确定此类部件的需求，以满足BF型应用部件或CF型应用部件的要求。国家委员会在这一版本的编写过程中对这一要求作出了回应。

Subclause 8.4.1 – PATIENT CONNECTIONS intended to deliver current

第8.4.1款-旨在提供电流的患者连接

This standard does not specify any limits for currents that are intended to produce a physiological effect in the PATIENT, but particular standards can do so. Any other currents flowing between PATIENT CONNECTIONS are subject to the specified limits for PATIENT AUXILIARY CURRENT. 本标准未规定任何旨在对患者产生生理效应的电流限值，但特定标准可以这样做。在病人连接之间流动的任何其他电流都要遵守病人辅助电流的规定限值。

Subclause 8.4.2 – ACCESSIBLE PARTS including APPLIED PARTS

第8.4.2款-可触及部件，包括应用部件

Subclause 8.4.2 b)

第8.4.2 b) 款

It is presumed that TOUCH CURRENT can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR. The limits for TOUCH CURRENT therefore apply to all ACCESSIBLE PARTS except PATIENT CONNECTIONS, which are covered by 8.4.2 a), and parts that satisfy the conditions specified in 8.4.2 c). 假定接触电流可以通过各种路径（包括经由操作者的路径）偶然接触到患者。因此，接触电流限值适用于除8.4.2 a) 所述的患者连接和满足8.4.2 c) 中规定条件的所有可触及部件。

Subclause 8.4.2 c)

第8.4.2 c) 款

There is little or no justification for the difference in the second edition between the cases where there is a cover that is removable without a TOOL and where there is no cover. The limit values have been harmonized with IEC 60950-1:20012005 because Information Technology (IT) equipment is commonly used in ME SYSTEMS, and the values in IEC 60950-1 are not much different from those in the second edition of this standard. (60 V dc is the same, and 42,4 V peak is not much different from 25 V r.m.s.).

在第二版中，有一个没有工具可拆卸的盖子和没有盖子的情况之间的区别几乎没有理由。限值已与IEC 60950-1:20012005一致，因为信息技术（IT）设备通常用于ME系统，并且IEC 60950-1中的值与本标准第二版中的数值差别不大。（60 V直流电相同，42.4 V峰值与25 V r.m.s.相差不大）。

Essentially OPERATOR protection is now based on IEC 60950-1 and, therefore, we need to incorporate the protection requirements from that standard. Previously IEC 60601-1 did not have a requirement for protection against hazardous energy but there is a definite RISK from burn, fire and flying debris. This is now addressed using the requirement from IEC 60950-1:20012005. The limit values have been established for many years in IEC 60950 and its predecessor standards. The maximum available energy is allowed to exceed 240 VA during the first 60 s after contact with the ACCESSIBLE PART (e.g. it takes time for the current limit circuit in a power supply to operate and during this time the hazardous energy level can be exceeded). 基本上操作员保护现在基于iec60950-1，因此，我们需要纳入该标准的保护要求。以前，IEC 60601-1没有针对危险能源的防护要求，但存在一定的烧伤、火灾和飞溅碎片的风险。现在使用IEC 60950-1:20012005的要求来解决这一问题。多年来，IEC 60950及其前身标准中已经确定了这些限值。在与可触及部件接触后的前60 s内，允许最大可用能量超过240 VA（例如，电源中的限流电路需要一段时间才能工作，在此期间可能会超过危险能量水平）。

Subclause 8.4.2 d)
第8.4.2 d) 款

As well as parts that are determined to be ACCESSIBLE PARTS in accordance with 5.9, electrical contact with internal parts is supposed to be made with:
以及根据5.9确定为可触及零件的零件，与内部零件的电气接触应采用：

- a pencil or pen, held in a hand, simulated by a guided test pin;
一支铅笔或钢笔，握在手上，由一个导向的测试针模拟；
- a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;
用一个类似的金属吊坠挂在一个类似的金属吊坠上；
- a screwdriver for adjustment of a preset control by the OPERATOR, simulated by an inserted metal rod.
一种螺丝刀，用来调节操作员预先设定的控制，用插入的金属棒来模拟。

Subclause 8.4.3 – ME EQUIPMENT intended to be connected to a power source by a plug
第8.4.3款-拟通过插头连接至电源的医用电气设备

The 45 °C limit is the same as that specified in IEC 60335-1, which is based on the limits in IEC 60479-1 [11]. It is comparable (though not exactly equivalent) to the 100 nF limit specified in the second edition of this standard. With regard to BASIC SAFETY there is no reason to specify a more stringent limit between the line and earth pins, as in the second edition. 45°C限值与IEC 60335-1中规定的相同，该限值基于IEC 60479-1[11]中的限值。它与本标准第二版中规定的100 nF限值相当（尽管不完全等效）。关于基本安全，没有理由像第二版那样，在线路和接地引脚之间规定更严格的限制。

Subclause 8.4.4 - Internal capacitive circuits
第8.4.4款-内部电容电路

The limit has been changed from the 2 mJ specified in the second edition of this standard to the same value as specified in the previous subclause, because whatever is safe for an OPERATOR, or even a PATIENT, who touches the pins of a MAINS PLUG is also safe for someone who opens an ACCESS COVER to gain access to the inside of ME EQUIPMENT. 该限值已从本标准第二版中规定的2 mJ改为上一子条款中规定的相同值，因为任何对接触电源插头插脚的操作员或患者来说是安全的，对于打开检修盖进入医用电气设备内部的人来说也是安全的。

Subclause 8.5.1 - MEANS OF PROTECTION
第8.5.1款-保护手段

Two MEANS OF PROTECTION can be provided in several ways. The following are examples: 有几种方法可以提供两种保护方法。以下是示例：

- 1) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION only, but PROTECTIVELY EARTHED and have such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.
患者连接和其他可触及部分仅通过基本绝缘与接地电位不同的部分分开，但进行保护性接地，并且对地具有低内阻，泄漏电流在正常条件和单一故障条件下不会超过允许值。
- 2) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION and an intermediate PROTECTIVELY EARTHED metal part, which could be a fully enclosing metal screen. 通过基本绝缘和中间保护性接地金属部件（可以是完全封闭的金属屏蔽）将患者连接和其他可触及部件与接地电位不同的部件分开。
- 3) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by DOUBLE or REINFORCED INSULATION. 通过双重或加强绝缘将患者连接和其他可触及部件与接地电位不同的部件分开。
- 4) Impedances of components prevent the flow to PATIENT CONNECTIONS and other ACCESSIBLE PARTS of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS exceeding the allowable values. 组件的阻抗防止泄漏电流和患者辅助电流超过允许值流向患者连接和其他可触及部分。

A survey of insulation paths is found in Annex J.
绝缘路径调查见附录J。

Previous editions of this standard also recognized the possibility of achieving separation by use of a PROTECTIVELY EARTHED intermediate circuit. However it is in general not possible for the whole of a circuit to be connected with very low impedance to the PROTECTIVE EARTH TERMINAL. Also, if one part of a circuit is earthed, other parts of the circuit are then different from earth potential, so have to be further separated from PATIENT CONNECTIONS and other ACCESSIBLE PARTS. 本标准以前的版本也承认使用保护接地中间电路实现隔离的可能性。然而，一般情况下，整个电路不可能以非常低的阻抗连接到保护接地端子。另外，如果电路的一部分接地，那么电路的其他部分就不同于地电位，因此必须进一步与患者连接和其他可触及的部分分开。

Air can form part or all of the BASIC INSULATION or SUPPLEMENTARY INSULATION. In general DOUBLE INSULATION is preferable to REINFORCED INSULATION.

空气可以构成基本绝缘或补充绝缘的一部分或全部。一般来说，双重绝缘优于加强绝缘。

The first edition of this standard specified numerous pairs of parts between which separation was required, but the list was incomplete. It was expanded in the second edition but still remained incomplete, for example with regard to the situation illustrated in Figure A.10. 本标准第一版规定了需要分离的多对零件，但列表不完整。它在第二版中进行了扩充，但仍然不完整，例如图A.10所示的情况。

Discussion in the working group at an early stage of the development of this edition established that test houses actually have to identify the various circuits inside ME EQUIPMENT and the various points at which separation could be needed. This edition therefore specifies this PROCEDURE explicitly. 在本版本开发的早期阶段，工作组进行了讨论，确定试验室实际上必须确定医用电气设备内部的各种电路以及可能需要分离的各个点。因此，本版本明确规定了该过程。

The distinction between MEANS OF OPERATOR PROTECTION and MEANS OF PATIENT PROTECTION was introduced in response to concerns that the requirements of previous editions of this standard for insulation testing, CREEPAGE DISTANCES and AIR CLEARANCES were too stringent. 针对本标准先前版本对绝缘试验、爬电距离和空气间隙的要求过于严格的担忧，引入了操作员保护方式和患者保护方式之间的区别。

Many ME SYSTEMS incorporate equipment complying with IEC 60950-1. Also many kinds of ME EQUIPMENT incorporate parts, such as power supplies, that have been primarily designed for use in equipment complying with IEC 60950-1. This led some experts and National Committees to propose that the requirements of this standard be harmonized with IEC 60950-1 as far as possible.

许多医用电气系统包含符合IEC 60950-1的设备。此外，许多类型的医用电气设备都包含一些部件，如电源，这些部件主要设计用于符合IEC 60950-1的设备中。国家委员会建议尽量使本标准与IEC 601的一些专家协调一致。

However the test voltages and the minimum values of CREEPAGE DISTANCES and AIR CLEARANCES specified in IEC 60950-1 are derived from IEC 60664-1 and are based on assumptions about possible overvoltages in mains and other circuits, particularly the frequency of occurrence of various levels of overvoltage. According to the understanding of the working group experts who revised the corresponding requirements of this standard, compliance with the requirements of IEC 60664-1 or IEC 60950-1 leaves a RISK that transient insulation breakdown could occur with a frequency up to about once per year. 然而，IEC 60950-1中规定的试验电压、爬电距离和空气间隙的最小值源自IEC 60664-1，并基于对电源和其他电路中可能存在的过电压的假设，特别是各种过电压的发生频率。根据修订了本标准相应要求的工作组专家的理解，符合IEC 60664-1或IEC 60950-1的要求会产生频率高达每年一次的瞬态绝缘击穿风险。

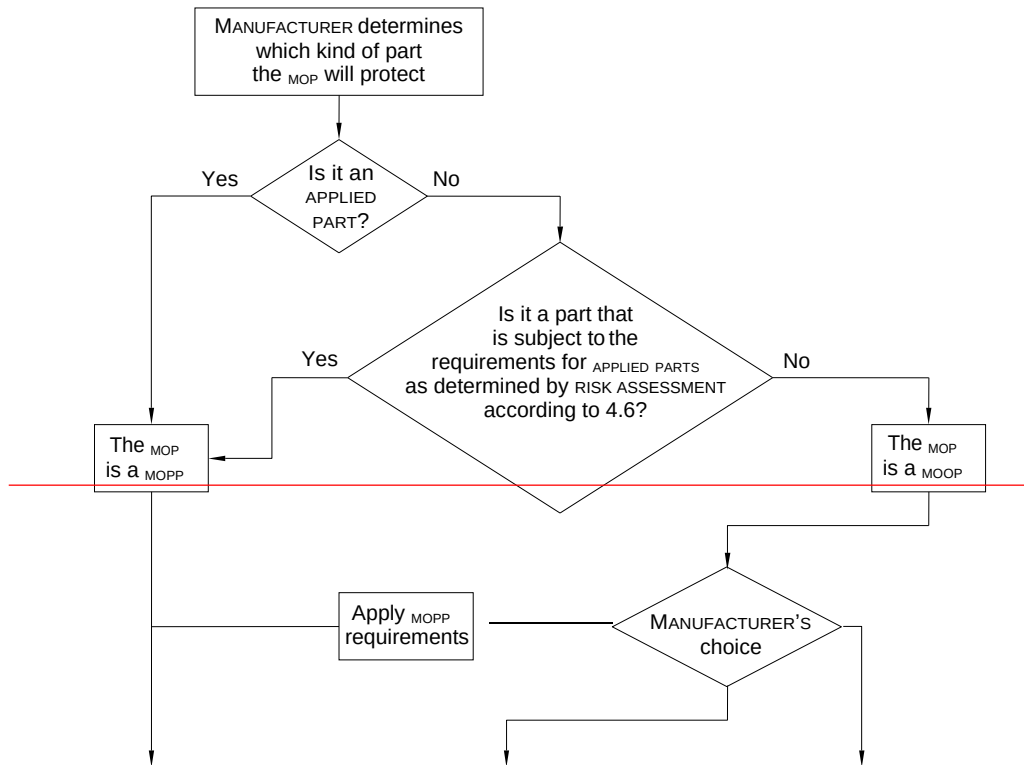
The probability of occurrence of an OPERATOR coming in contact with a relevant part and with earth at the moment when breakdown occurs is low, so the RESIDUAL RISK is acceptable for ME EQUIPMENT, just as it is for IT equipment. However the probability of occurrence of a PATIENT being in contact with an APPLIED PART and with earth is significantly higher. The working group therefore decided that a larger margin of safety should be applied where PATIENT safety is concerned. However there was no reliable basis for deciding what additional margin might be applied to the values from IEC 60664-1, so the same values that were specified in the second edition of this standard have been retained for MEANS OF PATIENT PROTECTION. 发生故障时，操作员接触相关部件和接地的概率很低，因此医用电气设备和IT设备的剩余风险是可以接受的。然而，患者与应用部件和地球接触的概率要高得多。因此，工作组决定，在涉及病人安全的情况下，应采用更大的安全边际。然而，没有可靠的依据来决定对IEC 60664-1中的值应用什么额外的裕度，因此本标准第二版中规定的相同值被保留用于保护患者。

For MEANS OF OPERATOR PROTECTION this revision of the standard allows the MANUFACTURER three options (see Figure A.12). One option is to apply the requirements of IEC 60950-1 and to identify the appropriate installation category and pollution degree. Alternatively, the MANUFACTURER can apply the values in the tables, which have been derived from IEC 60950-1 on the basis of reasonable assumptions about the installation category and pollution degree. The third option is to treat the MEANS OF OPERATOR PROTECTION as if it were a MEANS OF PATIENT PROTECTION.

对于操作员保护方法，本标准修订版允许制造商提供三个选项（见图A.12）。一种选择是应用IEC 60950-1的要求，并确定适当的安装类别和污染程度。或者，制造商可以应用表中的值，这些值是根据IEC 60950-1基于对安装类别和污染程度的合理假设得出的。第三种选择是将操作员保护的方式视为对患者的保护。

Y capacitors are used to reduce radio frequency interference by providing a low impedance path to earth for high frequency a.c. They are also used for bridging DOUBLE or REINFORCED INSULATION as part of the interference suppression regime. There are four types: Y1, Y2, Y3 and Y4. Y1 capacitors are designed for use with three phase mains and have a WORKING VOLTAGE of up to 500 V a.c. and a withstand voltage of 4 000 V a.c. Y2 capacitors are designed for use with single phase mains and have a WORKING VOLTAGE up to 300 V a.c. and a withstand voltage of 2 500 V a.c. Y3 capacitors are similar to Y2 capacitors but have a WORKING VOLTAGE up to 250 V a.c. Y4 capacitors are designed for use with low voltage mains and have a WORKING VOLTAGE up to 150 V a.c. and a withstand voltage of 1 000 V a.c. These capacitors are safety critical since they provide a leakage path to earth or across a barrier. So they must be certified and monitored by a recognised test house to IEC 60384-14, which serves to control their manufacture. Y电容器用于通过为高频交流提供低阻抗接地路径来减少射频干扰。它们还用于桥接双重或加强绝缘，作为干扰抑制机制的一部分。有四种类型：Y1、Y2、Y3和Y4。Y1电容器设计用于三相电源，工作电压高达500 V a.c.，耐受电压为4 000 V a.c. Y2电容器设计用于单相电源，工作电压高达300 V a.c.和2 500 V a.c. Y3电容器与Y2类似电容器的工作电压高达250 V a.c. Y4电容器设计用于低压主电路，其工作电压高达150 V a.c.且耐受电压为1 000 V a.c.这些电容器是安全关键，因为它们提供接地或穿过屏障的泄漏路径。因此，它们必须由公认的测试机构根据IEC 60384-14进行认证和监控，以控制它们的制造。

One Y1 capacitor can be used to provide two MOOP's but only one MOPP (PATIENTS need a higher level of protection than OPERATORS). A Y2 capacitor can be used to provide one MOOP only. 一个Y1电容器可用于提供两个MOOP，但只能提供一个MOPP（患者需要比操作员更高水平的保护）。Y2电容器只能用于提供一个MOOP。



MOP MEANS OF PROTECTION

拖把保护方式

MOPP MEANS OF PATIENT PROTECTION

MOOP MEANS OF OPERATOR PROTECTION

MOOP MEANS OF OPERATOR PROTECTION

MOPP患者保护方式

MOOP操作人员保护方式

MOOP操作人员保护方式

IEC 2434/05

国际电工委员会2434/05

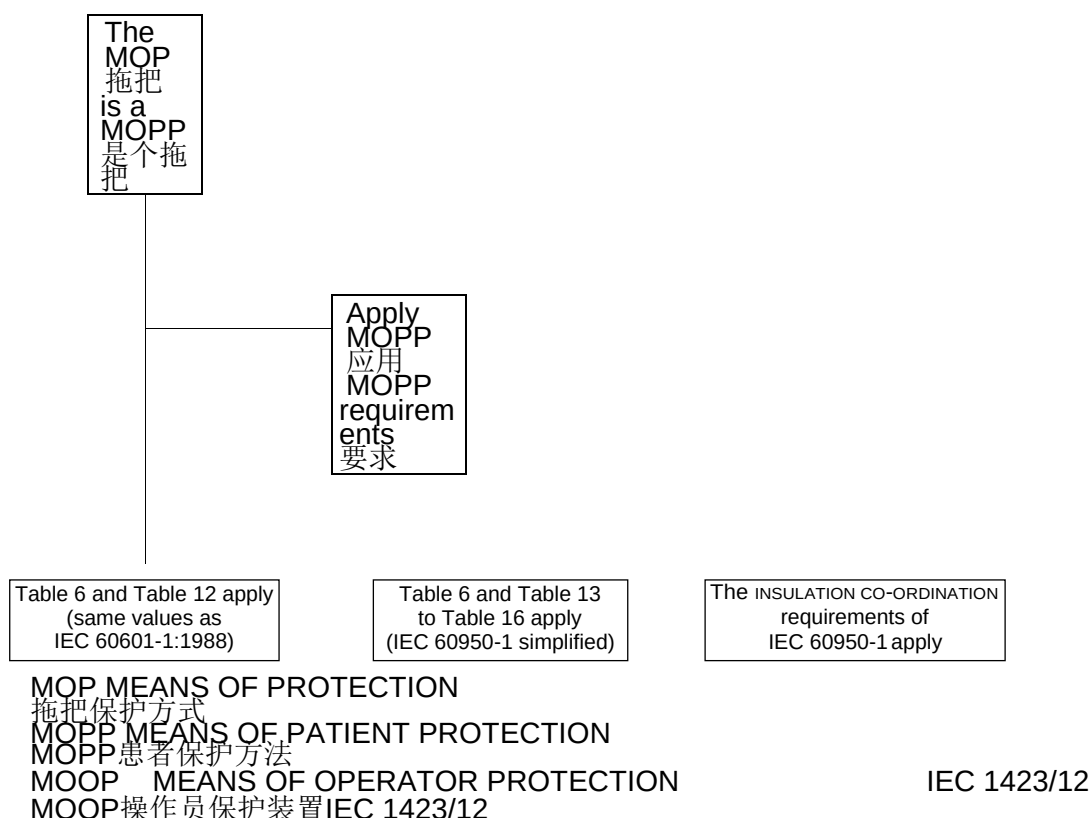


Figure A.12 – Identification of MEANS OF PATIENT PROTECTION
图A.12–确定患者保护方法
and MEANS OF OPERATOR PROTECTION
以及操作员保护措施

Subclause 8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP) 第8.5.1.2款-患者保护方法（MOPP）

When fitting Y capacitors across barriers, the dielectric strength requirement must be considered. For example, for voltages in the range of 212 V peak to 354 V peak, two MEANS OF PATIENT PROTECTION are required to be tested at 4 000 V a.c. This would then require the use of Y1 capacitors. Two Y2 capacitors in series would not withstand this voltage as they are rated at 1 500 V a.c. For voltages below 212 V peak, two Y2 capacitors would suffice as the dielectric strength requirement is 3 000 V a.c.

电容器安装时必须考虑绝缘层的强度要求。例如，对于212V峰值至354V峰值的电压，需要在交流4000V下测试两种保护患者的方法，然后需要使用Y1电容器。两个串联的Y2电容器不能承受此电压，因为它们的额定值为1500 V交流。对于低于212V峰值的电压，两个Y2电容器就足够了，因为介电强度要求为3000V交流。

Subclause 8.5.2.1 – F-TYPE APPLIED PARTS

第8.5.2.1款——F型应用部件

The essential feature of an F-TYPE APPLIED PART is its separation from other parts. This subclause specifies and quantifies the necessary degree of separation. F-TYPE应用部件的基本特征是与其它部件分离。本款规定并量化了必要的分离度。

Multiple functions can be considered as multiple APPLIED PARTS (which have to be separated from each other by one MEANS OF PATIENT PROTECTION) or as one APPLIED PART. This is decided by the MANUFACTURER after assessing the RISK that earthing of one or more of the PATIENT CONNECTION(S) of one function could result in excessive LEAKAGE CURRENT through the PATIENT CONNECTION(S) of another function, in the condition in which an unintended voltage originating from an external source becomes connected to the PATIENT. 多个功能可以被视为多个应用部分（必须通过一种患者保护手段将其相互分离）或作为一个应用部分。这是由制造商在评估一个功能的一个或多个患者连接的接地可能导致通过另一个功能的患者连接的过多泄漏电流的风险后决定的，在这种情况下，来自外部电源的意外电压连接到患者。

The 500 V r.m.s. limit for protective devices was already specified in the first edition of this standard. The original rationale is not known, but this voltage corresponds to the highest RATED voltage specified in 4.10. 本标准第一版中已经规定了保护装置的500 V r.m.s.限值。最初的原理尚不清楚，但该电压对应于4.10中规定的最高额定电压。

Subclause	8.5.2.2	—	TYPE	B	APPLIED	PARTS
第8.5.2.2款-B类应用部件						

This requirement addresses the possibility that an unintended voltage originating from an external source becomes connected to a part of the ME EQUIPMENT. In the absence of appropriate separation between such a part and PATIENT CONNECTIONS, an excessive PATIENT LEAKAGE CURRENT could result.
该要求说明了来自外部电源的意外电压连接到医用电气设备的一部分的可能性。如果此类部件和患者连接之间没有适当的分离，可能会导致患者泄漏电流过大。

According to Clause 17 c) of the second edition of this standard, this requirement applied to all APPLIED PARTS, but in many cases it no longer applies:
根据本标准第二版第17 c) 条，本要求适用于所有应用部件，但在许多情况下不再适用：

- For F-TYPE APPLIED PARTS, the isolation required by 8.5.2.1 also covers this situation (but for F-TYPE应用部件，8.5.2.1要求的隔离也包括这种情况（但是 TYPE BF APPLIED PARTS require an additional test, as explained in the rationale to BF型应用部件需要进行附加试验，如 8.7.4.7 d)). 8.7.4.7 d) 段）。
- The RISK cannot arise A HAZARDOUS SITUATION cannot develop if either the ME EQUIPMENT part concerned or the PATIENT CONNECTIONS of a TYPE B APPLIED PART are PROTECTIVELY EARTHED. (Failure of the PROTECTIVE EARTH CONNECTION together with the appearance of the unintended voltage would be a double fault condition.)
如果相关医用电气设备部件或B类应用部件的患者连接接地保护性接地，则不会出现危险情况。（保护接地连接的故障以及意外电压的出现将是双重故障情况。）
- If the ME EQUIPMENT part concerned is physically contiguous with the APPLIED PART (for example a dental handpiece) the requirement does not apply if the RISK of contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.
如果相关医用电气设备部件与应用部件（例如牙科机头）在物理上相邻，则如果接触电压源或泄漏电流高于允许限值的风险很低，则该要求不适用。

Subclause 8.5.2.3 – PATIENT leads or PATIENT

cables There are two sets of circumstances to guard against:

第8.5.2.3款-患者导线或患者电缆有两种情况需要防范：

- firstly, for TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead that can become detached from the ME EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth can have an adverse effect on the operation of the ME EQUIPMENT;
首先，对于BF型应用部件和CF型应用部件，不应存在通过任何可能从医用电气设备上脱落的导线进行意外的患者接地连接的可能性；即使对于B型应用部件，不必要的接地连接也会对医用电气设备的运行产生不利影响；
- secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to parts of ME EQUIPMENT or other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.
其次，对于所有类型的应用部件，不应意外地将患者连接到医用电气设备部件或附近的其他导电部件上，从这些部件中可以流出超过允许泄漏电流的电流。

An extreme case of the latter HAZARD would be a direct connection to the SUPPLY MAINS, resulting from insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD. It is essential to prevent this from occurring.

后一种危险的极端情况是将连接器插入电源插座或可拆卸电源线的插座端，从而直接连接到电源线。必须防止这种情况的发生。

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the
通过病人和电源连接器的某些组合，可以将
PATIENT connector accidentally into the mains socket.
患者连接器意外插入电源插座。

This possibility cannot reasonably be removed by dimensional requirements as to do so would make single-pole connectors excessively large. Such an incident is rendered safe by the requirement for the PATIENT connector to be protected by insulation having a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of at least 1 500 V. The latter on its own would not suffice as 1 500 V protection could easily be achieved by thin plastic foil that would not stand up to daily wear or to being pushed, possibly repeatedly, into a mains socket. For this reason also it can be seen that the insulation should be durable and rigid.
这种可能性不能通过尺寸要求合理地消除，因为这样做会使单极连接器过大。这样的事故是安全的，因为病人连接器需要用爬电距离至少为1的绝缘材料保护，0 mm和至少1500 V的介电强度。后者本身不足以实现1500 V保护，因为薄塑料箔经不起日常磨损或反复推入电源插座，很容易实现1500 V保护。因此，也可以看出，绝缘层应该是耐用和坚硬的。

The wording of this requirement was modified from that in the second edition of this standard to avoid use of the phrases “conductive connection”, which was eliminated as a defined term. This change was a direct result of National Committee comments during the preparation of this edition.
本要求的措辞在本标准第二版的基础上进行了修改，以避免使用“导电连接”这一术语，该术语已被删除。这一变化是国家委员会在编写本版时发表意见的直接结果。

According to the rationale in the second edition of this standard, the test in which the test finger is applied with a force of 10 N was intended “to check the strength of the insulating material.” This has now been supplemented by an explicit cross reference to 8.8.4.1.
根据本标准第二版中的基本原理，试验指施加10 N力的试验旨在“检查绝缘材料的强度”。现在，对8.8.4.1的明确交叉引用进行了补充。

In response to an enquiry, one National Committee stated that this test is “a mechanical test of the protective cover over the pin;” suggesting that the test was intended to apply specifically to one particular kind of connector design, in which the contact is surrounded by a movable sheath designed to allow contact with the correct mating connector but not with other parts.
一个国家委员会在答复一项询问时说，这项试验是“对插销上的保护罩进行的机械试验”；表明该试验旨在专门适用于一种特殊的连接器设计，在这种情况下，触点周围有一个可移动的护套，其设计允许与正确的匹配连接器接触，但不能与其他部件接触。

During the development of this edition of this standard, the question arose whether this test should be restricted to single-pole connectors, as in the second edition of this standard, or should apply to multi-pole connectors as well. Some multi-pole connectors are of similar shape to single-pole connectors and could similarly be inserted into a MAINS CONNECTOR, so the same considerations of adequacy of insulation apply equally. On the other hand, typical kinds of multi-pole connectors that are in common use cannot be inserted into a MAINS CONNECTOR, but would fail this test if they were subject to it, because the test finger can easily touch their contacts, even without the application of a 10 N force.

在本标准本版的制定过程中，出现了这样一个问题：本试验是否应像本标准第二版那样仅限于单极连接器，还是也应适用于多极连接器。一些多极连接器的形状与单极连接器相似，也可以类似地插入电源连接器，因此同样的绝缘充分性考虑同样适用。另一方面，通常使用的典型多极连接器不能插入电源连接器，但是如果进行测试，则测试失败，因为即使不施加10 N的力，测试手指也可以轻松地接触到它们的触点。

A further enquiry to the National Committees yielded a range of responses, with reasonable consensus on some questions but no consensus as to whether this test should apply to all connectors or should be restricted to single-pole connectors. 对国家委员会的进一步调查得到了一系列的答复，在一些问题上达成了合理的共识，但对于这项试验是应适用于所有连接器还是应仅限于单极连接器，没有达成共识。

This test should certainly apply to a multi-pole connector that is of such shape and size that it could be inserted into a mains socket. In this case, the RISK is the same as with a single-pole connector. 这项测试当然应该适用于多极连接器，它的形状和尺寸可以插入电源插座。在这种情况下，风险与单极连接器相同。

Another reason for applying this test to some multi-pole connectors is that the test with the flat plate does not exhaustively assess the possibility of contact with conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow. Almost any kind of connector, if detached from the ME EQUIPMENT or dropped, could possibly make contact with something besides the intended mating connector, but the RISK depends on the shape of the connector and the circumstances. In most cases the RISK is low. For example a typical “D” connector is likely to make contact with an earthed object only momentarily, whereas a straight pin could make contact for a prolonged period. However even prolonged contact with a metal object can result in a HAZARD HAZARDOUS SITUATION only if it occurs in combination with a fault or abnormal situation that allows an excessive current to flow through the PATIENT. The RISK is in all cases much less than the RISK if the connector can make contact with a mains socket. The requirements of this standard should be formulated in relation to the RISK. The standard should minimise RISK to the PATIENT, while allowing MANUFACTURERS a reasonable range of choice of connectors. 将该试验应用于某些多极连接器的另一个原因是，用平板进行的试验没有详尽地评估与附近导电部件接触的可能性，而导电部件附近的电流可能超过允许的泄漏电流。几乎任何类型的连接器，如果从医用电气设备上断开或掉落，都可能与预期匹配连接器以外的其他物体接触，但风险取决于连接器的形状和环境。在大多数情况下，风险很低。例如，一个典型的“D”型连接器可能只与接地物体短暂接触，而直销可能会长时接触。然而，即使是长时接触金属物体也会导致危险的情况，只有当它与允许过多电流流过患者的故障或异常情况相结合时才会导致危险。这种风险在任何情况下都比连接器能接触电源插座的风险小得多。应根据风险制定本标准的要求。该标准应将对患者的风险降至最低，同时允许制造商合理选择连接器。

“Any connector” should be understood to include multiple contact connectors, several connectors and connectors in series.

“任何连接器”应理解为包括多触点连接器、多个连接器和串联连接器。

The dimension of 100 mm diameter is not in the least important and merely serves to indicate the scale of the flat surface. Any sheet of conductive material larger than this would be suitable. 直径为100mm的尺寸并不重要，它只是用来表示平面的比例。任何比这个大的导电材料片都是合适的。

Subclause 8.5.3 第8.5.3款-最大电源电压

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MAXIMUM

MAINS

VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown; but according to the second

edition of this standard it was taken to be the highest RATED MAINS VOLTAGE, or for polyphase equipment the phase to neutral supply voltage. These values reflected a reasonable worst-case assumption that the actual unintended external voltage is unlikely to exceed the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used, and that ME EQUIPMENT is unlikely to be used in a location where the SUPPLY MAINS has a voltage higher than its highest RATED MAINS VOLTAGE. For INTERNALLY POWERED ME EQUIPMENT the value specified was (and remains) 250 V, because this is the highest commonly encountered phase-to-neutral voltage in locations where ME EQUIPMENT is used.

本标准的一些要求和试验与来自外部电源的意外电压连接到患者或医用电气设备的某些部分的可能性有关。这种电压的实际大小不得而知；但根据本标准第二版，它被视为最高额定电源电压，或多相设备的相对中性电源电压。这些值反映了一个合理的最坏情况假设，即实际意外外部电压不太可能超过医用电气设备使用位置的电源电压，并且医用电气设备不太可能用于供电干线电压高于其最高额定电源电压的位置。对于内部供电的医用电气设备，规定的电压值为（并保持）250 V，因为这是医用电气设备使用位置通常遇到的最高相对中性点电压。

In early drafts of this edition, the corresponding wording only referred to a.c. SUPPLY MAINS. This mistake was pointed out during the comment period. Discussion of this comment confirmed that the requirements should not depend on whether the SUPPLY MAINS is a.c. or d.c., but revealed a further anomaly. If ME EQUIPMENT is specified for connection to an extra- low voltage (ELV) SUPPLY MAINS (for example 12 V in an ambulance) but not to any higher voltage SUPPLY MAINS, the external voltage assumed for test purposes would be only the ELV. Such ME EQUIPMENT could however be used in locations where a higher voltage SUPPLY MAINS is also installed. The wording has therefore been revised to remove this anomaly.

在本版的早期草案中，相应的措辞仅指交流电源干线。这个错误是在评论期间指出的。对该意见的讨论证实，要求不应取决于供电干线是交流还是直流，而是揭示了进一步的异常情况。如果医用电气设备指定用于连接超低电压（ELV）电源（例如救护车上的12 V电源），但不连接任何更高电压的电源，则为测试目的假设的外部电压将仅为ELV。然而，此类医用电气设备也可用于安装了更高电压电源的位置。因此，对措辞进行了修改，以消除这一反常现象。

If ME EQUIPMENT has a highest RATED supply voltage less than 100 V, it will necessarily be used in a special location where that supply is available, and we do not know what other supplies could also be present. Therefore the external voltage assumed for relevant tests is 250 V, as for INTERNALLY POWERED ME EQUIPMENT.
如果医用电气设备的最高额定电源电压低于100 V，则必须将其用于可获得该电源的特殊位置，并且我们不知道还有哪些其他电源可供使用。因此，对于内部供电的医用电气设备，相关试验的外部电压假定为250 V。

However ME EQUIPMENT having a highest RATED MAINS VOLTAGE of around 115 V is unlikely to be used in locations having higher voltage SUPPLY MAINS, so the external voltage assumed for relevant tests is equal to the highest RATED MAINS VOLTAGE, as in the second edition of this standard.
然而，医用电气设备的最高额定电源电压约为115V，不太可能在电源电压较高的地方使用，因此相关试验中假设的外部电压等于最高额定电源电压，如本标准第二版所述。

Subclause 8.5.4 - WORKING VOLTAGE
第8.5.4款-工作电压

The dielectric strength test voltages specified in Table 6 are appropriate for insulation that is normally subjected to a continuous WORKING VOLTAGE and to transient overvoltages.
表6中规定的介电强度试验电压适用于通常承受连续工作电压和瞬态过电压的绝缘。

The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected, because either MEANS OF PROTECTION can be subjected to this voltage if the other MEANS OF PROTECTION fails.
形成双重绝缘的每种保护装置的工作电压是双重绝缘作为一个整体所承受的电压，因为如果另一种保护装置失效，任何一种保护装置都可以承受这种电压。

For insulation between two isolated parts or between an isolated part and an earthed part, the WORKING VOLTAGE could in some cases be equal to the arithmetic sum of the highest voltages between any two points within both parts.
对于两个隔离部件之间或隔离部件与接地部件之间的绝缘，在某些情况下，工作电压可能等于两个部件内任意两点之间最高电压的算术和。

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a WORKING VOLTAGE equal to the defibrillation peak voltage would be far too high for insulation that in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than 10 1 s and without additional overvoltage.
对于防除颤的应用部件，基于等于除颤峰值电压的工作电压推导出的试验电压对于正常使用中仅偶尔暴露于电压脉冲（通常短于10 1s且无额外过电压）的绝缘而言，太高了。

Subclause 8.5.5 - DEFIBRILLATION-PROOF APPLIED PARTS
第8.5.5款-防除颤应用部件

The special test described in 8.5.5 is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.
8.5.5中所述的特殊试验被认为是为了确保对除颤脉冲的充分防护，无需单独进行介电强度试验。

Subclause 8.5.5.1 - Defibrillation protection
第8.5.5.1款-除颤保护

One or the other of the defibrillation paddles could, by virtue of its clinical application, be connected to earth or at least referenced to earth.
除颤浆中的一个或另一个，由于其临床应用，可以连接到地球上，或者至少可以参考地球。

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the ME EQUIPMENT and another, or between such parts collectively and earth. ACCESSIBLE PARTS should be adequately isolated from PATIENT CONNECTIONS or protected in some other way. The insulation of the PATIENT

CONNECTIONS cannot be protected by voltage limiting devices relying on earthed connections.

当在病人身上使用除颤器时，可以在医用电气设备的一个部件和另一个部件之间，或者在这些部件和地面之间施加高压。可触及的部分应与患者的连接充分隔离或以其他方式加以保护。病人连接的绝缘不能通过依赖于接地连接的电压限制装置来保护。

The DEFIBRILLATION-PROOF APPLIED PART marking indicates that an APPLIED PART can safely remain attached to a PATIENT who is being defibrillated without any adverse effect on subsequent use of the ME EQUIPMENT. 防除颤应用部件标记表明，应用部件可以安全地连接到正在除颤的患者身上，而不会对医用电气设备的后续使用产生任何不利影响。

The

tests

ensure:

测试确保：

- a) that any ACCESSIBLE PARTS of ME EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not deliver a hazardous level of charge or energy due to flashover of defibrillation voltage; and 医用电气设备、患者电缆、电缆连接器等的任何可触及部分未进行保护性接地，不会因除颤电压闪络而产生危险的电荷或能量水平；以及
- b) that the ME EQUIPMENT will continue to function (at least with regard to BASIC SAFETY and 医用电气设备将继续运行（至少在基本安全和 ESSENTIAL PERFORMANCE) after exposure to defibrillation voltage. 基本性能）暴露于除颤电压后。

The requirement and the test PROCEDURE refer to “any necessary time” stated in the ACCOMPANYING DOCUMENTS. There is no requirement for the ACCOMPANYING DOCUMENTS to include a statement of a recovery time, but if there is no statement the ME EQUIPMENT has to recover and deliver its BASIC SAFETY and ESSENTIAL PERFORMANCE immediately.

要求和试验程序参考随附文件中规定的“任何必要时间”。随附文件不要求包括恢复时间声明，但如果没有声明，医用电气设备必须立即恢复并提供其基本安全和基本性能。

The tests are conducted with the ME EQUIPMENT connected to the SUPPLY MAINS and in operation according to the instructions for use because the tests deal not only with the effect of the defibrillation energy on BASIC SAFETY but also on the ability of the ME EQUIPMENT to deliver its ESSENTIAL PERFORMANCE after the stated recovery time. 测试是在医用电气设备连接到电源干线并按照使用说明运行的情况下进行的, 因为这些测试不仅涉及除颤能量对基本安全的影响, 还涉及医用电气设备在规定恢复时间后实现其基本性能的能力。

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the ME EQUIPMENT and, at the same time, the OPERATOR or another person is in contact with the ENCLOSURE. The possibility of this occurring at the same time as the SINGLE FAULT CONDITION of a defective PROTECTIVE EARTH CONNECTION is very unlikely and is therefore disregarded. However, interruption of functional earth connections is more probable, and is therefore required for these tests. 正常使用包括患者在连接医用电气设备时被除颤, 同时操作员或其他人与外壳接触。这种情况与有缺陷的保护接地连接的单一故障条件同时发生的可能性很小, 因此可以忽略不计。然而, 功能性接地连接中断的可能性更大, 因此这些测试需要中断。

The SEVERITY of electric shock that a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 □C) which can be felt and which could be unpleasant, but which is not dangerous. 在除颤器放电过程中, 当一个人接触到可触及的部件时, 触电的严重程度被限制在一个可以感觉到的值 (相当于100°C的电荷), 该值可能令人不快, 但并不危险。

SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote ME EQUIPMENT could otherwise carry energies that might be hazardous. 信号输入/输出部分包括在内, 因为到远程医用电气设备的信号线可能会携带危险的能量。

The test circuits of Figure 9 and Figure 10 of this standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R1). 本标准图9和图10中的试验电路旨在通过整合试验电阻 (R1) 上出现的电压来简化试验。

The value of the inductance L in the test circuits of Figure 9 and Figure 10 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means. 图9和图10所示试验电路中的电感L值被选择为提供比正常上升时间短的上升时间, 以便充分测试集成的保护装置。

If ME EQUIPMENT would be designed according to 8.5.2.1 and 8.5.5.1, it might have two different functions on one common APPLIED PART circuit. Consider the example in Figure A.21. In this example, the ECG and an invasive blood pressure catheter (IBP) share one common APPLIED PART circuit. In real use in the hospital, sometimes only one function (ECG) is used while the other function (IBP) is not connected. If the PATIENT needs to be defibrillated, there is a potential that a second OPERATOR would get an electric shock at unused IBP outlets during selecting of proper adjustments at the ME EQUIPMENT (e.g. at a multi-parameter patient monitor). It should be pointed out that in principle, the 5 KV could occur at every disconnected connector, which does not have adequate recessed pins. However, in practice, the probability of occurrence of HARM is much higher at the unused APPLIED PART outlets on the ME EQUIPMENT compared to any connector of adapter cables. Adapter cables will normally not be touched by the OPERATOR during defibrillation, because before defibrillation the command “stand clear” will be given. Even in the case that a disconnected adapter cable would be touched by an OPERATOR during defibrillation, it will most probably be touched at the isolated plastic parts, but not at its internal pins. 如果医用电气设备按照8.5.2.1和8.5.5.1进行设计, 它可能在一个公共应用部分电路上具有两个不同的功能。考虑图A.21中的示例。在这个例子中, ECG和有创血压导管 (IBP) 共用一个公共的应用部分电路。在医院的实际应用中, 有时只使用一个功能 (ECG), 而另一个功能 (IBP) 没有连接。如果患者需要除颤, 在选择医用电气设备 (如多参数患者监护仪) 的适当调整时, 第二名操作员可能在未使用的IBP插座处触电。应该指出的是, 原则上, 5 KV可能发生在每个断开的连接器上, 这些连接器没有足够的凹陷插脚。然而, 在实践中, 与适配器电缆的任何连接器相比, 医用电气设备上未使用的应用部件插座处发生损害的概率要高得多。除颤期间, 操作员通常不会接触适配器电缆, 因为在除颤之前, 会发出“禁止靠近”的命令。即使在除颤过程中操作员会接触断开的适配器电缆, 也很可能会在隔离的塑料部件上接触,

而不是在其内部引脚处。

5 KV defibrillation impulse
accessible at the unused
IBP outlet
5 KV去纤脉冲可在未使用
的IBP出口接入

5 KV defibrillation
impulse applied to
the ECG input
应用于ECG输入的
5 KV除颤脉冲

FE
铁

IEC 1424/12标准

Figure A.21 – Example of ME EQUIPMENT having two different functions on one common
图A.21–医用电气设备在一个公共设备上具有两个不同功能的示例

APPLIED PART circuit
应用部分电路

Rationale 脉冲试验电压的基本原理	for	impulse	test	voltage

When a defibrillation voltage is applied to the thorax of a PATIENT, via externally applied paddles (or defibrillation electrodes), the body tissue of the PATIENT in the vicinity of the paddles and between the paddles becomes a voltage dividing system.
当通过外部应用的电极（或除颤电极）将除颤电压施加到患者的胸部时，位于桨叶附近和桨叶之间的患者身体组织成为一个分压系统。

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity that is far from uniform.
电压分布可以用三维场理论粗略测量，但会受到局部组织电导率的影响，而局部组织的电导率远不均匀。

If the electrode of another item of ME EQUIPMENT is applied to the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position but will generally be less than the on-load defibrillation voltage.
如果将另一项医用电气设备的电极施加在患者身上，大致在除颤器叶片的罗盘范围内，则该电极所承受的电压取决于其位置，但通常会低于有载除颤电压。

Unfortunately it is not possible to say how much less as the electrode in question can be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant particular standard, it is required that such an electrode and the ME EQUIPMENT to which it is connected is able to withstand the full defibrillation voltage. This is the no-load voltage as one of the defibrillator paddles might not be making good contact with the PATIENT.

不幸的是，不可能说得更少，因为有问题电极可以放置在这个区域的任何地方，包括紧邻一个除颤器电极。在没有相关特殊标准的情况下，要求该电极及其连接的医用电气设备能够承受完全除颤电压。这是空载电压，因为其中一个除颤器叶片可能与患者接触不好。

This standard therefore specifies 5 kV d.c. as the appropriate test voltage in the absence of a relevant particular standard.
因此，本标准特别规定了5千伏电压。

Applying Subclause 4.5, a MANUFACTURER is allowed to use alternate means to address a

RISK covered by this standard if the RESIDUAL RISK after applying the alternate means is equal or less than the RESIDUAL RISK after applying the requirements of this standard. It is possible for a MANUFACTURER to determine that a lower test voltage is appropriate depending on the INTENDED USE of the ME EQUIPMENT and the location of the APPLIED PARTS on the PAIENT if it can be demonstrated that the test voltage selected is the maximum voltage that can appear on the APPLIED PART with 5 kV applied to the chest. Such parts can be classified and marked as a DEFIBRILLATION-PROOF APPLIED PARTS. 应用第4.5款，如果应用替代方法后的剩余风险等于或小于应用本标准要求后的剩余风险，则允许制造商使用替代方法来解决本标准所涵盖的风险。制造商可以根据医用电气设备的预期用途和设备上应用部件的位置来确定较低的试验电压是否合适，前提是可以证明所选的试验电压是在胸部施加5 kV电压的情况下出现在应用部件上的最大电压。此类部件可分类并标记为防除颤应用部件。

Subclause 8.6 – Protective earthing, functional earthing and potential equalization of
第8.6款-保护接地、功能接地和电位均衡

ME **EQUIPMENT**
医用电气设备

Typically, metal ACCESSIBLE PARTS of CLASS I ME EQUIPMENT are PROTECTIVELY EARTHED. 一般情况下，I类医用电气设备的金属可触及部分进行保护接地。

However, they could be separated by other MEANS OF PROTECTION, in accordance with 8.5. Also some metal ACCESSIBLE PARTS could be earthed incidentally, neither by a PROTECTIVE EARTH CONNECTION nor for functional purposes. For example, such a part could be in contact with another part that is PROTECTIVELY EARTHED but does not itself need to be PROTECTIVELY EARTHED. 但是，根据8.5的规定，它们可以通过其他保护手段分开。此外，一些可触及的金属部件可能会偶然接地，既不是通过保护性接地连接，也不是出于功能目的。例如，这样的一个部件可能与另一个保护性接地部件接触，但其本身不需要进行保护性接地。

Subclause8.6.1–Applicabilityofrequirements

第8.6.1款-要求的适用性

PROTECTIVE EARTH CONNECTIONS that are only relevant to the safety of OPERATORS are allowed to comply either with the requirements of this standard or with those of IEC 60950-1, but the latter alternative is not allowed for PROTECTIVE EARTH CONNECTIONS that are relevant to the safety of both OPERATORS and PATIENTS. 仅与操作人员安全相关的保护接地连接允许符合本标准或IEC 60950-1的要求，但后者不适用于与操作员和患者安全相关的保护性接地连接。

Subclause8.6.2–PROTECTIVEEARTHTERMINAL

第8.6.2款-保护接地端子

These requirements are intended to ensure a reliable connection between the ME EQUIPMENT and the protective earthing system of the electrical installation. 这些要求旨在确保医用电气设备之间的可靠连接以及电气装置的保护接地系统。

Subclause8.6.3–Protectiveearthingofmovingparts

第8.6.3款-活动部件的保护接地

Connections to moving parts, whether made by sliding contacts, by flexible wires or by any other means, could be more susceptible than ordinary FIXED connections to deterioration during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Therefore, they are not acceptable as PROTECTIVE EARTH CONNECTIONS unless their reliability is demonstrated. 在医用电气设备的预期使用寿命期间，与活动部件的连接，无论是通过滑动触点、软线还是任何其他方式，都比普通固定连接更容易发生劣化。因此，除非证明其可靠性，否则不可将其作为保护接地连接。

Subclause8.6.4a)

第8.6.4 a) 款

PROTECTIVE EARTH CONNECTIONS can only perform their protective function if they are able to carry the fault current resulting from a failure in BASIC INSULATION. 只有当它们的基本绝缘保护功能失效时，它们才能执行基本的保护性接地故障。

Such a current is assumed to have sufficient amplitude to cause operation of protective devices in the electrical installation (fuses, circuit-breakers, earth leakage circuit-breakers and the like) in a reasonably short time. 假定该电流具有足够的振幅，以使电气装置中的保护装置（保险丝、断路器、漏电断路器等）在合理的短时间内运行。

It is therefore necessary to check both the impedance and the current-carrying capability of PROTECTIVE EARTH CONNECTIONS. 因此，有必要同时检查保护接地连接。

The minimum time required for the test current is intended to reveal any overheating of parts of the connection due to thin wiring or a bad contact. Such a “weak spot” might not be discovered by resistance measurement alone. 测试电流所需的最短时间旨在揭示由于导线细或接触不良导致的连接部件过热。这样一个“薄弱点”可能不是单靠电阻测量就能发现的。

PROTECTIVE EARTH CONNECTIONS can have zones of higher impedance, for example due to oxidation of materials. Use of a current source with an unlimited voltage could prevent detection of such zones because of their ability to flash through. The impedance is therefore determined first, using a limited voltage. 保护接地连接可能具有高阻抗区域，例如由于材料氧化。使用电压不受限制的电流源可能会阻止对此类区域的检测，因为这些区域具有闪光的能力。因此，首先用有限的电压确定阻抗。

If this voltage is sufficient to drive the specified test current through the total impedance, then this one test also serves to demonstrate the current-carrying capability of the connection. Otherwise an additional test is necessary, either using a higher voltage or by assessing the cross-sectional area of the connection by inspection.
如果该电压足以驱动规定的试验电流通过总阻抗，则这一次试验也可用于证明连接的载流能力。否则，需要进行额外的测试，使用更高的电压或通过检查评估连接的横截面积。

Where a long (> 3 m) DETACHABLE POWER SUPPLY CORD is supplied, specified or used, the 200 m² total protective earth pathway requirement still applies. Therefore, it might be necessary to use a DETACHABLE POWER SUPPLY CORD with conductors of a greater cross sectional area than the minimum required by 8.11.3.3.
如果提供、规定或使用长（>3 m）可拆卸电源线，200 m²总保护接地路径要求仍然适用。因此，可能有必要使用可拆卸电源线，其导线的横截面积大于8.11.3.3要求的最小值。

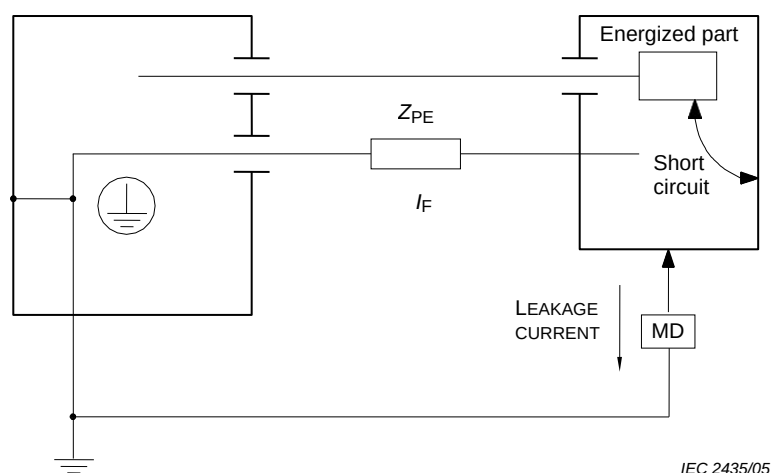
Subclause
第8.6.4 b) 款

8.6.4

b)

The fault current could be limited to a relatively low value because of inherent impedance or the characteristic of the power source, for example where the power system is not connected to earth or connected to it via a high impedance (see Figure A.13).
由于固有阻抗或电源特性，故障电流可能被限制在一个相对较低的值内，例如，当电力系统未接地或未通过高阻抗与之相连时（见图a.13）。

In such cases, the cross-section of the PROTECTIVE EARTH CONNECTION can be determined primarily by mechanical considerations.
在这种情况下，保护接地连接的横截面可主要根据机械因素确定。



Legend

图例

ZPE = Impedance of PROTECTIVE EARTH CONNECTION in ohms (exceeding the limit specified in 8.6.4 a))
ZPE=保护接地连接的阻抗，单位为欧姆（超过8.6.4 a) 条）

IF = Maximum continuous prospective fault current in amperes in the PROTECTIVE EARTH CONNECTION caused by a single failure of the insulation to earth
IF=由对地绝缘单一故障引起的保护接地连接中的最大持续潜在故障电流（单位：安培）

MD Measuring device (see Figure 12)

MD测量装置（见图12）

NOTE The figure shows ME EQUIPMENT having a main ENCLOSURE and a remote part in a separate ENCLOSURE, as an example of a situation where the impedance of a PROTECTIVE EARTH CONNECTION could exceed the limit specified in 8.6.4 a): however this situation could also exist in ME EQUIPMENT having a single ENCLOSURE.
 注：图中所示的医用电气设备在单独的外壳中有一个主外壳和一个远程部件，作为保护性接地连接的阻抗可能超过8.6.4 a) 中规定限值的一个例子：然而，这种情况也可能存在于具有单个外壳的医用电气设备中。

Figure A.13 – Allowable protective earth impedance where the fault current is limited

图A.13–故障电流受限时的容许保护接地阻抗

Subclause 8.6.7 – POTENTIAL EQUALIZATION CONDUCTOR

第8.6.7款-电位均衡导线

Medically used rooms in most countries have no facilities for the use of detachable POTENTIAL EQUALIZATION CONDUCTORS. This standard therefore does not require any means to be provided for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the ME EQUIPMENT. If however the ME EQUIPMENT does have such means, for use in locations where POTENTIAL EQUALIZATION CONDUCTORS are used, the appropriate requirements have to be satisfied.
 大多数国家的医疗用房没有使用可拆卸电位均衡导体的设施。因此，本标准不要求提供将电位均衡导体连接至医用电气设备的任何方法。但是，如果医用电气设备确实有此类装置，用于使用电位均衡导线的位置，则必须满足适当的要求。

Subclause 8.6.9 – CLASS II ME EQUIPMENT

第8.6.9款-II类医用电气设备

This requirement allows a CLASS II ME EQUIPMENT to have a connection to protective earth for functional reasons only. Green/yellow is required to avoid confusion in installation. The allowance does not degrade the degree of protection against electric shock. 该要求允许II类医用电气设备仅出于功能原因与保护接地连接。要求绿色/黄色，以避免在安装过程中混淆。该津贴不会降低电击防护等级。

The current flowing through the FUNCTIONAL EARTH CONDUCTOR has to be limited in the same way as current in the PROTECTIVE EARTH CONDUCTOR. To prevent the FUNCTIONAL EARTH CONDUCTOR from becoming a PROTECTIVE EARTH CONDUCTOR, the insulation between internal screens including internal wiring connected to them and ACCESSIBLE PARTS needs to provide two MEANS OF PROTECTION. 通过功能性接地导体的电流必须以与保护接地导体中的电流相同的方式进行限制。为了防止功能性接地导体成为保护性接地导体，内部屏蔽（包括连接到它们的内部布线）和可触及部件之间的绝缘需要提供两种保护方法。

Subclause 8.7.2 – SINGLE FAULT CONDITIONS

第8.7.2款-单一故障条件

Short circuiting of one part of DOUBLE INSULATION would be likely to increase LEAKAGE CURRENT by a factor of the order of 2. In some cases the test could be difficult to carry out and, as the allowable values for SINGLE FAULT CONDITION are five times those for NORMAL CONDITION, the test would not provide useful information. 双绝缘的一部分短路可能会使泄漏电流增加2倍。在某些情况下，试验可能很难进行，由于单一故障条件下的允许值是正常条件下的五倍，因此试验不能提供有用的信息。

Subclause 8.7.3 – Allowable values, Table 3 and Table 4
第8.7.3款-允许值，表3和表4

The value of electric current flowing in the human or animal body that can cause a certain degree of stimulation varies from individual to individual, according to the way in which the connection to the body is made and according to the frequency of the current applied and its duration. 在人体或动物体内流动的电流能引起一定程度的刺激，其值因个体而异，这取决于与身体连接的方式，以及所施加电流的频率和持续时间。

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation. For currents of medium or high frequency, the RISK of electric shock is less or negligible, but the RISK of burning remains. 直接流入或通过心脏的低频电流会大大增加心室颤动的危险。对于中高频电流，触电风险较小或可忽略不计，但燃烧的风险仍然存在。

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the ME EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS). TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS 人体或动物身体对电流的敏感性，取决于与医用电气设备接触的程度和性质，导致了一个反映应用部件（分为B型应用部件、BF型应用部件和CF型应用部件）提供保护程度和质量的分类系统。B型应用部件和BF型

APPLIED PARTS are generally suitable for applications involving external or internal contact with the PATIENT, excluding the heart. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATIONS with regard to LEAKAGE CURRENT. 应用部件通常适用于与患者进行外部或内部接触的应用，不包括心脏。CF型应用部件适用于泄漏电流方面的直接心脏应用。

In conjunction with this classification, the requirements for allowable LEAKAGE CURRENT have been formulated. The absence of sufficient scientific data concerning the sensitivity of the human heart for currents causing ventricular fibrillation still presents a problem. 结合此分类，制定了允许泄漏电流的要求。关于人体心脏对引起心室颤动电流的敏感性缺乏足够的科学数据仍然是一个问题。

Nevertheless, the publication of the first edition of this standard in 1977 provided engineers with data enabling them to design ME EQUIPMENT; and these requirements have proved over the years since then to ensure a very low level of RISK without being too onerous for designers. 然而，1977年本标准第一版的出版为工程师提供了设计医用电气设备的数据；自那以后的几年里，这些要求已经被证明可以确保非常低的风险水平，而不会对设计师造成太大的负担。

The requirements for LEAKAGE CURRENT were formulated taking into account: 制定泄漏电流要求时考虑到：

- that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters; 心室纤维性颤动的可能性除了受电参数的影响外，还受其他因素的影响；
- that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, in order not to present designers with unnecessary difficulties; and 考虑到统计因素，单一故障条件下的允许泄漏电流值应尽可能高，以免给设计人员带来不必要的困难；以及
- that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high safety factor with respect to SINGLE FAULT CONDITIONS.

在所有情况下，正常条件下的值是必要的，通过提供与单个故障条件相关的足够高的安全系数来创建安全条件。

The measurement of LEAKAGE CURRENTS has been described in a way that enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the RESPONSIBLE ORGANIZATION. 泄漏电流的测量以一种允许使用简单仪器的方式进行描述，避免了对给定情况的不同解释，并指出了责任机构定期检查的可能性。

Allowable values of LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz take account of the following considerations. 频率不超过1 kHz的交流和直流复合波形的泄漏和患者辅助电流的允许值应考虑以下因素。

da) In general the RISK of ventricular fibrillation or pump failure increases with the value or duration, up to a few seconds, of the current passing through the heart. Some areas of the heart are more sensitive than others. That is, a current that causes ventricular fibrillation when applied to one part of the heart could have no effect when applied to another part of the heart. da) 一般情况下，心室颤动或泵衰竭的风险随着通过心脏的电流值或持续时间（最多几秒钟）而增加。心脏的某些部位比其他部位更敏感。也就是说，当电流作用于心脏的一个部分时，引起心室颤动的电流，当施加到心脏的另一部分时，不会产生任何影响。

eb) The RISK is highest and approximately equal for frequencies in the 10 Hz to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by approximately 1,5 at 1 kHz. Beyond 1 kHz, the RISK decreases rapidly [45]. However lower limits are needed for d.c. to prevent tissue necrosis with long-term application. eb) 风险最高，在10 Hz至200 Hz范围内的频率大致相等。在直流电时，它的值低了近5倍，在1 kHz时降低了约1.5倍。超过1 kHz，风险迅速降低[45]。然而，长期使用，为了防止组织坏死，需要使用低限值。

The values in Table 3 and Table 4 apply to currents measured with the measuring device shown in Figure 12 a), which automatically allows for the reduced sensitivity at higher frequencies. SUPPLY MAINS frequencies of 50 Hz and 60 Hz are in the range of highest RISK. 表3和表4中的值适用于使用图12a)所示测量装置测量的电流，该装置可自动降低较高频率下的灵敏度。50赫兹和60赫兹的电源频率处于最高风险范围内。

fc) Although as a general rule requirements in a general standard are less restrictive than the requirements in particular standards, some of the allowable values in Table 3 and Table 4 have been set at such a value that:
 fc) 尽管作为一般规则, 一般标准中的要求比特定标准中的要求限制较少, 但表3和表4中的一些允许值已设定为这样一个值:

- the majority of ME EQUIPMENT types can comply, and
 大多数医用电气设备类型都符合要求, 并且
- they can be applied to most ME EQUIPMENT types (existing or future) for which no particular standards exist.
 它们可以应用于大多数没有特定标准的医用电气设备类型 (现有或未来)。

EARTH LEAKAGE CURRENT

接地漏电电流

The EARTH LEAKAGE CURRENT flowing through the PROTECTIVE EARTH CONDUCTOR is not a HAZARD per se. The PATIENT and OPERATOR are protected by specifying appropriately low values for PATIENT LEAKAGE CURRENT and TOUCH CURRENT in NORMAL CONDITION and in relevant SINGLE FAULT CONDITIONS including interruption of the PROTECTIVE EARTH CONDUCTOR. However, an excessive EARTH LEAKAGE CURRENT could pose a possible problem for the installation's earthing system and any circuit breakers operated by current imbalance detectors.
 流过保护接地导体的接地漏电电流本身不构成危险。在正常情况下以及在相关的单一故障条件下 (包括保护接地导体的中断), 患者和操作人员通过指定适当的低值来保护患者和操作人员。但是, 过大的接地漏电电流可能会对装置的接地系统和由电流不平衡检测器操作的任何断路器造成可能的问题。

See also IEC 60364-7-710 [10].

另见IEC 60364-7-710[10]。

TOUCH CURRENT

接触电流

The limits are based on the following considerations.

限制基于以下考虑。

gd) The TOUCH CURRENT of ME EQUIPMENT is subject to the same values regardless of the type(s) of APPLIED PARTS, if any, because even ME EQUIPMENT that does not itself have a TYPE CF APPLIED PART could be used in situations where intracardiac PROCEDURES are performed.

gd) 医用电气设备的接触电流受相同值的影响, 而不考虑应用部件的类型 (如有), 因为即使医用电气设备本身没有CF型应用部件, 也可以在进行心脏内手术的情况下使用。

he) Although TOUCH CURRENT flows from parts other than PATIENT CONNECTIONS, it can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR.

他) 尽管接触电流来自病人连接以外的其他部位, 但它可以通过各种途径偶然接触到病人, 包括通过操作者的路径。

if) The current density created at the heart by current entering the chest is 50 □A/mm² per ampere [46]. The current density at the heart for 500 □A (maximum allowable value in SINGLE FAULT CONDITION) entering the chest is 0,025 □A/mm², well below the level of concern.
 如果) 电流进入胸腔在心脏产生的电流密度为每安培50μA/mm²[46]。500μA (单一故障条件下的最大允许值) 进入胸部的电流密度为0.025μA/mm², 远低于关注水平。

jg) The probability of the TOUCH CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

jj) 接触电流流过心脏并导致心室颤动或泵衰竭的概率。

TOUCH CURRENT could conceivably reach an intracardiac site if careless PROCEDURES are used in handling intracardiac conductors or fluid filled catheters. Such devices should always be handled with great care and always with dry rubber gloves. The following RISK ANALYSIS is based on pessimistic assumptions about the degree of care exercised. 如果在处理心内导管或充液导管时使用不小心的操作，接触电流可以到达心内部位。处理此类设备时应始终非常小心，并始终戴上干燥的橡胶手套。以下风险分析基于对谨慎程度的悲观假设。

The probability of a direct contact between an intracardiac device and an ME EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 medical procedures. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 medical procedures. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 μ A, which itself has a probability of inducing ventricular fibrillation of 0,05. If the probability of indirect contact is 0,1 then the overall probability is 0,005. Although this probability would appear undesirably high, it should be recalled that with correct handling of the intracardiac device this probability can be reduced to that for mechanical stimulation alone, 0,001. 心内装置和医用电气设备外壳之间直接接触的概率被认为是非常低的，可能是百分之一的医疗程序。通过医务人员间接接触的概率被认为是更高的，比如每10个医疗程序中就有1个。正常情况下允许的最大泄漏电流为100 μ A，其本身诱发心室颤动的概率为0.05。如果间接接触的总概率为0.0005。尽管这种可能性看起来不太高，但应该记住，只要正确处理心内装置，这个概率可以降低到仅机械刺激的概率0001。

The probability of the TOUCH CURRENT rising to the maximum allowable level of 500 μ A (SINGLE FAULT CONDITION) is considered to be 0,1 in departments with poor maintenance PROCEDURES. The probability of this current causing ventricular fibrillation is taken as 1. 在维护程序较差的部门，接触电流上升到最大允许水平500 μ A（单一故障条件）的概率被认为是0.1。这种电流引起心室颤动的概率为1。

The probability of accidental contact directly with the enclosure is, as above, considered as 0,01, giving an overall probability of 0,001, equal to the mechanical stimulation alone probability. 如上所述，意外直接接触外壳的概率为0.01，总概率为0001，等于机械刺激单独发生的概率。

The probability of TOUCH CURRENT at the maximum allowable level of 500 □A (SINGLE FAULT CONDITION) being conducted to an intracardiac device via the medical staff is 0,01 (0,1 for the SINGLE FAULT CONDITION, 0,1 for accidental contact). Since the probability of this current causing ventricular fibrillation is 1, the overall probability is also 0,01. Again this probability is high; however it can be brought down to the mechanical stimulation alone probability of 0,001 by adequate medical procedures.

医务人员最大允许水平500μA（单一故障情况）下，通过医务人员传导至心内装置的接触电流的概率为0.01（单个故障情况为0.1，意外接触为0.1）。由于该电流引起心室颤动的概率为1，因此总概率也为0,01。同样，这种可能性很高；然而，通过适当的医疗程序，仅机械刺激的概率就可以降到0001。

kh) The probability of the TOUCH CURRENT being perceptible to the PATIENT.
kh) 患者能够感知到接触电流的概率。

The probability of 500 □A being perceptible is 0,01 for men and 0,014 for women when using grip electrodes with intact skin [45] [48]. There is a higher perceptibility for current passing through mucous membranes or skin punctures [48]. Since distribution is normal, there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 □A passing through a mucous membrane [48].

当使用完整皮肤的握把电极时，男性可感知到500μA的概率为0.01，女性为0.014[45][48]。电流通过黏膜或皮肤刺穿时有更高的感知能力[48]。由于分布是正态分布，有些病人可能会感觉到很小的电流。据报道，有一个人感觉到4μA穿过粘膜[48]。

PATIENT
病人漏电流

LEAKAGE

CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for ME EQUIPMENT with TYPE CF APPLIED PARTS in NORMAL CONDITION is 10 □A, which has a probability of 0,002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

在正常情况下，带有CF型应用部件的医用电气设备的患者泄漏电流允许值为10μA，当通过小面积施加到心内部位时，导致心室颤动或泵衰竭的概率为0002。

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation [50]. A limit of 10 □A is readily achievable and does not significantly increase the RISK of ventricular fibrillation during intracardiac procedures.

即使在零电流的情况下，已经观察到机械刺激会产生心室颤动[50]。10μA的限制是很容易实现的，并且不会显著增加心内手术期间心室颤动的风险。

The 50 □A maximum allowed in SINGLE FAULT CONDITION for ME EQUIPMENT with TYPE CF APPLIED PARTS is based on a value of current that has been found, under clinical conditions, to have a very low probability of causing ventricular fibrillation or interference with the pumping action of the heart.

具有CF型应用部件的医用电气设备在单一故障条件下的最大允许电流为50μA，这是基于在临床条件下发现的导致心室颤动或干扰心脏泵送动作的可能性非常低的电流值。

For catheters 1,25 mm - 2 mm diameter likely to contact the myocardium, the probability of 50 □A causing ventricular fibrillation is near 0,01 (see Figure A.14 and its explanation). Small cross-section area (0,22 mm² and 0,93 mm²) catheters used in angiography have higher probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

对于直径为1.25 mm-2 mm的导管可能接触心肌，50μA引起心室颤动的概率接近0.01（见图A.14及其说明）。血管造影中使用的小横截面积（0.22 mm²和0.93 mm²）导管如果直接放置在心脏的敏感区域，则更容易引起心室颤动或泵衰竭。

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in
患者漏电流引起心室颤动的总概率
SINGLE FAULT CONDITION is 0,001 (0,1 for probability of SINGLE FAULT CONDITION, 0,01
单一故障条件为0001（0,1表示单一故障条件的概率为0,01

probability of 50 μ A causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

50 μ A引起心室颤动的概率)等于单独机械刺激的概率。

The 50 μ A current allowed in SINGLE FAULT CONDITION is not likely to result in a current density sufficient to stimulate neuromuscular tissues nor, if d.c., cause necrosis. 单一故障条件下允许的50 μ A电流不太可能产生足以刺激神经肌肉组织的电流密度, 如果直流电, 也不会导致坏死。

For ME EQUIPMENT with TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 μ A, the same rationale applies as that for TOUCH CURRENT since this current will not flow directly to the heart. 对于带有B型应用部件和BF型应用部件的医用电气设备, 在单一故障条件下, 患者的最大允许泄漏电流为500 μ A, 同样的原理适用于接触电流, 因为该电流不会直接流向心脏。

As the existence of an earth connection to a PATIENT is a NORMAL CONDITION, not only PATIENT AUXILIARY CURRENT but also PATIENT LEAKAGE CURRENT can flow for a prolonged period. A very low value of direct current is therefore necessary to avoid tissue necrosis, regardless of the classification of the APPLIED PART. 由于与病人的接地连接是正常情况, 不仅病人辅助电流, 而且病人漏电流可以长时间流动。因此, 无论应用部位的分类如何, 都必须使用极低的直流电以避免组织坏死。

The appearance of MAINS VOLTAGE, from a low-impedance source, on the PATIENT CONNECTIONS of an F-TYPE APPLIED PART would have to be caused by a double failure of protective means in other ME EQUIPMENT, simultaneously connected to the PATIENT and complying with this standard or another IEC standard, or by a single failure of protective means in equipment not complying with a standard. As such this condition is extremely unlikely in good medical practice.

F-TYPE应用部件的患者连接上的低阻抗电源的电源电压的出现, 必须是由其他医用电气设备中的保护装置双重故障引起的, 这些设备同时连接到病人, 并符合本标准或其他IEC标准, 或因设备中的保护装置单一故障而不符合标准。因此, 这种情况在良好的医疗实践中极不可能发生。

However the appearance of a lesser voltage, or of a LEAKAGE CURRENT from a source having an open-circuit voltage of the order of MAINS VOLTAGE, is possible.
然而，出现较低的电压，或来自开路电压为市电电压量级的电源的泄漏电流是可能的。

Since the main safety feature of ME EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the ME EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth is to have a minimum quality. This is assured by the requirement that, even if a hypothetical voltage of supply frequency and equal to the highest supply voltage to earth present in the location where the ME EQUIPMENT is used would appear on the PATIENT CONNECTIONS, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.
由于带有F型应用部件的医用电气设备的主要安全特性是患者不通过与医用电气设备的连接接地，因此F型应用部件与接地之间的电气隔离应具有最低质量。这可以通过以下要求来保证：即使医用电气设备使用位置的假定电源频率电压和对地最高供电电压将出现在患者连接上，也不会超过患者泄漏电流的限值。

For TYPE CF APPLIED PARTS, the PATIENT LEAKAGE CURRENT will be limited to 50 □A, no worse than the previously discussed SINGLE FAULT CONDITION.
对于CF型应用部件，患者泄漏电流将限制在50μA，不比之前讨论的单一故障条件更糟。

For TYPE BF APPLIED PARTS the maximum PATIENT LEAKAGE CURRENT under these conditions is 5 mA. Even this value entering the chest would produce only a current density at the heart of 0,25 □A/mm². This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low. The RISK of harmful physiological effects is small and the MAXIMUM MAINS VOLTAGE used for this test represents a worst case, more severe than is likely to arise in practice.
对于BF型应用部件，在这些条件下，患者的最大泄漏电流为5毫安。即使这个值进入胸腔也只会产生0.25μA/mm²的电流密度。这种电流对病人来说是非常明显的，但是发生的概率很低。有害生理影响的风险很小，用于该测试的最大电源电压代表最坏情况，比实际操作中可能出现的更严重。

Total PATIENT LEAKAGE CURRENT

病人总漏电流

The values of PATIENT LEAKAGE CURRENT in this standard are for a single function of a TYPE B APPLIED PART or TYPE BF APPLIED PART or a single PATIENT CONNECTION of a TYPE CF APPLIED PART.
本标准中的患者漏电流值适用于B型应用部件或BF型应用部件的单一功能，或CF型应用部件的单个患者连接

PART. With multiple functions or multiple APPLIED PARTS the total PATIENT LEAKAGE CURRENT could be much higher. This total PATIENT LEAKAGE CURRENT is the vector sum of the individual PATIENT LEAKAGE CURRENTS. Therefore, it is necessary to specify limits for total PATIENT LEAKAGE CURRENT. These requirements are derived from IEC 60601-2-49:2001 [16].

部分。如果有多个功能或多个应用部件，患者的总漏电流可能会更高。患者总漏电流是单个患者漏电流的矢量和。因此，有必要规定患者总漏电流的限值。这些要求源自IEC 60601-2-49:2001[16]。

This standard does not fix the number of APPLIED PARTS connected to a single PATIENT. It has been estimated that the number of APPLIED PARTS connected to a single PATIENT ranges from one to five.
本标准并未规定连接到单个患者的应用部件的数量。据估计，与单个患者相连的应用部件的数量从1到5个不等。

Total PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS

CF型应用部件的患者总泄漏电流

For TYPE CF APPLIED PARTS the PATIENT LEAKAGE CURRENT for the NORMAL CONDITION is 10 □A.

对于CF型应用部件，正常情况下的患者泄漏电流为10 μ A。

The following is to be considered for multiple PATIENT functions:

对于多种患者功能，应考虑以下因素：

li) The current entering the heart is distributed over all of the PATIENT CONNECTIONS and is not applied to the same small sensitive area of the cardiac tissue.

li) 进入心脏的电流分布在所有患者的连接处，而不是施加在心脏组织的同一个小敏感区。

mj) The number of PATIENT CONNECTIONS connected directly to cardiac tissue is not likely to exceed three. Accordingly, the LEAKAGE CURRENT entering a single small area of the heart is less than 50 μ A and is in the vicinity of 15 μ A to 20 μ A for an algebraic summation of the currents. The current would be less for a vector summation. The probability of ventricular fibrillation, according to the rationale for PATIENT LEAKAGE CURRENT, is in the range of 0,003 even if all the PATIENT CONNECTIONS are very close together. This is not much different from the probability of 0,002 that is accepted for a single APPLIED PART connected directly to the heart.

mj) 直接连接到心脏组织的患者连接的数量不可能超过3个。因此，进入心脏单个小区域的泄漏电流小于50 μ A，对于电流的代数求和，在15 μ A到20 μ A附近。对于矢量求和，电流会更小。根据病人漏电流的基本原理，心室颤动的概率在0003范围内，即使所有病人的连接都非常紧密。这与直接连接到心脏的单个应用部分所接受的概率0002没有太大区别。

nk) The LEAKAGE CURRENT from APPLIED PARTS on the surface of the body flows in a distributed manner through the body. According to the rationale for PATIENT LEAKAGE CURRENT, 5 mA entering the chest produces a current density at the heart of 0,025 μ A/mm².

nk) 来自阀体表面应用部件的泄漏电流以分布方式流经阀体。根据病人漏电流的基本原理，5毫安进入胸腔，在心脏处产生0.025 μ A/mm²的电流密度。

Therefore, 50 μ A for NORMAL CONDITION for total PATIENT LEAKAGE CURRENT is considered acceptable.

因此，在正常情况下，患者总漏电流为50 μ A是可以接受的。

For SINGLE FAULT CONDITION the LEAKAGE CURRENT for TYPE CF EQUIPMENT APPLIED PARTS has

对于单一故障情况，CF型设备应用部件的泄漏电流

been increased to 0,1 mA. The rationale for PATIENT LEAKAGE CURRENT gives a probability of 0,07 of ventricular fibrillation for current directly entering the heart. The probability of a SINGLE FAULT CONDITION was given as 0,1. This was over a decade ago. Because of improvements in design, more reliable components, better materials, and the use of RISK MANAGEMENT in accordance with ISO 14971 and the consequent use of associated tools, such as HAZARD based RISK ANALYSIS, the probability of a SINGLE FAULT CONDITION should be much less. It is now felt to be in the vicinity of at least 0,02. The probability of ventricular fibrillation is 0,07 □ 0,02, or 0,0014, close to that accepted for a single TYPE CF APPLIED PART. 增加到0.1mA。病人漏电流的基本原理是电流直接进入心脏时心室颤动的概率为0.07。单一故障条件的概率为0.1。这是十多年前的事了。由于设计的改进、更可靠的部件、更好的材料、以及根据ISO 14971进行风险管理以及随后使用相关工具（如基于危险的风险分析），单一故障情况的概率应大大降低。现在感觉它至少在0.02附近。心室颤动的概率为 $0,07 \times 0,02$ 或00014，接近于单个CF应用部件的可接受值。

Total PATIENT LEAKAGE CURRENT for TYPE BF APPLIED PARTS

BF型应用部件的病人总漏电流

The total PATIENT LEAKAGE CURRENT has been increased to 500 □A for NORMAL CONDITION and to 1 000 □A for SINGLE FAULT CONDITION. As explained in c) k) above, the current density at the heart for current of 5 000 □A is quite small. There should be no concern for either the NORMAL CONDITION or the SINGLE FAULT CONDITION. 在正常情况下，患者总漏电流增加到500μA，单故障情况下增加到1000μA。如上文c) k)所述，电流为5000μA时，心脏处的电流密度相当小。无论是正常状态还是单一故障状态，都不应受到任何影响。

Total PATIENT LEAKAGE CURRENT caused by an external voltage on the PATIENT CONNECTION

由病人连接上的外部电压引起的病人总漏电流

For TYPE CF APPLIED PARTS, the limit has been increased to 100 □A. The rationale for PATIENT LEAKAGE CURRENT states that the probability of failure of protective earthing of CLASS I ME EQUIPMENT is 0,1 and that the probability of a fault in one MOP is less than 0,1. This was a decade ago. As explained earlier, these probabilities should be much lower today and are considered to be no worse than 0,02. The probability of MAINS VOLTAGE appearing on the PATIENT is 0,02 □ 0,02, or 0,0004. This is below the probability of 0,001 accepted in the second edition of IEC 60601-1.

对于CF型应用部件，限值已增加到100μA。患者泄漏电流的基本原理是，I类医用电气设备的保护接地故障概率为0.1，一个MOP中的故障概率小于0.1。这是十年前的事了。如前所述，这些概率在今天应该要低得多，并且被认为不低于0.02。电源电压出现在患者身上的概率为 $0,02 \times 0,02$ 或00004。这低于IEC 60601-1第二版中接受0001的概率。

PATIENT AUXILIARY CURRENT

病人辅助电流

The allowable values for PATIENT AUXILIARY CURRENT are based on similar considerations to those for PATIENT LEAKAGE CURRENT. They apply regardless of whether the PATIENT AUXILIARY CURRENT is necessary for the functioning of the ME EQUIPMENT (e.g. impedance plethysmographs) or incidental to its functioning. Lower values are given for d.c. to prevent tissue necrosis with long-term application. 病人辅助电流的允许值基于与病人漏电流相似的考虑。无论患者辅助电流对医用电气设备（如阻抗容积描记器）的运行是必要的还是附带的，它们都适用。d.c.值较低，以防止长期使用时组织坏死。

99,99
99, 99

99,9
99.9万
99,8
99,8个

99
99

98
98

95
95

90
90

80
80

70
70

60
60

50
50

10
10

5
5

1
1

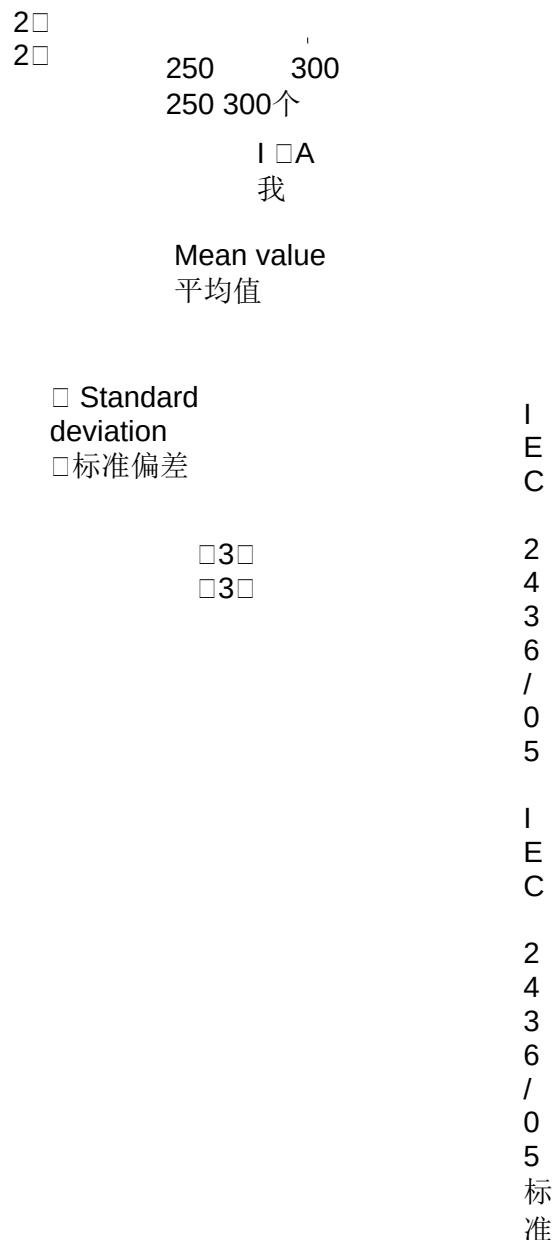
0,5
0,5个

0,2
0,2个

0,1
0,1

0,05
0.05

0,01
0.01秒



NOTE Refer to original papers by Starmer [53] and Watson [54] for interpretation of data.
 注：参考Starmer[53]和Watson[54]的原始论文来解释数据。

Figure A.14 – Probability of ventricular fibrillation
图A.14——心室颤动的概率

Explanation of Figure A.14
图A.14的说明

Articles by Starmer [53] and Watson [54] provide data on ventricular fibrillation caused by 50 Hz and 60 Hz currents applied directly to the hearts of human populations with cardiac disease. Fibrillation probability was obtained as a function of the electrode diameter and the magnitude of the current. For electrodes of 1,25 mm and 2 mm diameter and currents up to 0,3 mA, the distribution appears normal. Accordingly, it has been extrapolated to encompass the values commonly used in assessing PATIENT RISK (values noted on Figure A.14). From this extrapolation, it is seen that: Starmer[53]和Watson[54]的文章提供了由50赫兹和60赫兹电流直接作用于心脏病患者心脏所引起的心室颤动的数据。纤颤概率是电极直径和电流大小的函数。对于直径为1.25 mm和2 mm的电极，电流达到0.3 mA时，分布呈正态分布。因此，它被推断为包含了评估患者风险时常用的值（图A.14所示的值）。由此推断，可以看出：

- any value of current, however small, has some probability of causing ventricular fibrillation, and
 任何电流值，无论多么小，都有可能引起心室颤动，并且
- the commonly used values have low probabilities, ranging from approximately 0,002 to 0,01.

常用值的概率很低，大约在0.002到0.01之间。

Since ventricular fibrillation is governed by many factors (PATIENT condition, probability of current entering a more sensitive area of the myocardium, probability of fibrillation as a function of current or current density, physiology, electric field, etc.), it is reasonable to use statistics in determining the possibility of RISK for the multiple conditions. 由于心室颤动受许多因素（病人状况、电流进入心肌更敏感区域的概率、作为电流或电流密度函数的颤动概率、生理学、电场等）的影响，在确定多种情况下发生风险的可能性时，使用统计数据是合理的。

Heating effect of LEAKAGE CURRENTS 泄漏电流的热效应

A current of 10 mA will produce no sensation of heating with a typical PATIENT CONNECTION with a contact area of the order of 1 cm², but a current a few times higher than this would produce a burn. The RISK of a burn depends on the magnitude of the current but not on its frequency, so the current has to be measured with a non-frequency-weighted device, such as a device similar to that shown in Figure 12 a) but without C1 and R1. 10毫安的电流对接触面积约为1平方厘米的典型病人连接不会产生发热感，但比这高几倍的电流会产生灼伤感。烧伤的风险取决于电流的大小，而不是其频率，因此必须使用非频率加权装置来测量电流，例如类似于图12a)所示的装置，但没有C1和R1。

Subclause 8.7.3 第8.7.3 f) 款

LEAKAGE CURRENTS can flow through a FUNCTIONAL EARTH CONDUCTOR. This can lead to an unexpected RISK if CLASS II equipment is combined with CLASS I equipment or with an earthed trolley, e.g. using an MSO. Although proper application of the 'rules' for assembling an ME SYSTEM would eliminate this RISK, the causal RISK can be mitigated by limiting the allowed LEAKAGE CURRENT in a FUNCTIONAL EARTH CONDUCTOR.

泄漏电流可以流过功能性接地导体。如果II类设备与I类设备或接地小车（如使用MSO）组合，则可能会导致意外风险。虽然正确应用医用电气系统装配的“规则”可以消除这种风险，但通过限制功能性接地导体中的允许泄漏电流，可以降低因果风险。

Subclause 8.7.4.2 — Measuring supply circuits 第8.7.4.2款-测量电源电路

For correct results of LEAKAGE CURRENT measurements, it is essential to have a common reference point within the measuring circuit. The point also has to be electrically referenced to all parts of the circuit. Also the measured LEAKAGE CURRENT could be different according to the particular supply configuration. For example, if ME EQUIPMENT that is specified for connection to a supply having one side at earth potential is connected instead to a supply having two symmetrical phases (such as a 230 V supply in the USA) the measured LEAKAGE CURRENT will be much lower than the worst case. If the installed SUPPLY MAINS of the room where the measurements are made does not represent the worst case, a specific supply circuit has to be established. This can be done by using an isolating transformer with the appropriate point in the SECONDARY CIRCUIT connected to the reference point. Accurate and reproducible results when making LEAKAGE CURRENT measurements can also be obtained without an isolating transformer. However this would depend on the quality of the SUPPLY MAINS used for the measurements. Factors that need to be considered would include transients, interference signals and voltage differences between neutral and earth in the measuring circuit.

为了获得正确的泄漏电流测量结果，必须在测量电路中有一个共同的参考点。该点还必须与电路的所有部分进行电气参考。此外，根据特定的电源配置，测得的泄漏电流也可能不同。例如，如果指定用于连接一侧接地电位的电源的医用电气设备连接到具有两个对称相位的电源（如美国的230V电源），则测量的泄漏电流将远低于最坏情况。如果测量房间的已安装电源干线不代表最坏情况，则必须建立特定的供电电路。这可以通过使用隔离变压器来实现，二次电路中的适当点连接到参考点。在不使用隔离变压器的情况下，也可以获得准确和可重复的泄漏电流测量结果。然而，这将取决于用于测量的供电干线的质量。需要考虑的因素包括瞬态、干扰信号和测量电路中中性点和接地之间的电压差。

The earth symbols in the figures represent this common reference point, which is not connected to the protective earth of the SUPPLY MAINS. Such a separate reference point can provide additional protection for the person carrying out the measurements.

图中的接地符号表示该公共参考点，该参考点未连接至电源干线的保护接地。这样一个单独的参考点可以为测量人员提供额外的保护。

A variable-voltage transformer is necessary to provide 110 % of the RATED supply voltage to the ME EQUIPMENT. Although it would be possible to test with the MAINS VOLTAGE normally present in the test room and to multiply the measured LEAKAGE CURRENT values by the appropriate factor, this would not always produce the same result as testing with 110 % of the RATED supply voltage, particularly with ME EQUIPMENT that includes a switched-mode power supply. 为医用电气设备提供110%额定电源电压，需要一个可变电压互感器。虽然可以使用试验室中通常存在的电源电压进行试验，并将测量的泄漏电流值乘以适当的系数，但这并不总是产生与110%额定电源电压下测试相同的结果，尤其是对于包含开关电源的医用电气设备。

The switches S1 or S1 + S2 or S1 + S2 + S3 in Figure F.1 to Figure F.4 (inclusive) can be omitted and the interruptions of the relevant leads can be obtained by other means. 图S1+F中的其他开关（包括S1+F）可以省略。

Instead of the single or polyphase isolating transformers with adjustable output voltage(s), as shown in Figure F.1 to Figure F.5 (inclusive), a combination of an isolating transformer with set output voltage and an auto-transformer with adjustable output voltage can be used. 如图F.1至图F.5（含）所示，可使用具有设定输出电压的隔离变压器和输出电压可调的自耦变压器，而不是输出电压可调的单相或多相隔离变压器。

Subclause 8.7.4.3 – Connection to the measuring supply circuit **第8.7.4.3款-测量电源电路的连接**

Although it is not unlikely that ME EQUIPMENT is used while placed on or in an earthed metal environment, such a position would be rather difficult to describe in a way that test results would become reproducible. The advice in the note in 8.7.4.3 d) 1) is therefore to be considered as a convention.

尽管医用电气设备在接地金属环境中使用的可能性不大，但这种位置很难以测试结果可再现的方式进行描述。因此，8.7.4.3 d) 1) 中注释中的建议应被视为一项公约。

The fact that PATIENT cables can have a significant capacitance to earth is usually important and of considerable influence on test results. A position providing reproducible results is therefore prescribed.
病人电缆对地的电容通常很重要，对测试结果有很大的影响。因此，规定了提供可重复结果的位置。

The isolation transformer in the measuring supply circuit provides additional protection for the person making the measurements and increases the accuracy of the LEAKAGE CURRENT measurements. However, it is not absolutely necessary to use an isolating transformer when making LEAKAGE CURRENT measurements. In some cases, such as high input power ME EQUIPMENT and ME SYSTEMS, use of an insulating transformer is not feasible. When making LEAKAGE CUURENT measurement without an isolating transformer, the MANUFACTURER needs to consider the following:
测量电源电路中的隔离变压器为测量人员提供额外保护，并提高泄漏电流测量的精度。然而，在进行泄漏电流测量时，并非绝对需要使用隔离变压器。在某些情况下，如高输入功率医用电气设备和医用电气系统，使用绝缘变压器是不可行的。在不使用隔离变压器进行泄漏测量时，制造商需要考虑以下因素：

- is it possible to extrapolate the LEAKAGE CURRENTS at 110 % of the RATED supply voltage;
是否可以推断110%额定电源电压下的泄漏电流；
- the influence of currents that are driven by voltage differences between the protective earth and the mains supply neutral of ME EQUIPMENT or for ME SYSTEMS with multiple PROTECTIVE EARTH CONNECTIONS.
由医用电气设备的保护接地和电源中性点之间的电压差驱动的电流的影响，或对于具有多个保护接地连接的医用电气系统而言。

Measuring without an isolation transformer can produce LEAKAGE CURRENT readings that are greater than the LEAKAGE CURRENT measurement with an isolating transformer.
在没有隔离变压器的情况下进行测量会产生比使用隔离变压器测量的泄漏电流更大的泄漏电流读数。

Subclause 8.7.4.5 – Measurement of EARTH LEAKAGE CURRENT and current in FUNCTIONAL EARTH CONNECTION

第8.7.4.5款-测量接地漏电电流和功能性地连接中的电流

The measuring device represents a measuring method that takes into account the physiological effect of a current through the human body, including the heart, as well as the possibility of a low impedance contact between a PATIENT CONNECTION and the PATIENT. Although IEC 60990 [20] specifies some measuring devices for general use, none of these would be appropriate for measuring PATIENT LEAKAGE CURRENT. As the measuring device of the second edition is being retained for that purpose, it is most convenient to use the same device for all LEAKAGE CURRENT measurements, apart from the measurement of currents or current components with frequencies exceeding 1 kHz in relation to the 10 mA limit specified in the measuring device.
该测量装置表示一种测量方法，该方法考虑了通过人体（包括心脏）的电流的生理效应，以及患者连接与患者之间低阻抗接触的可能性。尽管IEC 60990[20]规定了一些通用的测量装置，但这些装置都不适用于测量病人的漏电电流。由于第二版的测量装置用于此目的，因此除了测量频率超过1 kHz的电流或电流分量（与10 mA限值相关）外，所有泄漏电流测量均应使用相同的装置

8.7.3

8.7.3 d) 段)。

Subclause 8.7.4.6 – Measurement of the TOUCH CURRENT

第8.7.4.6款-接触电流测量

Where metal foil is to be applied to an ENCLOSURE made of insulating material, intimate contact can be achieved by pressing the foil against the insulating material with a pressure of approximately 5 kPa (0,5 N/cm2).

如果将金属箔施加于由绝缘材料制成的外壳上，则可通过用大约5 kPa（0.5 N/cm2）的压力将金属箔压在绝缘材料上，从而实现紧密接触。

Subclause 8.7.4.7 – Measurement of PATIENT LEAKAGE CURRENT

第8.7.4.7款-病人漏电流测量

Subclause 8.7.4.7 b) 款

This test confirms that the separation between the PATIENT CONNECTIONS and other parts is adequate to limit the PATIENT LEAKAGE CURRENT to the allowed value when an external voltage is present.
当病人和其他部件之间的电流值足够时，病人和其他部件之间的电流值是允许的。

If the APPLIED PART can be disconnected from the ME EQUIPMENT, it is possible that the contacts of its connector could touch an earthed object, but that situation is covered by the tests of 8.5.2.3, not by 8.7.4.7 b), which applies to the ME EQUIPMENT and the APPLIED PART together. 如果应用部分可以从医用电气设备上断开，则其连接器的触点可能会接触到接地物体，但8.5.2.3中的测试涵盖了这种情况，而不是8.7.4.7 b)中的测试，该测试同时适用于医用电气设备和应用部分。

The 20 cm × 10 cm metal foil represents the size of a human hand. For some ME EQUIPMENT, the area of contact is greater than the size of the hand. In this case, the size of the foil can be increased.

20厘米×10厘米的金属箔代表一只手的大小。对于一些医用电气设备，接触面积大于手的大小。在这种情况下，可以增大箔材的尺寸。

Subclause
第8.7.4.7 c) 款

8.7.4.7

c)

Some of the tests specified in the second edition of this standard related to the possible presence of MAINS VOLTAGE on a SIGNAL INPUT PART or a SIGNAL OUTPUT PART (as defined in that edition, now covered by the combined term SIGNAL INPUT/OUTPUT PART). There were various exclusions, but if none of the exclusions applied this condition was regarded as a SINGLE FAULT CONDITION. The assumption made in this third edition is that, if the ACCOMPANYING DOCUMENTS place no restrictions on what other equipment is allowed to be
本标准第二版中规定的一些试验与信号输入部分或信号输出部分（如该版本中定义的，现在包含在信号输入/输出部分的组合术语中）上可能存在的电源电压有关。有各种除外责任，但如果没有任何一项排除适用，则该条件被视为单一故障条件。第三版中的假设是，如果随附文件对允许使用的其他设备没有限制

connected to the SIGNAL INPUT/OUTPUT PART, the presence of the MAXIMUM MAINS VOLTAGE
连接到信号输入/输出部分，存在最大电源电压
should be regarded as a NORMAL CONDITION.
应视为正常情况。

Instead of an isolating transformer T2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.
代替输出电压可调的隔离变压器T2，可以使用具有设定输出电压的隔离变压器和具有可调输出电压的自耦变压器的组合。

Subclause
第8.7.4.7 d) 款

8.7.4.7

d)

The test with an external voltage applied to unearthed metal ACCESSIBLE PARTS reflects the requirement in 8.5.2.2 for isolation between such parts and unearthed PATIENT CONNECTIONS of TYPE B APPLIED PARTS.
对未接地金属可触及部件施加外部电压的试验，反映了第8.5.2.2条对此类部件与B类应用部件未接地病人连接之间的隔离要求。

For TYPE BF APPLIED PARTS this test applies as well as the test of 8.7.4.7 b), even though both test the isolation between the PATIENT CONNECTIONS and other parts, because the PATIENT LEAKAGE CURRENT might not be the same in these two situations and different limit values apply.
对于BF型应用部件，本试验和8.7.4.7b)中的试验一样适用，即使这两种试验都试验病人连接和其他部件之间的隔离，因为在这两种情况下，病人的泄漏电流可能不相同，并且适用不同的限值。

Instead of an isolating transformer T2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.
代替输出电压可调的隔离变压器T2，可以使用具有设定输出电压的隔离变压器和具有可调输出电压的自耦变压器的组合。

Care should be taken that the capacitance of the measuring device and its connecting leads to earth and to the body of the ME EQUIPMENT is kept as low as possible.
应注意，测量装置及其连接导线至接地和医用电气设备主体的电容应尽可能低。

As explained in the rationale to 8.7.3, the presence of the MAXIMUM MAINS VOLTAGE on a PATIENT represents a worst case, this is more severe than is likely to arise in practice, and the allowable PATIENT LEAKAGE CURRENT for a TYPE BF APPLIED PART in this situation is 5 mA. It was pointed out that the application of MAINS VOLTAGE to an unearthed ACCESSIBLE PART could therefore cause a PATIENT LEAKAGE CURRENT of up to 5 mA to flow from the PATIENT CONNECTIONS of a TYPE BF APPLIED PART; whereas in the same situation a TYPE B APPLIED PART (which in general offers a lower level of safety) was allowed only 500 μ A. In order to resolve this anomaly, the test of 8.7.4.7 d), with 110 % of the MAXIMUM MAINS VOLTAGE on unearthed ACCESSIBLE PARTS, also applies to TYPE BF APPLIED PARTS, and in this condition the allowable PATIENT LEAKAGE CURRENT is the general 500 μ A value for SINGLE FAULT CONDITION.
如8.7.3的基本原理所述，患者的最大电源电压是最坏的情况，这比实际情况可能出现的情况更严重，在这种情况下，BF型应用部件的允许泄漏电流为5 mA。有人指出，对未接地的可触及部分施加电源电压，因此可能导致BF型应用部件的患者连接处产生高达5毫安的患者泄漏电流；而在相同的情况下，B型应用部件（通常提供较低的安全等级）仅允许500 μ A。为了解决这一异常情况，8.7.4.7 d)的试验（在未接地可触及部件上施加的最大电源电压为110%）也适用于BF型应用部件，在这种情况下，允许的病人泄漏电流是单一故障条件下的一般500 μ A值。

There is no need to perform the test of 8.7.4.7 d) on TYPE CF APPLIED PARTS because for these the same allowable value of 50 μ A would apply as in the test of 8.7.4.7 b).

无需对CF型应用部件进行8.7.4.7 d)的试验，因为对于这些部件，50μA的允许值将与8.7.4.7 b)的试验相同。

Subclause
第8.7.4.7 h) 款

8.7.4.7

h)

The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

该要求代表了一种折衷方案，即要求进行广泛的测试（大多数医用电气设备无法提供有用的信息）和没有解决此风险的具体要求。

Most TYPE B APPLIED PARTS are earthed, so the measurement according to 8.7.4.7 g) (all PATIENT CONNECTIONS of a single function connected directly together) will give the same result as the measurement according to 8.7.4.7 h) (all PATIENT CONNECTIONS of all APPLIED PARTS of the same type connected together). If this is within the PATIENT LEAKAGE CURRENT limit it will certainly be within the total PATIENT LEAKAGE CURRENT limit. However it is possible to have TYPE B APPLIED PARTS that are not directly earthed, and in that case the measured values can be different. 大多数B型应用部件都接地，因此根据8.7.4.7 g)（单个功能的所有患者连接直接连接在一起）的测量结果将与根据8.7.4.7 h)的测量结果相同（同一类型所有应用部件的所有患者连接连接在一起）。如果这在患者漏电流限值内，则肯定在总漏电流限值内。但是，B型应用部件可能不直接接地，在这种情况下，测量值可能不同。

Subclause 8.7.4.9 – ME EQUIPMENT with multiple PATIENT CONNECTIONS
第8.7.4.9款-带多个患者连接的医用电气设备

This requirement was introduced in the second amendment to the second edition of this standard. It addresses a RISK that can arise, for example, with equipment for measuring physiological signals where an amplifier drives one electrode to reduce common-mode interference. If one of the sensing electrodes is disconnected from the PATIENT and picks up a large voltage at mains frequency, the amplifier could drive a large current into the PATIENT in a vain attempt to cancel the interference. 此要求在本标准第二版的第二次修改中介绍。它解决了一个可能出现的风险，例如，在测量生理信号的设备中，放大器驱动一个电极以减少共模干扰。如果其中一个感测电极与病人断开连接，并在电源频率下接收到一个大电压，放大器可能会驱动一个大电流进入病人体内，但却徒劳地试图消除干扰。

The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

该要求代表了一种折衷方案，即要求进行广泛的测试（大多数医用电气设备无法提供有用的信息）和没有解决此风险的具体要求。

Subsequently IEC 60601-2-49:2001 [16] introduced a comprehensive set of tests, to be performed on all equipment within the scope of that standard. These include measurement of what is termed “PART LEAKAGE CURRENT” in that standard: this is the current flowing between the PATIENT CONNECTIONS of one function and the PATIENT CONNECTIONS of other function(s), which is covered in this edition of the general standard by the revised definition of PATIENT AUXILIARY CURRENT.

随后，IEC 60601-2-49:2001[16]引入了一套全面的试验，将在该标准范围内的所有设备上进行。这些包括测量该标准中所谓的“部分泄漏电流”：这是指在一个功能的患者连接和其他功能的患者连接之间流动的电流，修订后的患者辅助电流定义涵盖在本版通用标准中。

Consideration was given to incorporating these tests in this general standard, but it was decided that such specific testing should be left to particular standards. The scenarios to which they relate, such as having the PATIENT CONNECTIONS of one function in use and connected to the PATIENT while the PATIENT CONNECTIONS of another function are not in use and could make contact with earth or other objects, are likely to arise with multifunction PATIENT monitoring equipment but unlikely with most other kinds of ME EQUIPMENT. 考虑将这些试验纳入本通用标准，但决定将此类特定试验留给特定标准。与之相关的场景，例如一个功能的患者连接在使用中，而另一个功能的患者连接未使用，可能与地球或其他物体接触，可能会出现多功能病人监护设备，但不太可能与大多数其他类型的医用电气设备。

Figure A.15, based on Figure KK.101 of IEC 60601-2-49:2001 [16], shows an example of measuring the PATIENT LEAKAGE CURRENT from one function of a TYPE BF APPLIED PART while the PATIENT CONNECTIONS of another function of the same APPLIED PART and of two TYPE CF APPLIED PARTS are either floating or earthed. 图A.15基于IEC 60601-2-49:2001[16]中的图KK.101，显示了测量BF型应用部件的一个功能的患者漏电电流的示例，而同一应用部件的另一个功能和两个CF型应用部件的患者连接是浮动的或接地的。

Subclause 第8.8.1款-概述

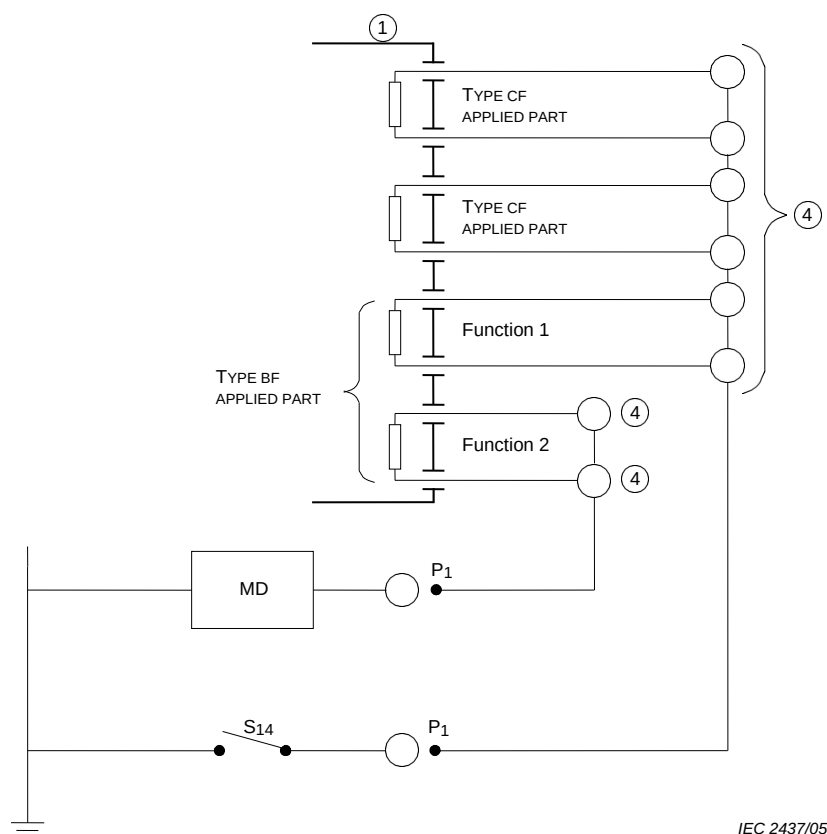
8.8.1

–

General

Care should be taken that the voltage applied to a REINFORCED INSULATION does not overstress either of the MEANS OF PROTECTION in the ME EQUIPMENT. If there are multiple paths between the same points, these might need to be tested separately. There could, for example, be one path from the MAINS PART to a PATIENT CONNECTION that has BASIC INSULATION plus a PROTECTIVE EARTH CONNECTION plus PATIENT CONNECTIONS isolation as required by 8.5.2.1, and a parallel path having REINFORCED INSULATION. ME EQUIPMENT parts might need to be disconnected to allow the REINFORCED INSULATION to be tested without overstressing the separate insulation of the MAINS PART or the PATIENT CONNECTIONS. 应注意施加在加强绝缘上的电压不会对医用电气设备中的任何一种保护措施施加过大的应力。如果相同点之间有多条路径，则可能需要分别测试这些路径。例如，可以有一条从电源部分到病人连接的路径，该路径具有基本绝缘、保护性接地连接和8.5.2.1要求的患者连接隔离，以及具有加强绝缘的平行路径。医用电气设备部件可能需要断开，以便在不过度拉伸电源部件或患者连接的单独绝缘的情况下，对加强绝缘进行测试。

This could be avoided, for example in the case of a transformer, by the use of a voltage divider with a tapping point connected to the core or some other suitable connecting point to ensure the correct voltage division over the actual insulations, or by the use of two test transformers, correctly phased. 这可以避免，例如在变压器的情况下，通过使用分接点连接到铁芯或其他适当连接点的分压器，以确保实际绝缘的正确分压，或使用两个相位正确的测试变压器。



For legends, see Table 5.
 图例见表5。

Key
 钥匙

All measurements are made with S14 closed and again with S14 open.
 在S14关闭和S14打开的情况下进行所有测量。

Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a
 图A.15–患者漏电流测量电路示例

PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS

医用电气设备的患者接地连接，具有多个患者连接

Subclause 8.8.2 – Distance through solid insulation or use of thin sheet material 第8.8.2款-通过固体绝缘或使用薄板材的距离

The second edition of this standard placed no restrictions on the thickness of solid insulation, except as specified in 57.9.4 e) for transformers and for the need for all insulation covered by Clause 20 to be thick enough to pass the dielectric strength test. A very thin film of insulating material might pass that test but might not provide reliable insulation during the EXPECTED SERVICE LIFE of all production items.

本标准第二版对变压器的固体绝缘厚度没有任何限制，但第57.9.4 e) 条中规定的情况除外，并且第20条所涵盖的所有绝缘厚度必须足以通过介电强度试验。一层非常薄的绝缘材料薄膜可能会通过测试，但在所有产品的预期使用寿命内可能无法提供可靠的绝缘。

Some National Committee comments during the development of this edition proposed introducing relevant requirements derived from IEC 60950-1 to address this omission. Both WG 14 (Testing) and WG 16 (Electrical hazards) recommended accepting these proposals. 在本版本的编制过程中，一些国家委员会的意见建议引入IEC 60950-1的相关要求，以解决这一遗漏。工作组14（测试）和工作组16（电气危险）均建议接受这些建议。

These requirements have been included in IEC 60950-1 for many years without causing problems. They should not be onerous in practice for ME EQUIPMENT, and indeed most ME EQUIPMENT designed according to the previous editions of this standard would have satisfied them.

这些要求多年来一直被列入IEC 60950-1中，没有引起任何问题。它们在实践中对医用电气设备不应过于繁重，事实上，根据本标准先前版本设计的大多数医用电气设备都能满足它们的要求。

The requirements that have been introduced are intended to be technically equivalent to those of IEC 60950-1, but the editorial structure has been changed for clarity, as follows. 已引入的要求旨在在技术上等同于IEC 60950-1的要求，但为了清楚起见，编辑结构已作了更改，如下所示。

- IEC 60950-1 specifies a general requirement for distance through insulation, with an exception for voltages up to 71 V. This has been changed to state explicitly that the requirement applies above 71 V. IEC 60950-1规定了通过绝缘的距离的一般要求，但电压不超过71 V的情况除外。这一要求已改为明确规定，该要求适用于71 V以上。

- IEC 60950-1 specifies an exception from the requirement for distance through insulation where the requirements for thin sheet material apply, as set out in another subclause, but that subclause does not refer explicitly to the 71 V limit. This has been made explicit by stating the requirements for thin sheet material as an alternative to the thickness requirement, under the same introductory wording. IEC 60950-1规定了适用于薄板材料要求的绝缘距离要求的例外情况，但孩子条款并未明确提及71 V限值。通过在相同的介绍性措辞下说明薄板材料的要求，作为厚度要求的替代品，这一点已经明确。
- IEC 60950-1 specifies that “Insulation in thin sheet materials is permitted . . provided that” certain conditions are satisfied. This has been changed to an explicit requirement that insulation in thin sheet materials needs to satisfy these conditions. IEC 60950-1规定“允许在薄板材料中进行绝缘。前提是“满足某些条件。这一点已改为明确的要求，即薄板材料的绝缘需要满足这些条件。
- IEC 60950-1 requires that insulation in thin sheet materials “is used within the equipment ENCLOSURE”. However the ENCLOSURE as defined in this standard includes all outer surfaces, including the surfaces of cables, APPLIED PARTS, etc. The requirement has therefore been rephrased. IEC 60950-1要求“在设备外壳内使用薄板材料绝缘”。然而，本标准中定义的外壳包括所有外表面，包括电缆表面、应用部件等。因此，对要求进行了重新表述。

Elsewhere in this standard the terms SUPPLEMENTARY INSULATION and REINFORCED INSULATION have mostly been replaced by references to MEANS OF PROTECTION, but they have been retained here because, as in IEC 60950-1, the requirements concerning distance through insulation and the use of thin sheet material apply to SUPPLEMENTARY INSULATION and to REINFORCED INSULATION, but not to BASIC INSULATION. Thus these requirements do not apply where BASIC INSULATION, as one MEANS OF PROTECTION, is used in conjunction with a PROTECTIVE EARTH CONNECTION as the other MEANS OF PROTECTION. Where DOUBLE INSULATION 在本标准的其他地方，术语“补充绝缘”和“加强绝缘”大多已被提及的保护手段所取代，但此处保留了这些术语，因为，如IEC 60950-1所述，有关绝缘距离和薄钢板材料使用的要求适用于补充绝缘和加强绝缘，但不适用于基本绝缘。因此，这些要求不适用于作为一种保护手段的基本绝缘与作为另一种保护手段的保护接地连接一起使用的情况。其中双重绝缘 is used, these requirements apply to whichever constituent part thereof is regarded as the 这些要求适用于被视为 SUPPLEMENTARY INSULATION. 辅助绝缘。

Subclause	8.8.3	-	Dielectric	strength
第8.8.3款-介电强度				

Components designed to limit the voltage might need to be removed in order to allow the full test voltage to be applied to the insulation being tested. 设计用于限制电压的部件可能需要拆除，以便将全部试验电压施加到被测绝缘上。

The purpose of this test is to check all solid insulation under the worst-case condition after having achieved operating temperature. For heating elements, the worst case is achieved with heaters remaining energized during measurement. 本试验的目的是在达到工作温度后，在最坏情况下检查所有固体绝缘。对于加热元件，最坏的情况是在测量期间加热器保持通电。

The test voltages specified are appropriate for solid insulation only. Spacings (CREEPAGE DISTANCES and CLEARANCES) are evaluated by 8.9. IEC 60664-1 gives details of electrical test methods for clearances using impulse voltage dielectric strength tests. These tests can be used under the IEC 60950-1 route for MOOPs, but are not specified for MOPPs. IEC 60664-1 states that the 2U + 1 000 V type of dielectric strength test “is not relevant for the testing of clearances”. 规定的试验电压仅适用于固体绝缘。间距（爬电距离和间隙）按8.9评估。IEC 60664-1给出了使用冲击电压介电强度试验进行电气间隙试验的详细方法。这些试验可在IEC 60950-1路由下用于MOOP，但未

对MOPP进行规定。IEC 60664-1规定 $2U+1000\text{ V}$ 绝缘强度试验“与间隙试验无关”。

Since the dielectric strength test is applied immediately after the humidity preconditioning treatment, with the ME EQUIPMENT still in the humidity cabinet, adequate precautions for the protection of laboratory personnel could be necessary.
由于在湿度预处理处理后立即进行介电强度试验，且医用电气设备仍在湿度柜中，因此有必要采取适当的预防措施保护实验室人员。

In Table 6, the values for OPERATOR protection are taken from IEC 60950-1 and the values for PATIENT protection are taken from the second edition of IEC 60601-1. In constructing the table, three principles were employed:
在表6中，操作员保护值取自IEC 60950-1，患者保护值取自IEC 60601-1第二版。在构建表格时，采用了三个原则：

- MOPP are always at a higher value than MOOP.
MOPP的值总是高于MOOP。
- Mains circuits are effected by transient overvoltages as detailed in Table 10. In SECONDARY CIRCUITS, the transient overvoltage level is at least one level less than the mains circuits.
电源电路受到表10中详述的瞬态过电压的影响。在二次电路中，瞬态过电压水平至少比电源电路低一级。
- The value of test voltage is primarily determined by the transient voltage on the SUPPLY MAINS which is usually orders of magnitude larger than the WORKING VOLTAGE.
试验电压值主要由供电干线上的瞬态电压决定，其通常比工作电压大几个数量级。

In order to align with the second edition of IEC 60601-1 for the common WORKING VOLTAGE of 220 V r.m.s to 240 V r.m.s , the test voltage of $4\,000\text{ V r.m.s}$ was retained even though this value is more than twice the test voltage for one MOPP. However, each individual MOPP has to meet the $1\,500\text{ V r.m.s}$ minimum requirement.
为了与IEC 60601-1第二版中 220 V r.m.s 至 240 V r.m.s 的共同工作电压保持一致，即使该值是一个MOPP试验电压的两倍以上，仍保留了 4000 V r.m.s 的试验电压。但是，每个MOPP必须满足 1500 V r.m.s 的最低要求。

Subclause 8.8.3 a)

第8.8.3 a) 款

The test voltage can be provided by a transformer, by a d.c. power source or by using the transformer(s) of the ME EQUIPMENT. In the last case, to prevent overheating, the test voltage can have a frequency that is higher than the RATED frequency of the ME EQUIPMENT. 试验电压可由变压器、直流电源或医用电气设备的变压器提供。在最后一种情况下，为了防止过热，测试电压的频率可以高于医用电气设备的额定频率。

The PROCEDURE and duration of the test for WORKING VOLTAGE equal to or higher than 1 000 V 工作电压等于或高于1000V的试验程序和持续时间
a.c. or 1 500 V d.c. or peak values can be specified further by particular standards. a、c.或1500 V直流电或峰值可由特定标准进一步规定。

Subclause 8.8.4.1 – Mechanical strength and resistance to heat

第8.8.4.1款-机械强度和耐热性

Tests concerning flammability of materials will be found in IEC 60695-11-10. 有关材料易燃性的试验见IEC 60695-11-10。

Subclause 8.9 – CREEPAGE DISTANCES and AIR CLEARANCES

第8.9款-爬电距离和空气间隙

For ME EQUIPMENT intended to be supplied from the SUPPLY MAINS, AIR CLEARANCE and dielectric strength requirements are based on the expected overvoltage transients that could enter the equipment from the SUPPLY MAINS. According to IEC 60664-1, the magnitude of these transients is determined by the normal supply voltage and the supply arrangements. These transients are categorized according to IEC 60664-1 into four groups called overvoltage categories I to IV (also known as installation categories I to IV). Elsewhere in this standard overvoltage category II is assumed. 对于拟由供电干线供电的医用电气设备，空气间隙和介电强度要求基于可能从供电干线进入设备的预期过电压瞬态。根据IEC 60664-1，这些瞬态的大小由正常电源电压和电源布置决定。根据IEC 60664-1，这些瞬态被分为四类，称为过电压类别I至IV（也称为安装类别I至IV）。在本标准的其他地方，假设过电压类别为II。

The design of solid insulation and AIR CLEARANCES should be co-ordinated in such a way that, if an incident overvoltage transient exceeds the limits of overvoltage category II, the solid insulation can withstand a higher voltage than the AIR CLEARANCES. 固体绝缘和空气间隙的设计应以这样的方式进行协调：如果事故过电压瞬态超过II类过电压限值，固体绝缘能够承受比空气间隙更高的电压。

The values in Table 13 to Table 15 correspond to those of IEC 60950-1 for overvoltage category II for MAINS PARTS and overvoltage category I for SECONDARY CIRCUITS. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is in overvoltage category III or IV, these values will be inadequate. 表13至表15中的值对应于IEC 60950-1中电源部件II类过电压和二次电路I类过电压的值。如果医用电气设备拟用于供电干线处于III类或IV类过电压的位置，则这些值将不充分。

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I if the SUPPLY MAINS is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 13. 如果供电干线为II类过电压，则来自供电干线的二次电路通常为I类过电压；表13的列标题中显示了I类过电压中各种电源电压的最大瞬态。

For insulation between the ENCLOSURE and the PATIENT CONNECTION of an F-TYPE APPLIED PART 用于外壳和F-TYPE应用部件的患者连接之间的绝缘
special rules apply: 特殊规则适用：

- 1) In the case of an F-TYPE APPLIED PART containing no voltage difference, the insulation

between the PATIENT CONNECTIONS and the ENCLOSURE will only be stressed to the MAINS VOLTAGE in the case of a fault in other equipment connected to the PATIENT.

如果F-TYPE应用部件没有电压差，只有在与患者相连的其他设备发生故障时，才会将患者连接和外壳之间的绝缘施加到电源电压。

This condition rarely occurs; furthermore this insulation is not normally subject to the transient overvoltages found in the MAINS PART. In view of the above, the insulation necessary between the APPLIED PART and the ENCLOSURE for the case quoted, need only satisfy the requirements for BASIC INSULATION.

这种情况很少发生；此外，这种绝缘通常不会受到电源部件中的瞬态过电压的影响。综上所述，所引用的情况下，应用部件和外壳之间所需的绝缘仅需满足基本绝缘的要求。

- 2) In the case of an F-TYPE APPLIED PART containing parts with voltage difference, the connection of a PATIENT CONNECTION to earth via an earthed PATIENT (NORMAL CONDITION) could subject the insulation between other parts and the ENCLOSURE to the whole of the voltage within the APPLIED PART. 如果F-TYPE应用部件包含有电压差的部件，则通过接地的患者（正常情况下）将患者连接至接地可能会使其他部件和外壳之间的绝缘受到应用部件内的全部电压的影响。

Since this voltage appears in NORMAL CONDITION, even though infrequently, the relevant insulation should satisfy the requirements for DOUBLE INSULATION or REINFORCED INSULATION. In view of the low probability of this condition occurring, the CREEPAGE DISTANCES and AIR CLEARANCES given in Table 11 are considered adequate.

由于该电压在正常情况下出现，即使很少出现，相关绝缘应满足双重绝缘或加强绝缘的要求。鉴于这种情况发生的可能性很低，表11中给出的爬电距离和空气间隙被认为是足够的。

- 3) The value to be applied is the highest of the values found according to Items 1) and 2) above.

要应用的值是根据上述第1)和2)项找到的值中的最高值。

In the absence of a theoretical background to refer to, it was decided that the values above 1 000 V would be drawn from Table 7 of IEC 61010-1:2001 [22] for CREEPAGE DISTANCES using the column for material group IIIa-b, pollution degree 3, which correlates with the existing values in the second edition of IEC 60601-1 or is slightly more onerous. For AIR CLEARANCES, the values have been estimated based on the relationship between creepage and clearance for values below 1 000 V r.m.s. from Table 12. These derived values are shown in Table A.1.

在缺乏可参考的理论背景的情况下，根据IEC 61010-1:2001[22]表7中的爬电距离，使用材料组IIIa-b，污染等级3的列，得出高于1000 V的值，该值与IEC 60601-1第二版中的现有值相关或稍高繁重的。对于空气间隙，根据表12中低于1000 V r.m.s.值的爬电和间隙之间的关系，对值进行了估算。这些导出值如表A.1所示。

Table 16 of the second edition of IEC 60601-1 was split into two tables in this standard (Tables 9 and 10). To align it with tables derived from other standards such as IEC 60950-1, the factor between the a.c. voltages and the d.c. voltages was changed from 1,2 to about 1,4. This relaxation was accepted as it is a common approach in other standards and it prevents having different CREEPAGE DISTANCES or AIR CLEARANCES in circuits where there is a d.c. voltage rectified from an a.c. voltage.

IEC 60601-1第二版的表16在本标准中分为两个表（表9和表10）。为了与其他标准（如IEC 60950-1）中的表格保持一致，交流电压和直流电压之间的系数从1,2改为约1,4。这种松弛是被接受的，因为这是其他标准中的一种常见方法，它可以防止在有交流电压整流的直流电压的电路中出现不同的爬电距离或空气间隙。

Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12
 表A.1—根据IEC 61010-1:2001表7和表12得出的空气间隙和爬电距离值

WORKING VOLTAGE 工作电压 V d.c. 直流电。 up to and including 包括	WORKING VOLTAGE 工作电压 V r.m.s. 电流有效值 up to and including 包括	Spacing providing 间距提供 one MEANS OF PATIENT PROTECTION 一种保护病人的方法		Spacing providing 间距提供 two MEANS OF PATIENT PROTECTION 两种保护病人的方法	
		AIR CLEARANCE 空气间隙 mm 毫米	CREEPAGE DISTANCE 爬电距离 mm 毫米	AIR CLEARANCE 空气间隙 mm 毫米	CREEPAGE DISTANCE 爬电距离 mm 毫米
1 500 1500个	1 250 1250个	11,5 十一点五	20 20	23,0 23,0分	40 40
1 920 1920年	1 600 1600个	14,5 14,5岁	25 25	29,0 0,29个	50 50
2 400 2400个	2 000 2000个	18,5 18,5岁	32 32	37,0 37,0分	64 64
3 000 3000个	2 500 2500个	23,0 23,0分	40 40	46,0 46,0分	80 80
3 840 3 840个	3 200 3200个	29,0 29,0分	50 50	58,0 58.0万	100 100
4 800 4800个	4 000 4000个	36,0 36,0分	63 63	72,0 72.0万	126 126
6 000 6000个	5 000 5000个	46,0 46,0分	80 80	92,0 92,0分	160 160
7 560	6 300	57,0	100	114,0	200

5607号	6300个	57.0万	100	114,0号	200
9 600 9600个	8 000 8000个	71,5 71,5个	125 125	143,0 143,0号	250 250
12 000 12000个	10 000 1万	91,5 91.5美元	160 160	183,0 183,0号	320 320

Table A.2 contains CREEPAGE DISTANCES for WORKING VOLTAGE above 1 000 V derived from IEC 60664-1:2007, Table 4 F.4.
表A.2包含根据IEC 60664-1:2007表4 F.4得出的工作电压高于1000 V的爬电距离。

Subclause 8.9.1 – Values

第8.9.1款-价值

When using the values of CREEPAGE DISTANCE and AIR CLEARANCE, it should be noted that peak, d.c. and r.m.s. values are all used. It is important to read the tables carefully.
当使用爬电距离和空气间隙值时，应注意，峰值、直流电和均方根值均采用。仔细阅读表格是很重要的。

The tables for MOOPs use values from IEC 60950-1 representing the following basic principles, taken from IEC 60664-1:
MOOP表格使用IEC 60950-1中的值，代表以下基本原则，摘自IEC 60664-1:

- “The basis for the determination of a CREEPAGE DISTANCE is the long-term r.m.s. value of the voltage existing across it.”
“确定爬电距离的依据是其上存在的电压的长期r.m.s.值。”
- “AIR CLEARANCES shall be dimensioned to withstand the required impulse withstand voltage”. Impulse withstand voltage is the “highest peak value of withstand voltage”
“空气间隙的尺寸应能承受要求的冲击耐受电压”。冲击耐受电压是“耐受电压的最高峰值.....”

However, the tables for MOPPs are taken from the second edition of IEC 60601-1, where both creepages and clearances were related to r.m.s. or d.c. voltages.
然而，MOPP的表格取自IEC 60601-1第二版，其中蠕变和间隙均与r.m.s.或直流电压有关。

Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1
表A.2—避免因IEC 60664-1跟踪而导致故障的爬电距离

WORKING VOLTAGE 工作电压 V 五 r.m.s or d.c. r、m.s或 d.c。	Spacing for one MEANS OF OPERATOR PROTECTION 一种操作员保护装置的间距						
	Pollution degree 1 污染程度1	Pollution degree 2 污染程度2			Pollution degree 3 污染程度3		
	Material group 材料组	Material group 材料组			Material group 材料组		
	I, II, IIIa, IIIb 一、二、 三、三、三	I 我	II 二	IIIa or IIIb IIIa或IIIb	I 我	II 二	IIIa or IIIb IIIa或IIIb
1 250 1250个	Use the 使用 AIR CLEARANC E 空气间隙 from the appropriate 从适当的 table 桌子	6,3 6,3 个	9,0 9,0 分	12,5 12,5 个	16,0 16,0 分	18,0 18,0分	20,0 20,0 分
1 600 1600个		8,0 8,0 分	11, 0	16,0 16,0 分	20,0 20,0 分	22,0 22,0分	25,0 25,0 万
2 000 2000个		10, 0	11, 0号	20,0 20,0 分	25,0 25,0 万	28,0 28,0分	32,0 32,0 万
2 500 2500个		10, 0分	14, 0	25,0 25,0 万	32,0 32,0 万	45,0 45,0分	40,0 40,0 分
3 200 3200个		12, 5	18, 0	32,0 32,0 万	40,0 40,0 分	56,0 56,0分	50,0 50,0 万
4 000 4000个		12, 5个	18, 0分	40,0 40,0 分	50,0 50,0 万	90,0 90,0	80,0 80,0
5 000 5000个		16, 0	22, 0	50,0 50,0 万	63,0 63,0 万	110,0 110,0	100, 0
6 300 6300个		16, 0分	22, 0分	63,0 63,0 万	80,0 80,0 万	140,0 140,0	100, 0
8 000 8000个		20, 0	28, 0	80,0 80,0 万	100,0 100,0	125,0 125,0	125, 0
10 000 1万		20, 0分	28, 0分	100, 0	125,0 125,0	160, 0	160, 0
		25, 0	36, 0	125,0 125,0 万	160, 0	200, 0	200, 0
		25, 0万	36, 0分	200, 0	250, 0	315, 0	315, 0
		32, 0	45, 0	315, 0	400, 0	500, 0	500, 0
		32, 0万	45, 0分	400, 0	500, 0	630, 0	630, 0
		40, 0	56, 0	630, 0	800, 0	1000, 0	1000, 0
		40, 0分	56, 0	800, 0	1000, 0	1250, 0	1250, 0
		50, 0	70, 0	1000, 0	1250, 0	1600, 0	1600, 0
		50, 0万	70, 0分	1250, 0	1600, 0	2000, 0	2000, 0
		63, 0	80, 0	1600, 0	2000, 0	2500, 0	2500, 0
		63, 0分	80, 0分	2000, 0	2500, 0	3150, 0	3150, 0

		50, 0 50, 0	0分 71, 0 71, 0分				

Subclause 8.9.1.6 – Interpolation

第8.9.1.6款-插值

Interpolation for CREEPAGE DISTANCES but not for AIR CLEARANCES is allowed, except where the WORKING VOLTAGE is above 2 kV r.m.s. or 2,8 kV d.c. This approach is generally consistent with IEC 60950-1 and IEC 61010-1 [22].
允许对爬电距离进行插值，但不允许对空气间隙进行插值，除非工作电压高于2 kV r.m.s.或2.8 kV直流电。这种方法通常与IEC 60950-1和IEC 61010-1[22]一致。

Subclause 8.9.1.15 – CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

第8.9.1.15款-除颤应用部件的爬电距离和空气间隙

From IEC 60664-1:2007, Table 2 F.2, a distance of 4 mm is adequate for pulses of 5 kV having a short duration of less than 10 ms, such voltages arising typically from the use of a defibrillator.
对于频率小于1:2007的频率为1:6kV的脉冲，使用频率小于1:2007的频率为6.6kV的脉冲时，距离为6.6kV。

Subclause 8.9.2 – Application

第8.9.2款-应用

Subclause 8.9.2 a)

第8.9.2 a) 款

Depending on the INTENDED USE of the ME EQUIPMENT, operation of the fuse or OVER-CURRENT RELEASE can be a HAZARD. The opening of a branch circuit breaker is not acceptable. Subclause 8.9.2 a) is based on the fact that there is an over-current device in the input of the ME EQUIPMENT before the part of the circuit where this subclause is applied. Before this over-current device, the spacings need to comply with the basic requirement for parts of opposite polarity within the MAINS PART.

根据医用电气设备的预期用途，操作保险丝或过电流释放装置可能存在危险。分支断路器的断开是不可接受的。子条款8.9.2 a) 基于这样一个事实，即在应用该子条款的电路部分之前，医用电气设备的输入中存在过电流装置。在这种过电流装置之前，间距必须符合电源部分内极性相反部分的基本要求。

Subclause 8.9.3 – Spaces filled by insulating compound

第8.9.3款-用绝缘化合物填充的空间

CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except for cemented joints, i.e. those in which:

爬电距离是通过绝缘屏障两部分之间的接头测量的，胶结接头除外，即：

- either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;
形成接头的两个零件在重要位置通过热密封或其他类似方式粘合；
- or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.
或者在必要的地方用粘合剂完全填充接缝，并且粘合剂粘结在绝缘屏障的表面上，这样湿气就不会被吸入接缝中。

In the second edition of this standard, the captions to Figures 43 to 45 referred to “uncemented joints.” Item 7 of the legends to these figures referred to 57.9.4 f), second dash, “for a description of cemented joints” but did not specify any test methods other than inspection. During the preparation of this edition, it was proposed to introduce relevant requirements derived from IEC 60950-1 to address the related subject of potting. 在本标准第二版中，图43至图45的标题指的是“非胶结接缝”。图中图例第7项指的是57.9.4 f)，第二个破折号，“用于水泥接缝的说明”，但没有规定除检验以外的任何试验方法。在本版本的编制过程中，建议引入iec60950-1的相关要求，以解决灌封的相关问题。

The requirements that have been introduced are closely based on those of IEC 60950-1 and cover potting, encapsulation, cemented joints, etc. The editorial structure has been somewhat revised from that of IEC 60950-1 for clarity. These requirements have been included in 8.9 rather than 8.8 because they specify circumstances that allow exemption from the requirements for CREEPAGE DISTANCES and AIR CLEARANCES, rather than additional requirements applying to solid insulation. 已引入的要求严格基于IEC 60950-1的要求，包括封装、封装、胶结接头等。为了清晰起见，编辑结构在IEC 60950-1的基础上进行了一些修改。这些要求包含在8.9而不是8.8中，因为它们规定了允许免除爬电距离和空气间隙要求的情况，而不是适用于固体绝缘的附加要求。

Subclause 8.9.4 – Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES **第8.9.4款-爬电距离和空气间隙的测量**

Narrow gaps, running in the direction of a possible creepage path and being some tenths of 1 mm wide only, should be avoided as far as possible, for dirt and moisture can deposit there. 应尽可能避免沿着可能的爬电路径方向运行的窄间隙，宽度仅为1 mm左右，因为灰尘和湿气会沉积在那里。

Subclauses 8.10.1 – Fixing of components **第8.10.1款-部件的固定**

In many cases it will be obvious that components and wiring are adequately secured (e.g. small components soldered to a printed circuit board) without the need for specific justification in the RISK MANAGEMENT FILE; but if any relevant information is included in the RISK MANAGEMENT FILE, it should be taken into account in assessing compliance with these requirements. 在许多情况下，显而易见的是，组件和接线已得到充分保护（例如，焊接到印刷电路板上的小组件），而无需在风险管理文件中提供具体理由；但是，如果风险管理文件中包含任何相关信息，在评估是否符合这些要求时，应将其考虑在内。

Subclause 8.10.2 – Fixing of wiring **第8.10.2款-布线固定**

It is generally accepted that wiring connections are subject to the SINGLE FAULT CONDITION. That is those having only one means of being secured that would prevent a loosened/broken wire from creating a HAZARD resulting in a HAZARDOUS SITUATION, such as removing a PROTECTIVE EARTH CONNECTION or bridging a MEANS OF PROTECTION, are considered not in compliance. 一般认为，接线连接受单一故障条件的影响。也就是说，只有一种固定方法可以防止松动/断开的电线产生危险，从而导致危险情况，例如拆除保护接地连接或桥接保护装置，则视为不符合要求。

Examples of connection that could comply with SINGLE FAULT CONDITION are:
符合单一故障条件的连接示例如下：

- double crimping of both the wire and the wire insulation;
导线和导线绝缘的双重压接；
- mechanical security of the wire and soldering;
导线和焊接的机械安全性；
- mechanical security of the wire and wire movement restraints such as tie wraps, wire clamps, bundling straps, etc.;
导线的机械安全性和导线运动限制，如系带、线夹、捆扎带等。；

- strain relief mechanisms and mechanical security.
应变消除机制和机械安全。

Subclause 8.10.4 – Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

第8.10.4款-绳索连接的手持部件和绳索连接的脚踏控制装置

HAND-HELD switches and footswitches are in practice exposed to severe conditions. This requirement ensures that even in the worst case, where the ENCLOSURE of such a switch is completely broken, only parts at voltages within the limits specified in 8.4.2 c), which are safe to touch, can become exposed.
手持式开关和脚踏开关实际上暴露在恶劣条件下。这一要求确保即使在最坏的情况下，这种开关的外壳完全损坏，也只有电压在8.4.2 c)中规定的限值范围内、可安全接触的零件才会暴露在外。

Subclause 8.10.5 – Mechanical protection of wiring

第8.10.5款-接线的机械保护

There is no requirement for specific justification to be given in the RISK MANAGEMENT FILE, but if any relevant information is included in the RISK MANAGEMENT FILE it should be taken into account in assessing compliance with these requirements.
没有要求在风险管理文件中给出具体的理由，但如果风险管理文件中包含任何相关信息，则在评估这些要求的合规性时应将其考虑在内。

Subclause 8.10.7 - Insulation of internal wiring
第8.10.7款-内部接线绝缘

Conductors can be routed in separated jacketed cords of adequate rating. Where conductors of different circuit categories have to be run through common cords, wiring channels, conduits or connecting devices, adequate separation is realized by sufficient rating of the conductor insulation and by arranging for sufficient AIR CLEARANCES and CREEPAGE DISTANCES, complying with the requirements of 8.9, between conductive parts in connecting devices. 导线可敷设在具有足够额定值的单独护套软线中。如果不同电路类别的导线必须穿过公共电线、接线槽、导管或连接装置，则应根据8.9的要求，通过导线绝缘的足够额定值和布置足够的空气间隙和爬电距离，实现充分的分离，在连接装置的导电部分之间。

Subclause 8.11.1 - Isolation from the SUPPLY MAINS
第8.11.1款-与电源隔离

Subclause 8.11.1 a) 第8.11.1 a) 款

Skilled persons, such as SERVICE PERSONNEL, who need to gain access to internal, possibly hazardous, ME EQUIPMENT parts, need a means by which the ME EQUIPMENT can be isolated from the SUPPLY MAINS. 需要接近内部（可能是危险的）医用电气设备部件的技术人员（如维修人员）需要一种方法将医用电气设备与电源隔离。

A mains isolating switch, where provided, could also serve as a functional off switch for routine use or for disabling hazardous output in an emergency. However it does not necessarily serve these purposes, nor does this standard specify any general requirement for an emergency off switch. 电源隔离开关（如有提供）也可作为日常使用或紧急情况下禁用危险输出的功能关闭开关。然而，它不一定用于这些目的，本标准也没有规定紧急关闭开关的任何一般要求。

Subclause 8.11.1 c) 第8.11.1 c) 款

In the second edition of this standard, the requirement for minimum contact spacing of switches used to provide isolation from the SUPPLY MAINS was specified in IEC Publication 328. IEC 61058-1 superseded IEC 328 in 1990. The first edition of IEC 61058-1 required 3 mm contact spacing for full disconnection from the SUPPLY MAINS. No mention of overvoltage category was made. The third edition of IEC 61058-1 introduced the concept of overvoltage category according to IEC 60664-1. For a 230 V SUPPLY MAINS in overvoltage category II, Table 22 of IEC 61058-1:2000 allows a minimum contact spacing of 1,5 mm. While the requirements in this standard generally relate to overvoltage category II (see 8.9.1.11), it was thought prudent to stay with the 3 mm requirement associated with a 230 V SUPPLY MAINS IN overvoltage category III for all switches intended to provide isolation from the SUPPLY MAINS. Not only is this consistent with the requirement of the second edition of IEC 60601-1 but it is also harmonious with the requirements of IEC 60065 and IEC 60950-1, which both require a minimum contact separation of 3 mm for switches intended to provide isolation from the SUPPLY MAINS. 3281990年，IEC 61058-1取代了IEC 328。第一版IEC 61058-1要求触点间距为3mm，以便完全断开电源。未提及过电压类别。第三版iec61058-1根据iec60664-1引入了过电压类别的概念。对于过电压类别为II的230V电源，IEC 61058-1:2000的表22允许最小接触间距为1.5 mm。虽然本标准中的要求通常与II类过电压有关（见8.9.1.11），但对于所有打算与电源隔离的开关，应谨慎遵守与III类过电压230V电源相关的3mm要求。这不仅符合第二版IEC 60601-1的要求，而且也符合IEC 60065和IEC 60950-1的要求，这两个标准都要求开关与电源隔离时的最小触点间距为3 mm。

Subclause 8.11.1 h) 第8.11.1 h) 款

Such a protective device whether or not it caused the operation of an over-current protection device built into the ME EQUIPMENT, would be likely also to cause a fuse or circuit breaker in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT. Such a device might also cause undesirable thermal effects inside the

ME EQUIPMENT and might anyway not be a reliable method of protecting against the relevant HAZARDS.

这种保护装置无论是否引起医用电气设备中内置的过电流保护装置的运行，都可能导致装置中的保险丝或断路器工作，从而切断其他医用电气设备（可能包括生命支持医用电气设备）的供电。这种装置也可能在医用电气设备内部产生不良的热效应，而且无论如何也不是一种可靠的防止相关危险的方法。

Subclause

8.11.1

第8.11.1 i) 款

Parts that cannot be disconnected from the supply might include, for example, a circuit for room lighting or a circuit for remote control of the mains switch. Such parts could become accessible when a cover is opened, for example for the purpose of maintenance. 不能与电源断开的部件可能包括，例如房间照明电路或电源开关遥控电路。当打开盖子时，例如出于维护目的，这些零件可能会变得容易接近。

A spatially separated arrangement is one where parts that need to be accessible for servicing are located such that the SERVICE PERSONNEL are unlikely to come in contact with parts energized at voltages exceeding those specified in this standard while performing the required service. In this case, a warning is deemed to provide adequate safety for the SERVICE PERSONNEL. 空间分离式布置是指需要接近维修的零件的位置，以便维修人员进行所需维修时，不可能接触到电压超过本标准规定电压的零件。在这种情况下，警告被视为为服务人员提供了足够的安全。

Subclause

8.11.2

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MULTIPLE

SOCKET-OUTLETS

第8.11.2款-多个插座

This requirement reduces the probability that other equipment is connected that might lead to excessive LEAKAGE CURRENT.

这一要求降低了连接其他设备可能导致过大泄漏电流的可能性。

Subclause8.11.3.4-器具耦合器8.11.3.4APPLIANCECOUPLERS

A POWER SUPPLY CORD connected to a MAINS CONNECTOR is subject to similar stresses to a non-DETACHABLE POWER SUPPLY CORD. If it is not adequately protected from excessive bending, a HAZARD HAZARDOUS SITUATION could result. 连接到电源连接器的电源线受到与不可拆卸电源线类似的应力。如果没有充分保护其不受过度弯曲的影响，可能会造成危险的情况。

Subclause8.11.3.5-绳索锚固8.11.3.5Cordanchorage

If a power cord were not adequately protected against strain and abrasion, there would be a high probability of damage to insulation providing MEANS OF PROTECTION and, with CLASS I ME EQUIPMENT, a high probability of breakage or disconnection of the PROTECTIVE EARTH CONDUCTOR. 如果电源线未得到充分的应变和磨损保护，则提供保护措施的绝缘材料很可能受损，对于I类医用电气设备，保护性接地导体极有可能断裂或断开。

Subclause8.11.3.6-绳索防护装置8.11.3.6Cordguards

If a power cord were not adequately protected against excessive bending, there would be a high probability of breakage of power-carrying conductors, giving a RISK of fire, and with CLASS I ME EQUIPMENT, a high probability of breakage of the PROTECTIVE EARTH CONDUCTOR. 如果电源线没有得到充分的保护以防止过度弯曲，则载电导体极有可能断裂，从而产生火灾风险；对于I类医用电气设备，保护性接地导线极有可能断裂。

The bending test described is identical to that specified in 3.29 of IEC 60950-1:20012005, subclause 3.2.8. The second edition of IEC 60601-1 included the wording “Guards which fail the above dimensional test shall have to pass the test described in IEC 60335-1, Amendment 所述弯曲试验与IEC 60950-1:20012005第3.2.8款中3.29规定的试验相同。IEC 60601-1第二版包括“未通过上述尺寸试验的防护装置必须通过IEC 60335-1修正案中所述的试验 6. 1988, subclause 25.10.” This alternative has been retained, but the reference is now to a later edition of IEC 60335-1. Also the requirement to perform one test in all cases, and then to perform the other test if the ME EQUIPMENT fails the first test, has been changed to allow either test to be performed first, because this makes no difference to whether the ME EQUIPMENT complies. 61988年，第25.10款。”本备选方案已保留，但现在参考的是IEC 60335-1的较新版本。此外，在所有情况下进行一次试验的要求，以及在医用电气设备未通过第一次试验的情况下进行另一次试验的要求已经改变，允许首先进行任何一次试验，因为这对医用电气设备是否符合要求没有任何区别。

Subclause8.11.4.1-电源终端设备的一般要求8.11.4.1General requirements for MAINS TERMINAL DEVICES

Mains terminals should ensure connections of sufficiently low resistance to avoid overheating and should minimise the RISK of disconnection. Reliable connection can be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods. 电源端子应确保连接具有足够低的电阻，以避免过热，并应将断开的风险降至最低。可靠的连接可以通过螺钉、螺母、焊接、夹紧、压接导线或同样有效的方法进行。

Use of terminals of components other than terminal blocks as terminals intended for external conductors is allowed in special cases where the terminal arrangement is adequate (accessible and clearly marked) and complying with this standard. The wiring terminals of certain types of components are often rated for field wiring purposes. These include fuse holders, EMC filters, circuit breakers, contactors, wiring strips, motor controllers and phase detectors. Each of these can be one of the first connected components thereby putting them in a good position to accept the first wiring connections. 在特殊情况下，允许使用除接线板以外的元件端子作为外部导线的端子，端子布置足够（可接近并清楚标记）并符合本标准。某些类型的部件的接线端子通常被定为现场接线的额定值。这些包括保险丝座、EMC滤波器、断路器、接触器、接线板、电机控制器和相位检测器。这些元件中的每一个都可以是第一

连接的元件之一，从而使它们处于良好的位置以接受第一布线连接。

Subclause8.11.4.2Arrangement of MAINS TERMINAL DEVICES

第8.11.4.2款-电源终端设备的布置

Subclause8.11.4.2a)

第8.11.4.2 a) 款

One naturally expects to see all the terminals for connection of external cords or POWER SUPPLY CORDS grouped together. The possibility of an incorrect connection can increase if the terminals are not grouped together.
人们自然希望看到连接外部电源线或电源线的端子组合在一起。如果端子未组合在一起，则不正确连接的可能性会增加。

Subclause8.11.4.4Connections to mains terminals

第8.11.4.4款-电源端子的连接

The term “special preparation of the conductor” covers soldering of the strands, use of cord lugs, attachment of eyelets, etc., by SERVICE PERSONNEL (i.e. in the field), but not the reshaping of the conductor before its introduction into the terminal or the twisting of a stranded conductor to consolidate the end. When preparation of the conductor is performed by the MANUFACTURER and the flexible cord is provided as the only acceptable replacement part, such part is considered to comply with this requirement.
术语“导线的特殊准备”包括由服务人员（即在现场）焊接钢绞线、使用电线接线头、连接孔眼等，但不包括在导线引入端子之前对导线进行整形或扭转绞合导线以加固端部。当制造商准备导线时，软线作为唯一可接受的替换零件提供，则认为该零件符合本要求。

Subclause8.11.5Mains fuses and OVER-CURRENT RELEASES

第8.11.5款-电源保险丝和过电流脱扣器

Provision of fuses or OVER-CURRENT RELEASES in ME EQUIPMENT reduces the RISK that a fault in the ME EQUIPMENT will cause a protective device in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT.
在医用电气设备中提供保险丝或过电流脱扣器可降低医用电气设备故障导致装置中的保护装置运行的风险，从而切断其他医用电气设备（可能包括生命支持医用电气设备）的供电。

It is obvious that fusing in a PROTECTIVE EARTH CONNECTION would be inappropriate.
很明显，在保护接地连接中熔断是不合适的。

Fusing of the neutral conductor of PERMANENTLY INSTALLED ME EQUIPMENT would serve no purpose and, with 3-phase equipment, might lead to overstressing of insulation in the event that such a fuse were to operate while the line connections remained intact. However an OVER-CURRENT RELEASE that interrupts all poles, including the neutral, simultaneously is acceptable. 永久性安装的医用电气设备的中性导线熔断将毫无用处，并且，对于三相设备，如果此类保险丝在线路连接保持完好的情况下运行，可能会导致绝缘过度应力。但是，同时中断所有极（包括中性点）的过电流释放是可以接受的。

The exemption for the case where DOUBLE INSULATION or REINFORCED INSULATION is present between all parts of opposite polarity within the MAINS PART was supported by the National Committees' responses to an inquiry during the preparation of this edition. It could apply where provision of a fuse or OVER-CURRENT RELEASE would be inconvenient, for example in a small plug-in power supply.
在编写本版本期间，国家委员会对调查的答复支持了对电源部分内所有相反极性部件之间存在双重绝缘或加强绝缘的豁免。它可以适用于不方便提供保险丝或过电流脱扣器的场合，例如在小型插入式电源中。

Clause 9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 第9条-医用电气设备和医用电气系统的机械危害防护

Requirements in Clause 9 describe HAZARDS of a mechanical nature caused by ME EQUIPMENT (HARM caused by moving parts, by rough surfaces, by sharp edges and corners, by instability, by expelled parts, by vibration and noise and by breakdown of PATIENT supports and of suspension means for ME EQUIPMENT parts). Requirements describing HAZARDS caused by damage or deterioration of ME EQUIPMENT (mechanical strength) have been collected into 15.3. 第9条中的要求描述了医用电气设备引起的机械性危害（移动部件、粗糙表面、锐边和尖角、不稳定性、排出部件、振动和噪音以及医用电气设备部件的患者支架和悬挂装置故障造成的伤害）。描述医用电气设备损坏或劣化（机械强度）引起的危险的要求已纳入15.3。

ME EQUIPMENT can become unsafe because of parts damaged or deteriorated by mechanical stresses such as blows, pressures, shocks, vibration, by ingress of solid particles, dust, fluids and moisture and aggressive gases, by thermal and dynamic stresses, by corrosion, by loosening of fastenings of a moving part or a suspended mass, and by radiation. 由于机械应力（如冲击、压力、冲击、振动）、固体颗粒、灰尘、液体、湿气和腐蚀性气体的进入、热应力和动态应力、腐蚀、移动部件或悬浮物的紧固件松动以及辐射，医用电气设备可能会变得不安全。

Effects of mechanical overloads, material failure or wear can be avoided by:
可通过以下方法避免机械过载、材料失效或磨损的影响：

- means that interrupt or render non-hazardous the operation or the energy supply (for example, fuses, pressure-relief valves) as soon as overloading occurs; or
指一旦过载，即中断或使操作或能源供应（例如，保险丝、泄压阀）无害；或
- means that guard against or catch flying or falling parts (caused by material failures, wear or overload) that could constitute a MECHANICAL HAZARD.
指防止或抓住可能构成机械危险的飞行或坠落部件（由材料故障、磨损或过载引起）。

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of safety catches.
可通过冗余或提供安全锁扣来防止患者支架和悬吊装置损坏。

ME EQUIPMENT parts that are intended to be held in the hand or positioned on a bed need to be sufficiently robust to withstand a fall. They can be subject to vibration and shocks, not only when transported but also when used in vehicles. 打算握在手上或放在床上的医用电气设备部件必须足够坚固，以承受坠落。它们不仅在运输时，而且在车辆上使用时，都会受到振动和冲击。

Subclause 9.2 – MECHANICAL HAZARDS associated with moving parts 第9.2款-与活动部件相关的机械危险

OPERATORS, PATIENTS and other people need to be protected from MECHANICAL HAZARDS. This can be achieved in a number of ways, for example:
操作人员、病人和其他人需要受到保护，免受机械危险。例如，可以通过以下几种方式实现：

- by providing sufficient distance between people and MECHANICAL HAZARDS;
为人员和机械危险提供足够的距离；
- by restricting access to areas that present MECHANICAL HAZARDS;
限制进入存在机械危险的区域；
- by providing a barrier, whether mechanical or non-mechanical, between people and MECHANICAL HAZARDS;
通过在人与人之间提供机械或非机械的屏障
机械危害；
- by reducing the RISK associated with MECHANICAL HAZARDS;
通过降低与机械危险相关的风险；
- by ensuring adequate OPERATOR control over the movements causing a MECHANICAL HAZARD; or
确保操作员对引起机械危险的运动进行充分控制；或
- by providing back-up systems so that an acceptable RESIDUAL RISK is achieved when the initial control system fails.
通过提供备用系统，以便在初始控制系统发生故障时实现可接受的残余风险。

When reference is made, in this subclause, to the RISK to persons, rather than to the PATIENT or OPERATOR, it should be noted, that there can be other people, in addition to the PATIENT or OPERATOR in the vicinity of ME EQUIPMENT. Depending upon the ME EQUIPMENT, visitors, family members and other non-qualified personnel could be in the vicinity.
在本款中，当提到对人的风险，而不是病人或操作员时，应注意的是，除了病人或操作员之外，医用电气设备附近可能还有其他人。根据医用电气设备的不同，访客、家庭成员和其他不合格人员可能就在附近。

Subclause

9.2.1

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General

第9.2.1款-概述

Requirements concerning moving parts have been based on those in other standards applying to non-medical equipment and machinery, but have been modified to take account of the necessity for ME EQUIPMENT to be in contact with or very close to the PATIENT. 有关活动部件的要求基于适用于非医疗设备和机械的其他标准，但考虑到医用电气设备与患者接触或非常接近的必要性，对其进行了修改。

Due to the diversity of situations, it is not possible in this standard to dictate where the warnings to address RESIDUAL RISK should be placed. Depending on the application, and the level of RESIDUAL RISK, it could be important to place a warning on the product. It might, however, be acceptable to place the warning only in the ACCOMPANYING DOCUMENTS. 由于情况的多样性，在本标准中，不可能规定应在何处放置针对剩余风险的警告。根据应用程序和残余风险水平，对产品进行警告可能很重要。不过，只在随附文件中发出警告可能是可以接受的。

Subclause

9.2.2.4

– GUARDS and protective other RISK CONTROL measures

第9.2.2.4款-防护和防护性其他风险控制措施

The degree of protection required for ENCLOSURES or GUARDS protecting moving parts depends upon the general design and INTENDED USE of the ME EQUIPMENT. Factors to be taken into consideration in judging the acceptability of exposed moving parts include the degree of exposure, the shape of the moving parts, the probability of occurrence of accidental contact, the speed of movement and the probability of occurrence that fingers, arms or clothing will be drawn into moving parts (for example where gears mesh, where belts travel on to a pulley or where moving parts close in a pinching or shearing action). 保护运动部件的外壳或防护装置所需的防护等级取决于医用电气设备的总体设计和预期用途。在判断外露运动部件的可接受性时，应考虑的因素包括暴露程度、运动部件的形状、意外接触的概率、移动速度和手指出现的概率，手臂或衣服会被拉进运动部件（例如齿轮啮合，皮带移动到滑轮上，或者运动部件在挤压或剪切作用下闭合）。

These factors can be considered with respect to both NORMAL USE and the setting of any adjustments, or the replacement of any ACCESSORY or attachment, possibly including the installation, because GUARDS can be provided at installation and might not be part of a single item of STATIONARY equipment. 这些因素可以考虑到正常使用和任何调整的设置，或任何附件或附件的更换，可能包括安装，因为防护装置可以在安装时提供，并且可能不是固定设备的一部分。

- Features of GUARDS that can be considered include:
- 防护装置的特点包括：
- removable with the use of TOOLS only;

仅可使用工具拆卸；

– removable for servicing and replacement;

可拆卸维修和更换；

– strength and rigidity;

强度和刚度；

– completeness;

完整性；

– creation of additional HAZARDS such as pinch points, and the necessity for additional handling because of the increased need for servicing such as for cleaning.

产生额外的危险，如夹点，以及由于清洁等服务需求的增加而需要额外的处理。

Protective measures addressed by this clause are also intended to include collision detection systems, such as those employing light barriers. 本条所述的保护措施也旨在包括碰撞检测系统，例如使用光屏障的系统。

Protective measures can be used in lieu of continuous activation type control. The protective measures need to provide feedback control.

可使用保护措施代替连续激活式控制。防护措施需要提供反馈控制。

Subclause

9.2.2.5

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Continuous

activation

第9.2.2.5款-持续激活

Motion control systems with the OPERATOR in the feedback loop need to employ continuous activation (e.g. momentary contact, dead-man switch). Such factors as speed of motion and visible feedback to the OPERATOR also need to be adequate. 操作员处于反馈回路中的运动控制系统需要采用连续激活（例如瞬时接触、死机开关）。运动速度和对操作者的可视反馈等因素也需要足够。

In some circumstances, OPERATOR training and other qualifications are necessary in order to have adequate OPERATOR control. In such cases, it could be desirable to utilize “lock out controls” that require intentional action to allow movement. Examples of such controls include: 在某些情况下，操作员培训和其他资格认证是必要的，以便对操作员进行充分的控制。在这种情况下，最好使用“锁定控制”，这种控制需要有意识的行动来允许移动。此类控制的例子包括：

- a key switch with an “enable” function;
具有“使能”功能的按键开关；
- a finger print switch with an “enable” function;
具有“启用”功能的指纹开关；
- a password card.
密码卡。

In other circumstances, accidental control can be a concern. In this case, controls could employ such construction techniques as:

在其他情况下，意外控制可能是一个问题。在这种情况下，控制可采用如下施工技术：

- control with an “enable” function, before any motions are possible;
在可能发生任何动作之前，使用“启用”功能进行控制；
- controls with recessed actuators; this could prevent movement if a hand or leg hits actuator unintentionally.
带有嵌入式执行机构的控制装置；如果手或腿无意中撞到执行机构，则可防止移动。

If the OPERATOR could have access to hazardous moving parts, controls could be designed which would prevent access to the TRAPPING ZONE by location of the OPERATOR controls. An example is a control system that needs two-hand activation. 如果操作员可以接触到危险的活动部件，则可以设计控制装置，通过操作员控制装置的位置防止进入捕捉区。一个例子是需要双手激活的控制系统。

For OPERATOR control systems without continuous activation, there can be an acceptable mitigation of RISKS, however it is necessary to evaluate the system to the other options in 9.2.2.1. 对于没有连续激活的操作员控制系统，可以采用可接受的风险缓解措施，但有必要根据9.2.2.1中的其他选项对系统进行评估。

This clause deals with electronic motion control systems. For manually driven motion systems see other options in 9.2.2.1. 本条款涉及电子运动控制系统。对于手动驱动的运动系统，见9.2.2.1中的其他选项。

Subclause 9.2.2.6 – Speed of movement(s)

第9.2.2.6款-移动速度

For some medical equipment there will be unavoidable HAZARDS due to moving parts. 对于某些医疗设备，由于运动部件的存在，会不可避免地产生危险。

Subclause 9.2.3 – Other MECHANICAL HAZARDS associated with moving parts

第9.2.3款-与活动部件相关的其他机械危险

Subclause 9.2.2.1 deals with MECHANICAL HAZARDS caused by TRAPPING ZONES. Movement could result in other MECHANICAL HAZARDS, such as impact, puncture, etc. 第9.2.2.1款涉及由陷波区引起的机械危害。移动可能导致其他机械危险，如撞击、刺穿等。

Subclause 9.2.4 – Emergency stopping devices

第9.2.4款-紧急停止装置

Emergency stopping devices are designed to prevent accidental damage by preventing or stopping movements of ME EQUIPMENT parts. There could be more than one emergency stopping device on ME EQUIPMENT. ME EQUIPMENT can also include emergency off devices that are intended to disconnect all power to the installation. Emergency off devices are not subject to the requirements of this subclause unless they are also intended to provide the emergency stopping function. Emergency stopping devices could be only one part of the emergency switching function. 紧急停止装置旨在通过防止或停止医用电气设备部件的移动来防止意外损坏。医用电气设备上可能有多个紧急停止装置。医用电气设备还可包括用于断开装置所有电源的紧急关闭装置。紧急关闭装置不受本子条款要求的约束，除非它们也打算提供紧急停止功能。紧急停止装置只能是紧急切换功能的一部分。

Subclause 9.2.5 – Release of PATIENT

第9.2.5款-释放患者

This requirement takes account of the possible effect of a power interruption causing unwanted movements, and the likely need in that situation, for the removal of compression forces or the removal of PATIENTS from a hazardous position. 这一要求考虑了电源中断引起不必要移动的可能影响，以及在这种情况下可能需要消除压缩力或将患者从危险位置移开。

Subclause 9.3 – MECHANICAL HAZARD associated with surfaces, corners and edges

第9.3款-与表面、角落和边缘相关的机械危险

The RISK associated with a sharp edge depends upon the position of the sharp edge and the application of the ME EQUIPMENT. For this reason, compliance with this subclause is checked by inspection. In cases of doubt, the test for sharp edges described in UL 1439 [43], can be used as guidance.

与锐边相关的风险取决于锐边的位置和医用电气设备的应用。因此，通过检查检查是否符合本款的规定。如有疑问，可使用UL 1439[43]中描述的锐边测试作为指导。

This subclause applies for surfaces accessible during NORMAL USE. Care should be given to protecting SERVICE PERSONNEL, or other internal systems where damage could result in an unacceptable RISK (e.g. fluid systems).
本款适用于在正常使用期间可接触的表面。应注意保护维修人员或其他内部系统，如果损坏可能导致不可接受的风险（例如流体系统）。

Subclause 第9.4款-不稳定危害

9.4

-

Instability

HAZARDS

In NORMAL USE, many types of ME EQUIPMENT are exposed to a variety of conditions during transport (movement from room to room during NORMAL USE). While the requirements of this standard attempt to represent those that might be encountered, the RISK MANAGEMENT PROCESS should evaluate the conditions under which the ME EQUIPMENT is intended to be used and how those conditions might impact BASIC SAFETY or ESSENTIAL PERFORMANCE.

在正常使用中，许多类型的医用电气设备在运输过程中暴露在各种条件下（正常使用期间从一个房间移动到另一个房间）。虽然本标准的要求试图代表可能遇到的要求，但风险管理过程应评估医用电气设备的预期使用条件，以及这些条件对基本安全或基本性能的影响。

Where failure to remain stable during the performance of these tests could cause HARM to the OPERATOR, PATIENT and other persons (e.g. from crushing or falling); or result in the ME EQUIPMENT failing to meet the applicable BASIC SAFETY requirements of this standard (such as: exposing hazardous voltages, reducing CREEPAGE DISTANCES or AIR CLEARANCES or creating breaches in fire proof ENCLOSURES which are not clearly obvious) or causing a loss of ESSENTIAL PERFORMANCE, instability should be considered to result in an unacceptable RISK.
如果在进行这些试验期间未能保持稳定，可能会对操作员、病人和其他人造成伤害（例如，由于挤压或坠落）；或导致医用电气设备不符合本标准适用的基本安全要求（例如：暴露危险电压，减小爬电距离或空气间隙，或在防火外壳中造成不明显的缺口）或导致基本性能损失，应将不稳定性视为导致不可接受的风险。

All ME EQUIPMENT is tested for overbalance with 5° tip, 10° tip, and push in 9.4.2.1, 9.4.2.2, 9.4.2.3 a) and b). In 9.4.3.1 a), b) and c) and 9.4.3.2 a) and b), only MOBILE ME EQUIPMENT is tested as these are requirements for wheels and their brakes.
9.4.2.3 a) 和 b)。在 9.4.3.1 a)、b) 和 c) 以及 9.4.3.2 a) 和 b) 中，仅对移动式医用电气设备进行测试，因为这些是对车轮及其制动器的要求。

Subclause 9.4.2 – Instability – overbalance
第9.4.2款-不稳定性-失衡

As an aid to understanding, Table A.3 and Figure A.16 illustrate the logic behind the stability test requirements.
为了便于理解，表A.3和图A.16说明了稳定性试验要求背后的逻辑。

Table A.3 – Instability test conditions
表A.3-不稳定性试验条件

Transport warning 运输警告	Test plane angle 试验平面角	
	10° plane 10度平 面	5° plane 5度平 面
Transport warning not provided 未提供运输警告	Must pass in all positions 所有位置都必须通过	Not applicable (represented by 10° test) 不适用（用10°试验表 示）
Transport warning provided 提供运输警告	Must pass in transport position (only) Must pass in all positions except transport 必须在运输位置通过（仅 限）必须在除运输以外的 所有位置通过	Must pass in all positions except transport 必须通过除运输以外的所 有位置

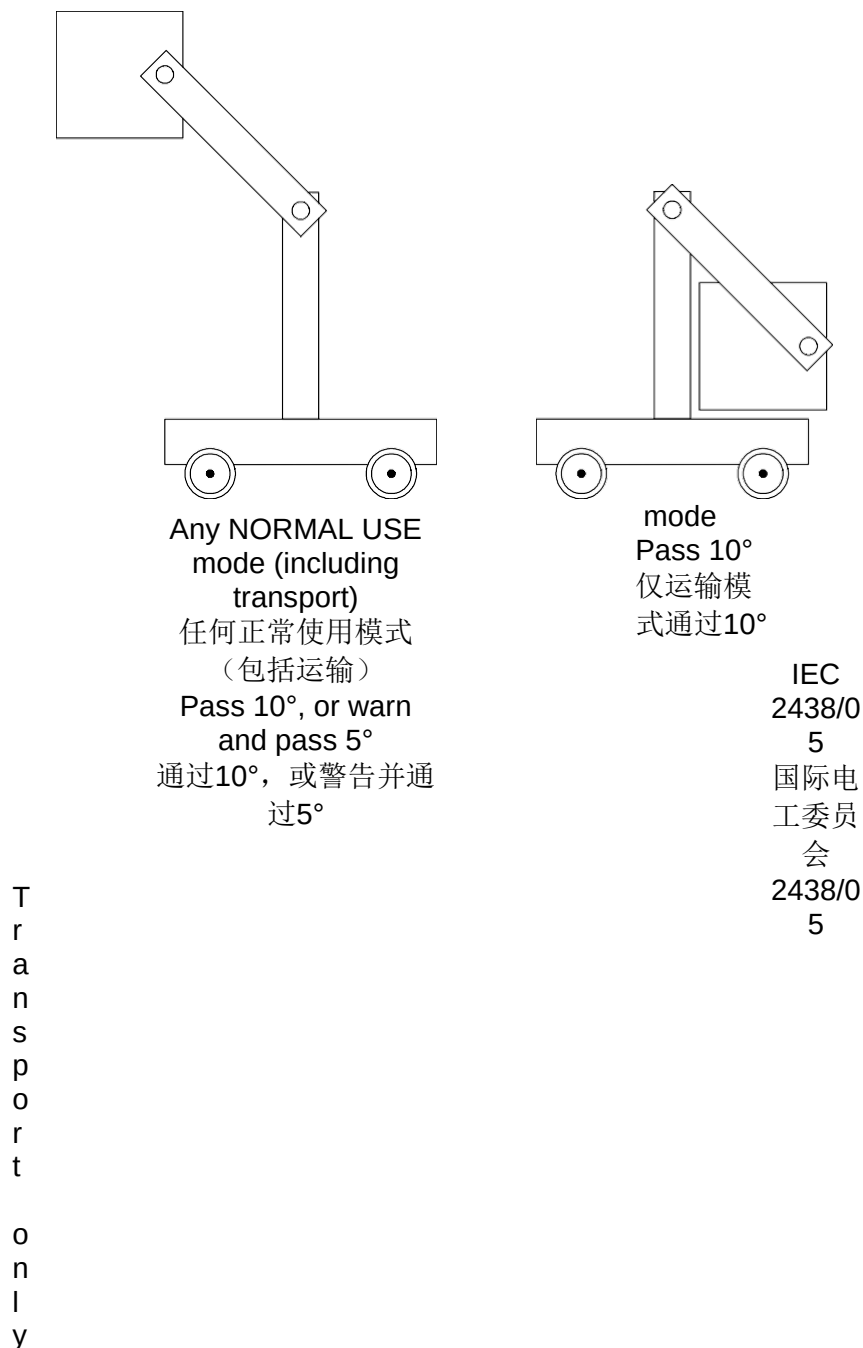


Figure A.16 – Instability test conditions
图A.16–不稳定性试验条件

Subclause 9.4.2.3 a)
第9.4.2.3 a) 款

The push force of 15 % of the ME EQUIPMENT'S weight or a maximum of 150 N was selected in order to represent foreseeable misuse for typical ME EQUIPMENT, based on input from ME EQUIPMENT MANUFACTURERS. The marking option for ME EQUIPMENT that overbalances with this push force is considered something that provides medical care benefit, and with the no- pushing marking the committee presumes that the RISK would be acceptable, but the MANUFACTURER needs to make this determination based on their own analysis, which might include usability studies, including the location of the marking.

根据医用电气设备制造商的输入，选择医用电气设备重量的15%或最大150 N的推力，以代表典型医用电气设备的可预见误用。医用电气设备的标记选项与此推力过度平衡被认为是提供医疗保健益处的选择，在无推力标记的情况下，委员会认为风险是可以接受的，但制造商需要根据其自身的分析（可能包括可用性研究）来确定，包括标记的位置。

Subclause 9.4.2.4 – Castors and wheels

第9.4.2.4款-脚轮和车轮

Compliance with this subclause is required not only to avoid obvious unacceptable RISK but also to ensure the substantially operative movement as an ESSENTIAL PERFORMANCE. For ME EQUIPMENT to be considered MOBILE, it must be able to be moved from room to room. MOBILE ME EQUIPMENT is defined as equipment intended to be moved from one location to another. 遵守本款要求不仅是为了避免明显的不可接受的风险，而且也是为了确保基本的操作动作作为一项基本性能。对于被认为是移动的医用电气设备，它必须能够从一个房间移动到另一个房间。移动式医用电气设备是指拟从一个位置移动到另一个位置的设备。

Subclause 9.4.2.4.3 – Movement over a threshold

第9.4.2.4.3款-超过阈值的移动

The 10 mm threshold height came from the thought that cables are represented by an 8 mm to 10 mm height. The committee felt that elevator alignment is now closer to 10 mm (e.g. 4 mm) rather than 20 mm. Normally, hospitals would not have door threshold. 10毫米的阈值高度来自于这样一种想法：电缆由8毫米到10毫米的高度来表示。委员会认为，电梯校准现在更接近10毫米（例如4毫米），而不是20毫米。一般情况下，医院不会有门槛。

The manual speed of 0,8 m/s was selected from an anticipated range of 0,4 m/s to 1,5 m/s during NORMAL USE, based on input from ME EQUIPMENT MANUFACTURERS. A speed of 0,8 m/s was felt to be the most representative of NORMAL USE and normal walking speed. There's a balance between too slow a speed such that the ME EQUIPMENT won't go over the threshold and too fast a speed causing the ME EQUIPMENT to become unstable. A single speed was selected for the test as this was felt to be necessary for reproducibility among testers. 根据医用电气设备制造商的输入，在正常使用期间，从0.4 m/s到1.5 m/s的预期范围内选择0.8 m/s的手动速度。0.8 m/s的速度被认为是最能代表正常使用和正常步行速度的速度。过慢的速度（使医用电气设备无法超过阈值）和过快的速度（导致医用电气设备不稳定）之间存在平衡。选择单一速度进行试验，因为这对于试验人员之间的再现性是必要的。

Some MOBILE ME EQUIPMENT is provided with castors for convenience but not as means to be wheeled across thresholds or similar obstacles. When the MANUFACTURER clearly indicates this use is not intended there should be no need for the threshold test. Examples of equipment that might not require a threshold test include trolleys and treatment tables that are fitted with castors to enable them to be moved easily aside for cleaning the floor or making space. 一些移动式医用电气设备配备有脚轮，以方便使用，但不是通过车轮通过门槛或类似障碍物的方式。如果制造商明确表示不打算使用，则无需进行阈值试验。可能不需要阈值测试的设备包括手推车和治疗台，这些设备装有脚轮，以便能够轻松地移动到一边，以便清洁地板或腾出空间。

Subclause 9.4.3 – Instability from unwanted lateral movement (including sliding)

第9.4.3款-不必要的横向移动（包括滑动）引起的不稳定性

The braking functional verification tests allow the braking system to be assessed with compliance giving the presumption of acceptable RISK. The test criteria assume that generally any initial elastic movement and subsequent movement up to 50 mm are acceptable. In accordance with 4.2, if these movements for a specific piece of ME EQUIPMENT and its INTENDED USE seem inappropriate, the RISK should be lowered with additional RISK CONTROL measures. 制动功能验证试验允许对制动系统进行合规性评估，并假定可接受的风险。试验标准假定，一般情况下，任何初始弹性移动和小于等于50 mm的后续移动都是可接受的。根据4.2的规定，如果医用电气设备的这些移动及其预期用途似乎不合适，则应采用额外的风险控制措施降低风险。

The braking push force of 15 % or the maximum of 150 N was selected in order to represent reasonably foreseeable misuse for typical ME EQUIPMENT based on input from ME EQUIPMENT MANUFACTURERS.

根据医用电气设备制造商的输入，选择15%或最大150 N的制动推力，以代表典型医用电气设备可合理预见的误用。

The intent of braking requirements is to provide a generic test for general ME EQUIPMENT. Thus compliance criteria are black and white. It is acknowledged that some slow unwanted movement of

low weight carts (low momentum), could be considered an acceptable RISK. 制动要求旨在为通用医用电气设备提供通用试验。因此，合规性标准是黑白的。众所周知，低重量手推车的一些缓慢的不必要的移动（低动力）可被视为可接受的风险。

It is accepted that for many carts with 4 wheels, providing 2 brakes is a reasonable RISK CONTROL measure to mitigate unwanted movement due to inadequate braking. Placing 4 brakes on many carts will not result in greater usage of the brakes, as some of the wheels will typically be pivoted out of reach.

公认的是，对于许多四轮手推车，提供2个制动器是一个合理的风险控制措施，以减轻由于制动不足而产生的不必要的移动。在许多手推车上放置4个制动器不会导致更多的制动器使用，因为一些车轮通常会旋转到无法触及的位置。

Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to test method, or test compliance criteria, with justification. 第4.5款始终适用，并允许制造商使用替代风险控制措施，或试验方法的变更，或试验合规性标准，并提供理由。

Subclause 9.4.3.1 c) – Instability in transport

第9.4.3.1 c) 款——运输不稳定性

The hard flat surface used in this test should reflect the worst case of INTENDED USE. Slippage of wheels against the hard flat surface is a secondary concern. If slippage is detected, it should be determined whether a more appropriate surface should be chosen for the test or the wheel material is inappropriate.

本试验中使用的硬平面应反映预期用途的最坏情况。车轮在坚硬的平面上打滑是次要问题。如果检测到打滑，则应确定是否应选择更合适的表面进行试验，还是车轮材料不合适。

Subclause

9.5

–

Expelled

parts

HAZARD

第9.5款-排出部件危险

Expelled parts are ME EQUIPMENT parts or fragments of ME EQUIPMENT parts, such as parts of a damaged vacuum display, a mechanical spring, a gas pressure cylinder, a rotating flywheel or an exploded lithium battery that could be expelled by collision, expansion etc. 排出零件是医用电气设备零件或医用电气设备零件的碎片，如损坏的真空显示器、机械弹簧、气压缸、旋转飞轮或爆炸的锂电池的零件，这些零件可能因碰撞、膨胀等而排出。

The degree of protection against “expelled parts” depends upon the probability of occurrence of HARM and the SEVERITY of HARM. Protective measures can include an ENCLOSURE, barrier, or electronic means (e.g. redundant means to prevent lithium battery charging current). 对“排出部件”的防护程度取决于损害发生的概率和危害的严重程度。保护措施可包括外壳、屏障或电子装置（例如，防止锂电池充电电流的冗余装置）。

Subclause

9.6.1

–

General

第9.6.1款-概述

Excessive noise can cause fatigue, interference with speech and acoustic signals, or even damage to hearing. Limits to prevent hearing damage are described in ISO standards. 过多的噪音会导致疲劳，干扰语音和声音信号，甚至损害听力。ISO标准中描述了防止听力损伤的限制。

In medically used rooms, much lower limits are needed for the comfort of PATIENTS and medical personnel. The actual effect of ME EQUIPMENT noise is strongly influenced by the acoustical properties of the room, the insulation between rooms and interaction of ME EQUIPMENT parts. 在医疗用房里，病人和医务人员的舒适度需要低得多的限制。医用电气设备噪声的实际效果很大程度上受房间的声学特性、房间之间的绝缘以及医用电气设备部件之间的相互作用的影响。

Excessive vibration will cause discomfort to the PATIENT, OPERATOR, and other persons. Prolonged exposure can cause vascular, neurological, or osteo-articular disorders. Excessive vibration can also cause damage to ME EQUIPMENT or a shift in calibration. 过度振动会对患者、操作员和其他人造成不适。长时接触可导致血管、神经或骨关节疾病。过度振动也可能导致医用电气设备损坏或校准偏移。

Most ME EQUIPMENT covered by this standard exposes the PATIENT and OPERATOR or other persons to negligible levels of noise and vibration. The RISK MANAGEMENT PROCESS should be able to clearly identify those cases where measurements are required. 本标准涵盖的大多数医用电气设备会使患者、操作员或其他人员受到可忽略的噪音和振动。风险管理过程应该能够清楚地识别需要度量的情况。

Subclause

9.6.2

–

Acoustic

energy

第9.6.2款-声能

These values are based on the potential for long term hearing impairment. The value usually used for regulatory purposes worldwide is currently 90 dBA with an offset of 5 dBA. However the latest research indicates a value of 85 dBA for 8 h over a 24 h period with an offset of 3 dBA when the time doubles or halves [34]. 这些数值基于长期听力损伤的可能性。全世界通常用于监管目的的值目前为90 dBA，偏移量为5 dBA。然而，最新研究表明，在24小时内，8小时的值为85 dBA，当时间加倍或减半时，偏移量为3 dBA[34]。

Although the criteria for judging whether a noise is considered impact noise is intentionally not provided, judgement should be used referring to the situation. Examples of impact noise include: the gradient noise of MRI equipment, and lithotripsy impulses. 虽然无意提供判断噪声是否被视为冲击噪声的标准，但应根据具体情况进行判断。撞击噪声的例子包括：MRI设备的梯度噪声和碎石术脉冲。

Subclause

9.6.3

–

Hand-transmitted

vibration

第9.6.3款-手传振动

Threshold values for vibration are much less clear than those for acoustic energy (noise). The value used here is from the Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents

(vibration) (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). It corresponds to about a 10 % incidence of blanching (indicative of neurological damage) after 8 years of regular exposure according to ISO 5349-1. It is more difficult to establish limit values for whole body vibration. Therefore this standard does not specify such limits. The end points such as back pain and other adverse health effects are not easily quantifiable, and so no agreed-upon exposure standards have been developed. Relevant information of this subject can be found in standards such as ISO 5805 [28], and ISO 8041 [29]. 振动的阈值远不如声能（噪声）的阈值清晰。此处使用的数值来自欧洲议会和理事会关于工人暴露于物理因素（振动）风险的最低健康和安全要求的指令（指令89/391/EEC第16（1）条含义内的第十六个单独指令）。根据ISO 5349-1，在8年的定期暴露后，约10%的白化发生率（表明神经损伤）。更难确定全身振动的极限值。因此，本标准未规定此类限值。诸如背痛和其他有害健康影响的终点不容易量化，因此还没有商定的接触标准。该主题的相关信息可在ISO 5805[28]和ISO 8041[29]等标准中找到。

When a person is exposed to various levels of acceleration over a 24 h period, allowable cumulative exposure can be determined as follows. Consider first Table A.4 of allowable time of exposure over a 24 h period for each level of acceleration. 当一个人在24小时内暴露于不同水平的加速度下时，允许的累积暴露量可按如下方法确定。考虑表A.4中每一级加速度下24小时允许暴露时间。

Table A.4 – Allowable time exposure for level of acceleration
表A.4——加速度水平的容许时间暴露

Allowable time of exposure over a 24 h period 24小时允许暴露时间 h h	Acceleration 加速度 m/s ² 米/秒 ²
1 1	7,07 7月7日
2 2	5,00 5.00美元
3 三	4,08 2008年4月
4 4	3,54 3,54个
5 5	3,16 3,16个
6 6	2,89 2,89个
7 7	2,67 2,67个
8 8	2,50 2,50个
9 9	2,36 2,36个
12 12	2,04 2004年2月
16 16	1,77 1,77个
24 24	1,44 1,44个

Some examples of allowable cumulative exposure are provided below.
下面提供了一些允许累积暴露的示例。

If a person were exposed to a 5 m/s² acceleration for 1 h (which represents 1/2 daily allowable exposure time for this acceleration), followed by an exposure to a 1,44 m/s² acceleration for 12 h (which represents 1/2 daily allowable exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.
如果一个人暴露在5 m/s²加速度下1 h（代表该加速度的1/2每日容许暴露时间），然后暴露于1,44 m/s²加速度下12 h（代表该加速度的每日容许暴露时间的1/2），则这将是24 h内可接受的累积暴露。

If a person were exposed to a 4,08 m/s² acceleration for 1 h (which represents 1/3 the allowable daily exposure time for this acceleration), followed by exposure to a 2,36 m/s² acceleration for 3 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 1,44 m/s² acceleration for 8 h (which represents 1/3 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.
如果一个人暴露于4,08 m/s²加速度下1 h（相当于该加速度的容许每日暴露时间的1/3），然后暴露于2,36 m/s²加速度下3 h（代表该加速度的每日容许暴露时间的1/3），然后暴露于1,44 m/s²的加速度加

速8小时（相当于该加速度允许的每日暴露时间的1/3），这是一个可接受的24小时内的累积暴露。

If a person were exposed to a 5 m/s² acceleration for 1 h (which represents 1/2 the allowable daily exposure time for this acceleration), followed by exposure to a 4.08 m/s² acceleration for 1 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 2.04 m/s² acceleration for 2 h (which represents 1/6 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period. 如果一个人暴露于5 m/s²加速度下1 h（相当于该加速度的容许每日暴露时间的1/2），然后暴露于4.08 m/s²加速度下1 h（代表该加速度容许每日暴露时间的1/3），然后暴露于2.04 m/s²的速度加速2小时（相当于该加速的1/6容许每日暴露时间），这是24小时内可接受的累积暴露。

To summarize, for each acceleration determine the fractional value of allowable daily exposure by dividing the actual exposure time for a given acceleration by the allowable daily exposure time for that acceleration. The sum of the fractional values for each acceleration is not to be greater than 1. 综上所述，对于每个加速度，通过将给定加速度的实际暴露时间除以该加速度的允许每日暴露时间，来确定容许每日暴露的分数值。每次加速度的分数总和不得大于1。

Subclause 9.7 – Pressure vessels and parts subject to pneumatic and hydraulic pressure

第9.7款-承受气压和液压压力的压力容器和零件

The requirements of this subclause do not represent the most stringent combination of national regulations or standards. 本款要求不代表国家法规或标准的最严格组合。

In some countries such regulations or standards apply. 在一些国家，此类法规或标准适用。

Type of systems considered include pneumatic pressure systems, hydraulic pressure systems, steam pressure systems and combinations thereof. These systems might or might not include pressure vessels.

考虑的系统类型包括气动压力系统、液压系统、蒸汽压力系统及其组合。这些系统可能包括也可能不包括压力容器。

HAZARDS

危害

a) Mechanical rupture or breakage (HARM: lacerations, puncture wounds)

机械破裂或破裂（伤害：裂伤、刺伤）

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this subclause, and remain unchanged.
 第二版第45条中关于该危害的要求已移至本款，并保持不变。

Requirements have been clarified to indicate that all parts have a MAXIMUM PERMISSIBLE WORKING PRESSURE not less than the pressure in NORMAL CONDITION or SINGLE FAULT CONDITION. In principal there should be a suitable safety factor between the MAXIMUM PERMISSIBLE WORKING PRESSURE and the bursting pressure, where the bursting pressure is the pressure at which a part suffers from permanent (plastic) deformation or leakage. Industry standards for pressure parts vary, but suitable safety factors are 3 □, 4 □, and sometimes 5 □ (ISO, ASME, SAE). As a suitable safety factor can vary, depending on factors associated with the end-use application and RISK, it was considered inappropriate to specify a minimum safety factor in the definition of MAXIMUM PERMISSIBLE WORKING PRESSURE, but instead leave this to the declaration of the MANUFACTURER of such part. It is assumed that MAXIMUM PERMISSIBLE WORKING PRESSURE declarations will be based on recognized international or national standards, and therefore below bursting pressures at least in line with the multiplication factor shown in Figure 32, (3 □, derated after 1 MPa to as low as 1,3 □ after 30 MPa).
 已澄清要求，以表明所有零件的最大允许工作压力不低于正常条件或单一故障条件下的压力。原则上，在最大允许工作压力和爆破压力之间应该有一个合适的安全系数，其中爆破压力是零件遭受永久（塑性）变形或泄漏的压力。压力部件的行业标准各不相同，但合适的安全系数是3×、4×，有时是5×（ISO、ASME、SAE）。由于适当的安全系数可能会根据与最终用途应用和风险相关的因素而变化，因此认为在最大允许工作压力的定义中规定最小安全系数是不合适的，而是由此类零件的制造商声明。假定最大允许工作压力声明将基于公认的国际或国家标准，因此至少低于爆破压力，符合图32所示的倍增系数（3倍，在1兆帕后降额至30兆帕后降至1.3倍）。

For pressure vessels exceeding both an energy limit (pressure □ volume) and a maximum pressure limit, the requirement is to conduct a hydrostatic overpressure test based on the MAXIMUM PERMISSIBLE WORKING PRESSURE declaration and the multiplication factor shown in Figure 32, (3 □, derated after 1 MPa to as low as 1,3 □ after 30 MPa).
 对于超过能量极限（压力×体积）和最大压力限值的压力容器，要求根据最大允许工作压力声明和图32所示的倍增系数（3×在1 MPa后减额至30 MPa后低至1.3×进行静水压试验）。

b) Mechanical loss of support (HARM: crush, puncture wounds)

机械失去支撑（危害：挤压、刺伤）

Requirements have been clarified to specify that components in a pressure system, such as those in a hydraulic lift system whose integrity is relied on to reduce the RISK from loss of support need to comply with the NORMAL CONDITION TENSILE SAFETY FACTORS specified in 已经澄清了要求，以规定压力系统中的部件，例如液压提升系统中的部件，其完整性是为了减少支架损失的风险，需要符合中规定的正常条件下的拉伸安全系数

9.8. The TENSILE SAFETY FACTOR is typically 4 □ for parts not impaired by wear, and 8 □ for parts impaired by wear (Case B). Thus parts subject to pressure whose failure could result in mechanical rupture and loss in support need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the higher of the SINGLE FAULT CONDITION pressure and the MANUFACTURER's declaration for each system component as specified in 9.7, or the NORMAL CONDITION pressure and the TENSILE SAFETY FACTOR as specified in 9.8.
 9.8条。拉伸安全系数通常为4倍（未受磨损影响的零件），8倍（磨损受损零件）（情况B）。因此，承受压力的零件（其故障可能导致机械破裂和支撑损失）需要具有最大允许工

作压力，该最大允许工作压力基于单个故障条件压力和制造商对每个系统部件的声明，如9.7所述，或9.8中规定的正常条件压力和拉伸安全系数。

c) Leakage of toxic gas or liquid (HARM: chemical or biological cell damage)

有毒气体或液体泄漏（危害：化学或生物细胞损伤）

The requirements from Clause 45 of the second edition dealing with this HAZARD have been moved to this clause, and remain unchanged.
第二版第45条中关于此危害的要求已移至本条，并保持不变。

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION

已澄清要求，以表明所有压力系统部件需要基于单一故障条件具有最大允许工作压力
pressure and the MANUFACTURER'S declaration for each system component.
每个系统部件的压力和制造商声明。

d) Leakage of flammable gas or liquid (HARM: fire causing burns or property damage)

易燃气体或液体泄漏（危害：引起烧伤或财产损失的火灾）

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this clause, and remain unchanged.
第二版第45条中关于此危害的要求已移至本条，并保持不变。

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION

已澄清要求，以表明所有压力系统部件需要基于单一故障条件具有最大允许工作压力
pressure and MANUFACTURER'S declaration each system component.
每个系统部件的压力和制造商声明。

Subclause 9.7.5 – Pressure vessels

第9.7.5款-压力容器

The Oxford dictionary defines a pressure vessel as “a to at ” This is the usage intended by this standard.

牛津词典将压力容器定义为“a to at”，这是本标准的用途。

It is assumed that a hydraulic test is not necessary if the pressure is less than or equal to 50 kPa or the product of the pressure and volume is less than or equal to 200 kPa □ l. 假设压力小于或等于50 kPa或压力与体积的乘积小于或等于200 kPa□l，则无需进行液压试验。

The safety factors implied by Figure 32 are higher than those generally applied in testing pressure vessels. However, whereas hydraulic testing is normally used to verify that a pressure vessel is free from production faults or serious deterioration, the adequacy of the design being determined in other ways, the present hydraulic test is intended to verify the adequacy of a design where this cannot be established in other ways.

图32所示的安全系数高于压力容器试验中通常采用的安全系数。然而，液压试验通常用于验证压力容器是否存在生产故障或严重劣化，而设计的充分性则通过其他方式确定，而目前的水压试验旨在验证设计的充分性，而这种设计无法通过其他方式确定。

The deletion of national references in the amended text avoids subordinating the requirements of the standard to those of local regulations. The ME EQUIPMENT will sometimes have to satisfy both, or the more demanding, assuming that there are no local regulations that conflict with this standard. 修改后的文本中删除了国家参考文献，避免了将本标准的要求从属于地方法规的要求。如果没有与本标准冲突的地方法规，医用电气设备有时必须同时满足这两个或更高要求。

A hydraulic test is specified even for pneumatic vessels, as this is safer for the tester. In achieving the test pressure with a gas, the gas will compress, resulting in more stored energy in the test vessel than would a hydraulic test method. Both methods result in the same test pressure, which is the objective of the test. 甚至对气动容器也规定了水压试验，因为这对试验人员更安全。在用气体达到试验压力时，气体将被压缩，从而在试验容器中产生比液压试验方法更多的储能。两种方法产生相同的试验压力，这是试验的目的。

Subclause 9.8 – MECHANICAL HAZARDS associated with support systems

第9.8款-与支撑系统相关的机械危险

The term “support” is taken to include “suspension” and loads can include PATIENTS, OPERATORS and other masses.

术语“支撑”包括“悬吊”，荷载可包括患者、操作员和其他群众。

Support systems can broadly be categorized as follows.

支持系统大致可分为以下几类。

- A suspension system is one that contains flexing or rigid elements that are designed to suspend masses, including PATIENTS and OPERATORS during NORMAL USE.
悬挂系统是一种包含柔性或刚性元件的系统，设计用于在正常使用过程中悬挂患者和操作人员等重物。
- Flexing elements include ropes, cables, chains, belts, bands and springs. Additionally a jack screw nut is considered impaired by wear to the extent needing a higher TENSILE SAFETY FACTOR.
弯曲元件包括绳索、电缆、链条、皮带、带和弹簧。此外，千斤顶螺丝螺母被认为因磨损而受损，需要更高的拉伸安全系数。
- An actuating system is one that contains elements such as electric, pneumatic or hydraulic actuators, motors, gearboxes, shafts, bearings, pulleys, sheaves, band wheels and guides.
执行系统是包含诸如电动、气动或液压执行机构、电机、齿轮箱、轴、轴承、滑轮、滑轮、带轮和导轨等元件的系统。
- A support structure is generally a rigid device that can be static or moving and which

supports ME EQUIPMENT, external loads and, where necessary, PATIENTS and OPERATORS.

支撑结构通常是一种刚性装置，可以是静态的或移动的，它支撑医用电气设备、外部荷载，必要时还可以支撑病人和操作员。

Subclause 9.8.2 – TENSILE SAFETY FACTOR

第9.8.2款-拉伸安全系数

TENSILE SAFETY FACTORS are applied to provide a margin of safety to the design after all reasonable allowances for operating conditions, material and manufacturing variables, etc., have been made.

拉伸安全系数用于在对操作条件、材料和制造变量等进行了所有合理的容差后，为设计提供安全裕度。

In determining whether case A or B is to be used from Table 21, certainty of material strength is required in order to apply case A values. Additionally there needs to be confidence in the determination of TOTAL LOAD in order to apply case A values. TOTAL LOAD is constituted from “static force” and “dynamic force” components. The static force is normally clear. But the dynamic force/loading is sometimes uncertain. When the dynamic forces are known as well as static forces, the TENSILE SAFETY FACTOR is determined with case A. When the dynamic forces are not clear, and the static forces are known, the TENSILE SAFETY FACTOR is determined with case B. 在确定是否使用表21中的情况A或B时，需要确定材料强度，以应用情况A的值。此外，为了应用案例A的值，需要确定总荷载的置信度。总荷载由“静力”和“动力”组成。静态力通常是透明的。但动力/载荷有时是不确定的。当动态力和静态力已知时，拉伸安全系数用情况A确定。当动态力不明确且静态力已知时，使用情况B确定拉伸安全系数。

External forces for PATIENT supports can include those generated by application of CPR, etc. 病人支撑的外力可以包括心肺复苏术等产生的外力。

Elongation at break of 5 % is based on historical experience with metallic materials, in particular steel and cast iron. Materials with elongation at break less than 5 % are considered brittle and their failure is likely catastrophic, and therefore a higher safety factor is considered appropriate. 5%的断裂伸长率基于金属材料的历史经验，尤其是钢和铸铁。断裂伸长率小于5%的材料被视为脆性材料，其失效很可能是灾难性的，因此，更高的安全系数被认为是适当的。

For

non-metallic

materials:

对于非金属材料:

- Where no other experience exists, and where failure mode is likely catastrophic, this elongation factor is considered appropriate, and therefore a higher TENSILE SAFETY FACTOR is considered appropriate. 如果不存在其他经验，并且故障模式可能是灾难性的，则认为该延伸系数是适当的，因此更高的拉伸安全系数被认为是适当的。
- Where experience and testing show otherwise, an elongation at break of less than 5 % can be appropriate before a higher TENSILE SAFETY FACTOR is justified. 如果经验和试验表明，在证明较高的拉伸安全系数之前，小于5%的断裂伸长率是合适的。

For example, PATIENT tables of X-ray/CT/MR systems are often designed with plastic materials laminated or reinforced by carbon fibres/cloths or glass fibres/cloths, since these PATIENT tables must be optimised for low absorption of X-ray radiation (aluminium equivalence), MR compatibility (low proton signal), as well as structural stability. Although these plastic materials reinforced by carbon fibres/cloths can have elongation at break of less than 5 %, many years knowledge, acquired expertise, and post-market surveillance can provide sufficient evidence that suitable structural stability of PATIENT tables is achieved by applying a TENSILE SAFETY FACTOR from Table 21, Situation 1 (rather than Situation 2). 例如，X射线/CT/MR系统的病人检查床通常采用由碳纤维/布或玻璃纤维/布层压或加固的塑料材料设计，因为这些病人检查床必须针对X射线辐射的低吸收率（铝当量）、磁共振兼容性（低质子信号）以及结构稳定性进行优化。虽然这些由碳纤维/布加固的塑料材料的断裂伸长率小于5%，但多年的知识、获得的专业知识和上市后的监督可以提供充分的证据，证明通过应用表21中的拉伸安全系数，可以实现患者检查床的适当结构稳定性，情况1（而不是情况2）。

At end of life or periodic maintenance cycle, ME EQUIPMENT needs to maintain structural integrity. Line 1 of Table 21 is normally appropriate for end of life or the end of the periodic maintenance cycle since wear is no longer considered. 在使用寿命或定期维护周期结束时，医用电气设备需要保持结构完整性。表21的第1行通常适用于寿命终止或定期维护周期结束，因为不再考虑磨损。

Suspension and actuating systems have TENSILE SAFETY FACTORS that are necessarily high to reduce the effects of deterioration through wear and fatigue. 悬架和执行系统的拉伸安全系数必须很高，以减少磨损和疲劳引起的劣化影响。

Particular attention should be given to the fixing of structures to floors, ceilings, etc. that are subject to variable TENSILE SAFETY FACTORS. 应特别注意将结构固定到受可变拉伸安全系数影响的地板、天花板等上。

A hidden defect is one that is not revealed during manufacture, service or normal operation of the ME EQUIPMENT but that could cause failure of a part that could result in a HAZARD. Examples are high internal stresses in heat-treated parts such as springs, broken strands of wire inside castings. 隐藏缺陷是指在医用电气设备的制造、维修或正常运行过程中未发现的缺陷，但可能导致部件故障，从而导致危险。例如热处理零件的高内应力，如弹簧、电缆内部的断股和铸件内部的孔隙。

Figure A.17 contains an example of determining the appropriate TENSILE SAFETY FACTOR using Table 21. Figure A.18 contains an example of determining design and test loads. These examples are not intended to cover all possible cases. For a particular design, these TENSILE SAFETY FACTORS and design/test loads can vary according to the materials used, their wear characteristics, loading conditions, etc. 图A.17包含使用表21确定适当拉伸安全系数的示例。图A.18包含确定设计和试验荷载的示例。这些例子并不打算涵盖所有可能的情况。对于特定设计，这些拉伸安全系数和设计/试验荷载可根据所用材料、其磨损特性、荷载条件等而变化。

This subclause focuses on safety factors as the suggested approach to have confidence that the equipment will maintain structural integrity during its EXPECTED SERVICE LIFE. In some cases the specified safety factors are more than needed, and in some cases even larger factors could be considered appropriate. The compliance criteria can be satisfied by RISK MANAGEMENT rather than by the use of the safety factor route. For new materials or for structures with sophisticated monitoring of stresses, the safety factors might not be necessary. 本款侧重于安全系数，作为建议的方法，以确保设备在其预期使用寿命内保持结构完整性。在某些情况下，规定的安全系数超过需要，在某些情况下，甚至更大的安全系数也可以被认为是适当的。合规性标准可以通过风险管理而不是通过使用安全系数路径来满足。对于新材料或具有复杂应力监测的结构，安全系数可能不需要。

If it is deemed that the failure mode of the part does not result in an unacceptable RISK, the TENSILE SAFETY FACTORS specified in Table 21 do not apply. For example, for proprietary components such as bearings it is acceptable to rely on the component MANUFACTURER'S data for load and life expectancy without applying a TENSILE SAFETY FACTOR. 如果认为零件的失效模式不会导致不可接受的风险，则表21中规定的拉伸安全系数不适用。例如，对于轴承等专有部件，可以在不应用拉伸安全系数的情况下依赖部件制造商的载荷和预期寿命数据。

A jack screw nut considered impaired by wear is usually intentionally constructed from a material softer than the jack screw. The intent is to have generic requirement provided for general ME EQUIPMENT.

由于磨损而受损的千斤顶螺丝螺母通常是故意用比千斤顶螺丝更软的材料制成的。目的是为通用医用电气设备提供通用要求。

Newer jack screw designs can have less friction than traditional designs, and, for example, can include multiple ball bearings. Such designs can be considered as less "impaired by wear" as dictated by vendor declarations and a MANUFACTURER'S RISK ASSESSMENT. 较新的千斤顶螺丝设计比传统设计的摩擦力更小，例如，可以包括多个滚珠轴承。根据供应商声明和制造商的风险评估，此类设计可被视为“磨损受损”程度较低。

Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to a test method or test compliance criteria, with justification. 第4.5款始终适用，并允许制造商使用替代风险控制措施，或对试验方法或试验合规性标准的变更，并说明理由。

Subclause 9.8.3 – Strength of PATIENT or OPERATOR support or suspension systems 第9.8.3款-患者或操作员支撑或悬挂系统的强度

This subclause deals with forces applied on support or suspension parts of ME EQUIPMENT, intended to support or suspend the mass of a human body or part of the mass of a human body, and to ACCESSORIES used on such support or suspension parts. For adult PATIENTS or OPERATORS the 135 kg mass represent the 99 percentile of the population. For specific populations, higher mass or lower mass can be used (e.g. heavy person or paediatric application). 本款涉及医用电气设备支撑或悬挂部件上施加的力，用于支撑或悬挂人体或人体的一部分，以及用于此类支撑或悬挂部件上的附件。对于成人患者或操作员，135 kg的质量代表99%的人群。对于特定人群，可使用较高质量或较低质量（例如，重型人或儿科应用）。

Pulley wheel shaft, elongation >5 % 滑轮轮轴，伸长率>5% SF = 2,5 (case 1A) or B SF = 4 (case 1B) SF=2,5（情况1A）或B SF=4（情况1B）	g. safety catch) （例如安全锁销） C SF = 2,5 (case 7A) or C SF=2,5（情况7A）或 SF = 4 (case 7B) SF=4（案例7B）	
Cable with MECHANICAL PROTECTIVE DEVICE (item C) 带机械保护装置 的电缆（C项） SF = 2,5 (case 5A) or SF=2,5（情况5A）或A SF = 4 (case 5B) SF=4（案例5B）	Casting not impaired by wear, elongation <5 % D No MECHANICAL PROTECTIVE DEVICE 铸件不受磨损影响，伸长率 <5%D无机械保护装置 SF=4（情况2A）或 SF = 6 (case 2B) SF=6（案例2B） Movement 运动	
MECHANICAL PROTECTIVE DEVICE 机械保护装置 (		
Fixing, elongation >5 % 固定，伸长率>5% SF = 2,5 (case 1A) or F SF = 4 (case 1B)		PATIENT support 病人支持 SF=2,5（情况1A）或F SF=4（情况1B）

Movement

Jack screw nut, no MECHANICAL
PROTECTIVE DEVICE
千斤顶螺丝螺母，无机械保护装置
SF = 5 (case 3A) or
E
SF=5（情况3A）或E
SF = 8
(case 3B)
SF=8（案
例3B）

IEC 2439/05
国际电工委员会
2439/05

Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21
图A.17——使用表21确定拉伸安全系数的示例

	Structure 结构	
Weight W2 重量W2	2,5 (case 1A), design/test load = 2,5 □ (W1 + W2); or SF = 4 (case 1B), design/test load = 4 (W1 + W2) SF=2,5（情况1A），设计/试验荷载=2,5× （W1+W2）；或SF=4（工况1B），设计/ 试验荷载=4（W1+W2）	
	Support part (cable) impaired by wear, no 支撑件（电缆）磨损受损，无 MECHANICAL PROTECTIVE DEVICE 机械保护装置 TOTAL LOAD = 0,5 □ W1 总荷载=0.5×W1	
Weight W1 重量W1	SF = 5 (case 3A), design/test load = 5 □ 0,5 □ W1 or SF = 8 (case 3B), design/test load = 8 □ 0,5 □ W1 SF=5（情况3A），设计/试验荷载 =5×0,5×W1或SF=8（情况3B），设计/ 试验荷载=8×0,5×W1	
Support part (bolt) not impaired by wear, no 支撑件（螺栓） 无磨损损坏，无 MECHANICAL PROTECTIVE DEVICE 机械保护装置 TOTAL LOAD = W1 + W2 总荷载=W1+W2	Movement 运动	
S F =		IEC 2440/05 IEC 2440/05标准

NOTE TOTAL LOAD is shown based on only static forces to obtain actual total loads, dynamic forces also need to be included.

注：总荷载仅基于静态力显示，以获得实际总荷载，还需要包括动态力。

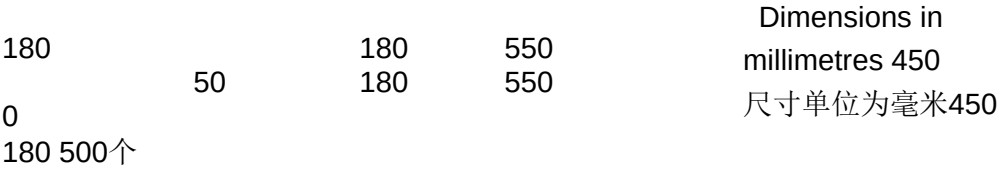
Figure A.18 – Example of determining design and test loads

Subclause 9.8.3.2 – Static forces due to loading from persons

图A.18——确定设计和试验荷载的示例——第9.8.3.2款——由人员荷载引起的静力

Figure A.19 contains an example of human body mass distribution for PATIENT support surfaces.

图A.19包含了患者支撑表面的人体质量分布示例。



IEC 2441/05
IEC 2441/05标准

Figure A.19 – Example of human body mass distribution
图A.19——人体质量分布示例

The distribution mass of a body diagram is an average distribution based on anthropometrical data.
Due to the variety of population or specific categories of age, it can vary. For sedentary
人体图的分布质量是基于人体测量数据的平均分布。由于人口的多样性或特定的年龄类别，它可能会
有所不同。久坐

people not having a physical activity the mass of the upper part of the body can represent a more important percentage.

上半身的一个重要部分不能代表一个更重要的部分的身体活动。

The variety of ME EQUIPMENT does not allow more precision to be given in this general standard. It is up to the particular standard to define more adequately the distribution area or the worst-case position, rather than dynamic tests. 医用电气设备的多样性不允许在本通用标准中给出更高的精度。根据特定标准，更充分地定义分布区域或最坏情况位置，而不是动态测试。

A foot rest is tested for twice its normal load, rather than a load based on a TENSILE SAFETY FACTOR value from Table 21, as it is intended to support a PATIENT'S weight for only a short duration of time.

脚踏板的测试负荷是正常负荷的两倍，而不是基于表21中的拉伸安全系数值的负荷，因为它只打算在短时间内支撑患者的体重。

The test with a mass of 80 kg placed 60 mm from the outer edge is intended to simulate the centre of gravity of a PATIENT sitting or leaning on the edge of a support surface. 在距离外边缘60 mm处放置80 kg质量的试验旨在模拟患者坐在或靠在支撑面边缘上的重心。

During the static loading tests, it's intended that any temporary elastic deflection (during the test), and permanent plastic deflection (after the test) are checked for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE.

静载试验期间，应检查任何临时弹性挠度（试验期间）和永久塑性挠度（试验后）是否对基本安全或基本性能产生不利影响。

For the step loading test, the committee felt that a 5° deflection would provide a measurable quantity that would represent a reasonable limit for acceptance. The 2X loading factor is a precedent from the 2nd edition of IEC 60601-1, and seems to recognize the temporary loading that steps represent during their life.

对于阶跃荷载试验，委员会认为5°挠度将提供一个可测量的量，代表验收的合理限制。2X荷载系数是IEC 60601-1第2版的先例，似乎认识到台阶在其寿命期间所代表的临时荷载。

For the sitting surface loading test, no specific linear or arc limits are specified. The intent is to evaluate any temporary elastic or permanent plastic deflections for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE. The 60 % sitting loading factor was considered representative of actual sitting load, when legs are dangling off the edge of the sitting surface. Loss of function is not considered unacceptable unless associated with ESSENTIAL PERFORMANCE. The intent is damage should not result in injury to persons, or loss of RISK CONTROL measures. Surfaces that are intended to support sitting and at other times full patient loads are also evaluated for compliance with the appropriate loading factor(s) in 9.8.2. 对于坐面载荷试验，未规定具体的线性或弧限值。其目的是评估任何临时弹性或永久塑性变形对基本安全或基本性能的任何不利影响。当腿悬垂在坐面边缘时，60%的坐姿载荷系数被认为代表实际的坐姿载荷。除非与基本性能有关，否则不认为功能丧失是不可接受的。其目的是损害不应导致人身伤害，或丧失风险控制措施。还应评估用于支撑坐位和其他时候患者满载的表面是否符合9.8.2中的适当荷载系数。

Subclause 9.8.3.3 – Dynamic forces due to loading from persons 第9.8.3.3款-人员荷载引起的动力

A general dynamic test is defined which represents common situations represented by a person sitting down or standing up. 一般动态测试是指一个人坐下来或站起来所代表的常见情况。

The requirement of this subclause is intended to apply to the chairs for dental surgical procedures, X-ray tables, and many other similar types of ME EQUIPMENT. The ME EQUIPMENT should be in all operating modes and positions where dynamic loads from PATIENTS can be reasonably expected. For example, when a PATIENT table is positioned in an area of a CAT or magnet structure, the dynamic test is not applicable as the dynamic loading caused by a PATIENT is negligible. 本款要求适用于牙科手术椅、X光检查床和许多其他类似类型的医用电气设备。医用电气设备应处于所有操作模式和位置，以合理预期患者的动态负载。例如，当病人检查床放置在猫或磁铁结构的某个区域时，动态测试不适用，因为病人引起的动态载荷可以忽略不计。

ME EQUIPMENT should be designed to bear a repeating force, by considering appropriate TENSILE SAFETY FACTORS and the results of fatigue calculations. TENSILE SAFETY FACTORS exist to show the reliability of the equipment without real testing. 医用电气设备的设计应考虑适当的拉伸安全系数和疲劳计算结果，以承受重复力。拉伸安全系数的存在表明设备的可靠性，而无需进行实际测试。

The bottom portion of the human body test mass apparatus shown in Figure 33 is foam, and should simulate contact by the relevant PATIENT part. 图33所示人体试验质量装置的底部是泡沫，应模拟与患者相关部位的接触。

Subclause 9.8.4 – Systems with MECHANICAL PROTECTIVE DEVICES
第9.8.4款-带机械保护装置的系统

The intent of a MECHANICAL PROTECTIVE DEVICE is to act to prevent HARM in the event of the failure of the primary support means that is subject to wear. The failure of the primary support means subject to wear is considered a SINGLE FAULT CONDITION if it has a TENSILE SAFETY FACTOR in accordance with Table 21, rows 5 and 6. To protect against HARM in this SINGLE FAULT CONDITION, the MECHANICAL PROTECTIVE DEVICE acts as a backup, and needs to have the TENSILE SAFETY FACTOR indicated in Table 21, Row 7. It is considered good engineering practice to construct a MECHANICAL PROTECTIVE DEVICE from non-brittle materials, and therefore Row 7 does not include an elongation column.

机械保护装置的目的是在主支撑装置发生磨损时防止损坏。根据表21第5行和第6行，如果主支撑装置的拉伸安全系数符合表21第5和第6行的要求，则将其视为单一故障状态。为防止在这种单一故障条件下受到伤害，机械保护装置作为备用装置，需要具有表21第7行所示的拉伸安全系数。从非脆性材料构造机械保护装置被认为是良好的工程实践，因此第7行不包括伸长柱。

To test a MECHANICAL PROTECTIVE DEVICE, the primary support means subject to wear needs to be defeated. For example if the primary support system is a cable, the cable would be cut. 为了测试一个机械保护装置，需要破坏易磨损的主要支撑装置。例如，如果主支撑系统是电缆，则电缆将被切断。

Clause 10 – Protection against unwanted and excessive radiation HAZARDS **第10条-防止有害和过度辐射危害**

Radiation from ME EQUIPMENT can occur in all forms known in physics. BASIC SAFETY requirements are concerned with unwanted radiation. Protective measures are necessary for ME EQUIPMENT and for the environment and methods for determining levels of radiation need to be standardized.

医用电气设备的辐射可以以物理已知的所有形式出现。基本安全要求与有害辐射有关。医用电气设备和环境必须采取防护措施，确定辐射水平的方法需要标准化。

This clause is intended to deal with stray radiation (such as scattered radiation from radiological equipment) and incidental radiation (such as X-ray emitted by CRTs). A requirement for unintended or excessive output of radiation that ME EQUIPMENT is intended to deliver to the PATIENT is covered in 12.4.5.

本条款旨在处理杂散辐射（如辐射设备的散射辐射）和附带辐射（如CRT发射的X射线）。12.4.5中涵盖了医用电气设备向患者提供的意外或过量辐射输出的要求。

For ionizing radiation IEC requirements generally comply with the International Commission for Radiation Protection (ICRP) Recommendations. Their purpose is to provide data that are immediately usable by designer and RESPONSIBLE ORGANIZATION. 对于电离辐射，IEC的要求一般符合国际辐射防护委员会（ICRP）的建议。它们的目的是提供设计人员和责任组织可以立即使用的数据。

Their evaluation is possible only by adequate study of operating methods and duration of operation of ME EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations that might hamper proper diagnosis or treatment. 只有充分研究医用电气设备的操作方法和持续时间，以及操作员和助手的位置，才能对其进行评估，因为最坏情况下的情况会导致可能妨碍正确诊断或治疗的情况。

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

最近的ICRP出版物也指导操作者如何限制有意辐射。

Subclause 10.1.1 – ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation

第10.1.1款-医用电气设备不用于产生诊断或治疗性X射线

Spurious X-radiation from components such as Video Display Units (VDU) is a potential source of concern for ME EQUIPMENT, many of which contain VDUs. Annex H of IEC 60950-1:2001 contains a well-accepted PROCEDURE for measuring such spurious emissions for information technology equipment. The limits in that annex are based on ICRP 60 [39]. The requirements from Annex H of IEC 60950-1:2001 were incorporated into the body of this standard because this was the only normative reference that required the use of IEC 60950-1. 来自视频显示单元（VDU）等部件的虚假X射线是医用电气设备的一个潜在问题，其中许多设备包含VDU。IEC 60950-1:2001的附录H包含了一个公认的测量信息技术设备杂散发射的程序。该附件中的限额是根据ICRP 60[39]确定的。IEC 60950-1:2001附录H中的要求包含在本标准正文中，因为这是要求使用IEC 60950-1的唯一规范性参考。

Other normative references to IEC 60950-1 are alternative means of addressing items such as CREEPAGE DISTANCE and AIR CLEARANCE. A user of this standard does not have to reference 60950-1 unless they wish to use the insulation coordination methods contain in that document. IEC 60950-1的其他规范性引用是解决爬电距离和空气间隙等项目的替代方法。本标准的用户无需参考60950-1，除非他们希望使用该文件中包含的绝缘配合方法。

第10.3款-微波辐射

This subclause specifies a microwave power density limit to mitigate thermal harm to whole body tissue. The intention is that compliance might be appropriately determined with engineering judgement, in lieu of testing, when it's obvious that emissions are nowhere near the 10 W/m² power density limit. Knowledge about equipment transmission specifications and engineering judgement might be used to determine compliance. The safety threshold of 10 W/m² greatly exceeds that allowed for wireless communication uses, where SAR (W/kg) limits are applicable. For example, equipment with microprocessor clock oscillators or intentional transmission radios such as Wi-Fi™, Bluetooth®, GPS, or cellular would comply with this threshold since these meet more stringent limits for their applicable bandwidth. When this confidence does not exist, appropriate power density measurements should be conducted.

本款规定了微波功率密度限制，以减轻对全身组织的热伤害。其目的是，当很明显排放量远未接近10 W/m²功率密度限值时，可通过工程判断适当确定合规性，而不是进行试验。有关设备传输规范和工程判断的知识可用于确定合规性。10 W/m²的安全阈值大大超过了无线通信应用的安全阈值，其中SAR（W/kg）限制适用。例如，带有微处理器时钟振荡器或有意传输无线电（如Wi-Fi）的设备™、Bluetooth®、GPS或cellular将符合此阈值，因为这些设备满足更严格的适用带宽限制。当不存在这种置信度时，应进行适当的功率密度测量。

Subclause 10.4 – Lasers and light emitting diodes (LEDs) 第10.4款-激光器和发光二极管（LED）

A dated reference to IEC 60825-1 was used because at the time of publication of this standard IEC/TC 76 was in the early stages of developing a third edition of IEC 60825-1 and was considering removing the requirements for LEDs from IEC 60825-1. 使用了注明日期的IEC 60825-1参考文件，因为在本标准出版时，IEC/TC 76处于制定第三版IEC 60825-1的早期阶段，并且正在考虑从IEC 60825-1中删除对LED的要求。

IEC 60825-1 is applicable to safety of laser products emitting laser radiation in the wavelength range 180 nm to 1 mm. A laser product can consist of a single laser with or without a separate power supply or it can incorporate one or more lasers in a complex optical, electrical, or mechanical system. IEC 60825-1适用于在180 nm至1 mm波长范围内发射激光辐射的激光产品的安全性。一个激光产品可以由一个有或没有单独电源的激光器组成，也可以在一个复杂的光学、电气或机械系统中包含一个或多个激光器。

Any laser product is exempt from all further requirements of IEC 60825-1 if classification by the manufacturer of that product according to Clauses 3, 8 and 9 of IEC 60825-1 shows that the emission level does not exceed the AEL (Accessible Emission Limit) of Class 1 under all conditions of operation, maintenance, service and failure. 如果制造商根据IEC 60825-1第3、8和9条对任何激光产品进行分类，表明在所有操作、维护、维修和故障条件下，激光产品的发射水平不超过1级AEL（可接近发射限值），则该产品不受IEC 60825-1的所有进一步要求的约束。

In previous editions of IEC 60825-1, LEDs were included in the scope of that standard, and they can be still included in other parts of the IEC 60825 series. However, with the development of lamp safety standards, optical radiation safety of LEDs in general can be more appropriately addressed by lamp safety standards. The removal of LEDs from the scope of IEC 60825-1 does not preclude other standards from including LEDs whenever they refer to lasers. IEC 62471 can be applied to determine the risk group class of an LED or product incorporating one or more LEDs. 在iec60825-1的以前版本中，led被包括在该标准的范围内，并且它们仍然可以包括在iec60825系列的其他部分中。然而，在安全性方面，LED灯的安全性可以通过更一般的安全标准来解决。从IEC 60825-1的范围中删除LED并不排除其他标准在提及激光器时将其包括在内。IEC 62471可用于确定LED或包含一个或多个LED的产品的风险组等级。

IEC 62471 gives guidance for evaluating the photobiological safety of lamps and lamp systems including luminaires. Specifically, it specifies the exposure limits, reference measurement technique and classification scheme for the evaluation and control of photobiological hazards from all electrically powered incoherent broadband sources of optical radiation, including LEDs but excluding lasers, in the wavelength range from 200 nm through 3 000 nm. IEC 62471 was originally prepared as Standard CIE S 009:2002 by the International Commission on Illumination. IEC 62471给出了评估灯和灯系统（包括灯具）光生物安全性的指南。具体而言，本标准规定了用于评估和控制波长范围为200 nm至3000 nm的所有电力非相干宽带光辐射源（包括LED但不包括激光器）的光生物危害的暴露限值、参考测量技术和分类方案。IEC 62471最初是由国际照明委员会作为标准CIE S 009:2002编制的。

Subclause 11.1 – Excessive temperatures in ME EQUIPMENT

第11.1款-医用电气设备温度过高

Temperature limits are required to prevent HAZARDS HAZARDOUS SITUATIONS for almost all types of ME EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where ME EQUIPMENT is touched or manipulated, or injuries where PATIENTS could contact ME EQUIPMENT parts. 几乎所有类型的医用电气设备都需要温度限值，以防止在接触或操作医用电气设备时绝缘层快速老化和不适，或防止患者可能接触医用电气设备部件造成伤害。

ME EQUIPMENT parts might be inserted into body cavities, usually temporarily but sometimes permanently.

医用电气设备部件可能会被插入体腔，通常是暂时的，但有时是永久性的。

For PATIENT contact, special temperature limits have been set.

对于病人接触，设置了特殊的温度限制。

Subclause 11.1.1 – Maximum temperature during NORMAL USE

第11.1.1款-正常使用期间的最高温度

Table 22 addresses limits for parts that could affect compliance of the ME EQUIPMENT with this standard in general (e.g. electrical BASIC SAFETY).

表22给出了可能影响医用电气设备符合本标准的部件限值（例如电气基本安全）。

It is not intended that the ME EQUIPMENT parts be tested in every possible configuration of NORMAL USE as long as the MANUFACTURER can determine the worst-case conditions. The “worst case” will almost always include the highest allowable ambient temperature and operation of the ME EQUIPMENT at the maximum DUTY CYCLE, but other specific aspects of the configuration of the ME EQUIPMENT (such as attachment of ACCESSORIES) should be determined by the MANUFACTURER based on a thorough understanding of the ME EQUIPMENT'S design.

只要制造商能够确定最坏的情况，就不打算在正常使用的所有可能配置中对医用电气设备部件进行试验。“最坏情况”几乎总是包括最高允许环境温度和医用电气设备在最大占空比下的运行，但医用电气设备配置的其他具体方面（如附件附件）应由制造商在充分了解医用电气设备设计的基础上确定。

Subclause 11.1.2 – Temperature of APPLIED PARTS

第11.1.2款-应用部件的温度

Table 23 and Table 24 addresses HAZARDS that could arise from human contact with higher temperatures. Human contact temperatures were based on clinical expertise, clinical literature [52] and experimentation. In addition, the values agree with those of the European Norm EN 563 [38]. 表23和表24说明了人体接触高温可能产生的危害。人体接触温度基于临床专业知识、临床文献[52]和实验。此外，这些值符合欧洲标准EN 563[38]的规定。

Although the maximum surface temperature for an APPLIED PART was raised from 41 °C to 43 °C in response to the clinical input mentioned above, input from some clinicians pointed out that infants as well as some other (thermally) high risk groups could be more prone to HARM from heated surfaces at 43 °C.

尽管根据上述临床输入，应用部件的最高表面温度从41°C提高到43°C，但一些临床医生的输入指出，婴儿以及其他一些（热）高危人群更容易受到43°C高温表面的伤害。

Ideally, particular standards for ME EQUIPMENT used for these PATIENT groups would have requirements for (where necessary) lower contact temperatures. In order to address those cases where such particular standards do not exist, the working group felt that notification of the RESPONSIBLE ORGANIZATION when temperatures exceed the second edition limit of 41 °C was adequate. However, the new 43 °C limit is to be considered an absolute maximum. 理想情况下，用于这些患者群体的医用电气设备的特定标准要求（如有必要）降低接触温度。为了处理不存在这种特殊标准的情况，工作组认为，当温度超过第二版41℃的限值时，向责任组织发出通知是足够的。然而，新的43℃极限被视为绝对最高温度。

When measuring APPLIED PART temperatures, the method used should simulate the worst-case configuration when possible using real or simulated human skin. Determination of the worst- case configuration should consider aspects such as the likely body temperature and whether or not the part of the body or APPLIED PART itself is covered (such as with a blanket). Simulated human skin for these purposes could include materials such as silicon rubber. 在测量应用部件温度时，所用方法应尽可能使用真实或模拟的人体皮肤模拟最坏情况下的配置。在确定最坏情况下的结构时，应考虑可能的体温以及身体部位或应用部位本身是否被覆盖（例如用毯子）。用于这些目的的模拟人体皮肤可能包括硅橡胶等材料。

Subclause 11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

第11.1.2.2款-不用于向患者供热的应用部件

Table A.5 is provided as guidance for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation. Normative requirements have not been included in this standard because such ME EQUIPMENT is uncommon. 表A.5作为医用电气设备的指南，该设备可产生低温（冷却）用于治疗目的或作为其操作的一部分。由于此类医用电气设备不常见，因此本标准中未包含规范性要求。

Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation

表A.5——医用电气设备表面温度指南，该设备用于治疗目的或作为其操作的一部分产生低温（冷却）

ME EQUIPMENT and its parts 医用电气设备及其部件		Minimum Temperature a 最低温度a □C 摄氏度	
		Aluminium 铝	Steel 钢
External surface of 外表面 ME EQUIPMENT and its parts that are likely to be touched for a time “t”.b 医用电气设备及其可能接触一段时间的部件	t < 1 s t<1秒	□20 □20个	□20 □20个
	1 s □ t < 10 s 1s□t<10秒	□10 □10个	□15 □15
	10 s □ t < 60 s 10秒□t<60秒	□2 □2个	□7 □7个
a The allowable minimum temperature limit values for external surfaces that are likely to be touched by the PATIENT, OPERATOR and other persons are based on freezing threshold a病人、操作人员和其他人员可能接触的外表面允许的最低温度限值基于冻结阈值 values of a finger touching different materials (frostbite threshold). 手指接触不同材料的值（冻伤阈值）。			

b The probability of occurrence of contact and the duration of contact should be determined and documented in the RISK MANAGEMENT FILE.
b应确定接触发生的概率和接触的持续时间，并记录在风险管理文件中。

Subclause
第11.1.3款-测量

11.1.3

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Measurements

The proper use of thermocouples is recognized in other standards as a valid test technique. The temperature limits are lowered to compensate for errors that could occur in the construction and placing of the thermocouple.
热电偶在其他试验中被认为是正确使用的有效方法。降低温度限值，以补偿热电偶构造和放置过程中可能出现的误差。

During development of the requirements of 11.1.3, the working group discussed whether it would be appropriate to reduce the maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes. In response to this question, a thorough evaluation was performed by Dr. Joachim Kohl, an expert member of the group. The following summarizes the results of that evaluation (see Figure A.22).
在制定第11.1.3条的要求期间，工作组讨论了降低高海拔表面和应用部件的最高允许温度是否合适。针对这一问题，专家组成员约阿希姆·科尔博士进行了全面评估。以下总结了评估结果（见图A.22）。

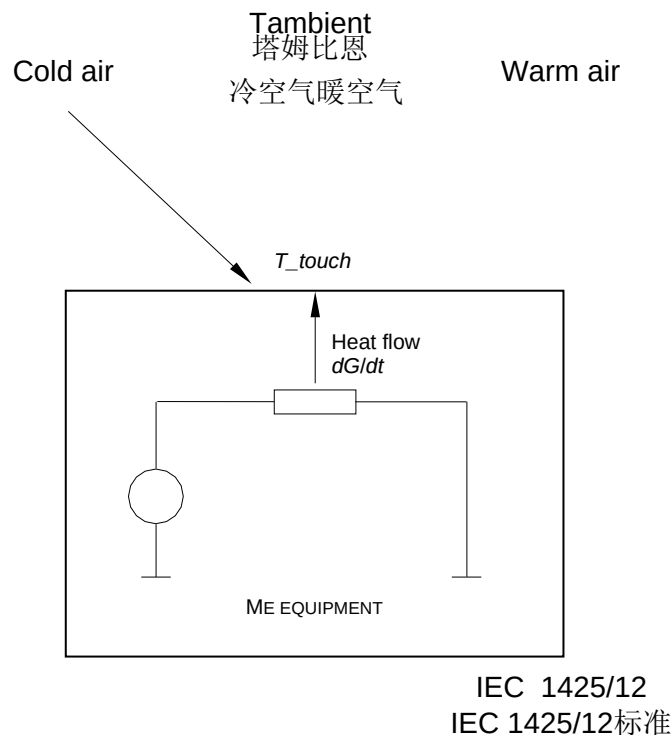


Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS
图A.22–表面和应用部件的最高允许温度
at higher altitudes
在高海拔地区

The following variables and symbols are used in the evaluation:
评估中使用了以下变量和符号：

T_{touch} touch temperature at the surface of the ME EQUIPMENT
医用电气设备表面的触摸温度

ΔT temperature difference of the touched area to ambient
接触区域与环境的温差

$R_{thermal}$ thermal resistance of the ME EQUIPMENT area under test to ambient
受试医用电气设备区域对环境的热阻

Q heat
 $Q_{热}$

dQ/dt heat flow
 dQ/dt 热流

$P_{ambient}$ ambient air pressure
环境空气压力

α heat transfer coefficient = $dQ/dt / (\Delta T * area)$
 α 传热系数 = $dQ/dt / (\Delta T * 面积)$

L characteristic length of the heat transfer area
 L 传热区特征长度

$area$ cooling area of the device
装置区域冷却面积

λ heat conductance
 λ 热导率

η dynamic viscosity
 η 动态粘度

ρ density of gas

rho 气体密度

Nu Nusselt number

Nu-Nusselt 编号

Re Reynold number

雷诺数

Gr Grashof number

Gr 格拉肖夫数

sqrt square root

平方根

~ proportional

~ 比例

Evaluation of the effects of altitude on thermal transfer:

高度对热传递影响的评估:

The standard heat transfer equation is:

标准传热方程为:

$$\Delta T = R_{\text{thermal}} * dQ/dt$$

$$\Delta T = R_{\text{热}} * dQ/dt$$

For R_{thermal} , one can estimate:

对于 $R_{\text{热}}$, 可以估计:

$$R_{\text{thermal}} \sim 1 / P_{\text{ambient}}^m$$

$$R_{\text{热}} \sim 1 / P_{\text{ambient}}^m$$

with the exponent $m = 0,6 \dots 0,8$, we will assume 1.

当指数 $m=0,6 \dots 0,8$ 时, 我们假设 1。

Equations about the proportionality to $1/P_{ambient}$:

关于 $1/P_{ambient}$ 比例的方程式：

Therefore,
因此，

$$R_{thermal} \sim 1 / \alpha$$

热导率 $\sim 1/\alpha$

where the proportionality factor contains geometric data.
其中比例系数包含几何数据。

Definition of Nu:

Nu的定义：

$$Nu = \alpha * L / \lambda$$

$$Nu = \alpha * L / \lambda$$

Results of theoretical investigations:

理论研究结果：

$$Nu \sim Re_m$$

Nu $\sim$ 雷姆

The proportionality factor depends on geometry and on the kind of gas and the way of air flow, but not on temperature, pressure, density.

比例系数取决于几何形状、气体种类和空气流动方式，但不取决于温度、压力和密度。

The exponent m is determined by geometry and the way of air flow. For free convection due to a temperature gradient Re is given by:

指数m由几何形状和气流方式决定。对于温度梯度引起的自由对流，Re由下式给出：

$$Re = \sqrt{0,4 * Gr}$$

$$Re = \sqrt{0,4 * Gr}$$

The definition of Gr leads to:

Gr的定义导致：

$$Gr \sim (\rho / \eta)^2$$

$$Gr \sim (\rho / \eta)^2$$

so that:

以便：

$$Re \sim \rho / \eta.$$

回复 ρ/η 。

This last relationship also holds true for forced convection.

最后一种关系也适用于强迫对流。

From the general gas equation we can see:

从一般气体方程我们可以看出：

$$\rho \sim P_{ambient}$$

菱形

Lambda and eta do not depend on pressure (according to standard physics textbooks). Putting it all together leads to the above stated proportionality between $R_{thermal}$ and $P_{ambient}$.
Lambda和eta不依赖于压力（根据标准物理教科书）。把它们放在一起就可以得到上面所说的 $R_{thermal}$ 和 $P_{ambient}$ 之间的比例关系。

Within most environments where ME EQUIPMENT is used, other sources of “fuel” for combustion are typically far more significant than that provided by the ME EQUIPMENT itself. The requirements addressing fire in this standard focus on preventing the ME EQUIPMENT from being the source of combustion. For this reason, these requirements focus on ME EQUIPMENT that contains or is used in the presence of OXYGEN RICH ENVIRONMENTS. These requirements attempt to ensure that any potential source of ignition remains isolated from the OXYGEN RICH ENVIRONMENTS under NORMAL USE and SINGLE FAULT CONDITIONS. 在大多数使用医用电气设备的环境中，其他用于燃烧的“燃料”来源通常远比医用电气设备本身提供的燃料重要得多。本标准中有关火灾的要求侧重于防止医用电气设备成为燃烧源。因此，这些要求侧重于含有或在富氧环境中使用的医用电气设备。这些要求旨在确保任何潜在的火源在正常使用和单一故障条件下与富氧环境保持隔离。

Where ME EQUIPMENT is not used in such environments, assuring that the limits for operating temperatures and requirements for overload protection are met should be considered adequate. 如果医用电气设备未在此类环境中使用，则应充分考虑满足工作温度限值和过载保护要求。

For ME EQUIPMENT that could provide a significant source of fuel (in comparison to the normal operating environments) additional requirements should be provided by particular standards. Where no particular standard exists, such issues should be specifically addressed in applying the RISK MANAGEMENT PROCESS as required in 4.2. 对于能够提供重要燃料来源（与正常运行环境相比）的医用电气设备，应根据特定标准提供附加要求。如果不存在特定标准，则应根据4.2的要求，在应用风险管理流程时具体解决这些问题。

Subclause 11.2.1 –Strength and rigidity required to prevent fire in ME EQUIPMENT.
第11.2.1款-医用电气设备防火所需的强度和刚度。

At least all electrical parts that could result in a HAZARD HAZARDOUS SITUATION, with the exception of POWER SUPPLY CORDS and other necessary interconnecting cords, should be enclosed in material that will not support combustion. 至少所有可能导致危险危险情况的电气部件，除了电源线和其他必要的互连电线外，都应封装在不支持燃烧的材料中。

This does not preclude the use of an outer cover of other material covering an inner cover complying with the above recommendation. 这并不排除使用其他材料制成的外盖覆盖符合上述建议的内盖。

For guidance on assessing fire HAZARDS, see IEC 60695-1-10 [17]. 有关评估火灾危险的指南，见IEC 60695-1-10[17]。

Subclause 11.2.2 – ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

第11.2.2款-与富氧环境一起使用的医用电气设备和医用电气系统

While not a flammable mixture, the presence of an OXYGEN RICH ENVIRONMENT increases the flammability of many substances. Reports of fires in OXYGEN RICH ENVIRONMENTS in ME EQUIPMENT are unusual. However, when such fires do occur in the hospital environment they can have tragic consequences. 虽然不是易燃混合物，但富氧环境的存在增加了许多物质的可燃性。关于医用电气设备富氧环境中发生火灾的报告并不常见。然而，当这种火灾发生在医院环境中时，可能会造成悲惨的后果。

ME EQUIPMENT intended to operate in conjunction with an OXYGEN RICH ENVIRONMENT should be designed to minimize the probability or occurrence of ignition of flammable materials. 拟与富氧环境一起运行的医用电气设备的设计应尽量减少易燃材料着火的可能性或发生。

Where appropriate, particular standards should specify the corresponding requirements. 在适当的情况下，特殊标准应规定相应的要求。

Subclause 11.2.2.1 a) 款

11.2.2.1

a)

Cotton is regarded to be the material with the lowest ignition temperature and energy in comparison with electronic circuits and it is assumed that it can be found in the interior of a device as dust. 与电子电路相比，棉花被认为是点火温度和能量最低的材料，并且假定它可以作为灰尘存在于设备内部。

The maximum surface temperature limit is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen that is given in NFPA 53 [41] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in ME EQUIPMENT with OXYGEN RICH ENVIRONMENTS. 因此，在富氧环境中，阻燃剂的最低温度为310°C，这是基于100°C的燃烧极限。

The worst case conditions described in the text make it possible to provide simple numbers as limitations. 文本中描述的最坏情况可以提供简单的数字作为限制。

The values for sparking are taken from Kohl, H.-J. et al., ASTM STP 1395 [37]. 火花值取自Kohl, H.-J.等人，ASTM STP 1395[37]。

This subclause allows the use of electronic circuits in OXYGEN RICH ENVIRONMENTS only when their power supply is limited. The resistive limitation of the power input is necessary for the SINGLE FAULT CONDITION of an open solder joint that might spark. The same reason applies to the limitation of energy in capacitances and inductances. In most cases the limitation in item 本条款仅允许在富氧环境中使用电子电路，当其电源受到限制时。对于可能产生火花的开放式焊点的单一

故障情况，电源输入的电阻限制是必要的。同样的原因也适用于电容和电感的能量限制。在大多数情况下，项目的限制

4) to 300 °C is more restrictive than these. For most small components like decoupling capacitors, or where the failure of a component causes the maximum possible power to be drawn from the source, it is necessary to limit the power to about 1 W. The PROCEDURE to find the necessary value to limit the power so that the 300 °C limit is not exceeded can be as follows:

到300°C比这些限制更严格。对于去耦电容器等大多数小部件，或某个部件的故障导致从电源中消耗最大功率，有必要将功率限制在1 W左右。找到限制功率以避免超过300°C限值的必要值的步骤如下：

– look for the smallest component that can match to the power source in a SINGLE FAULT CONDITION;

寻找在单一故障条件下能与电源相匹配的最小元件；

– estimate its thermal resistance;
估计其热阻；

– calculate the power limitation = 200 °C / thermal resistance.
计算功率限制=200°C/热阻。

Subclause 11.2.2.1 b) 2)

第11.2.2.1 b) 2) 款

This item addresses the condition of an undetected oxygen leak. In accordance with the definition of SINGLE FAULT SAFE, such a leak (because it is undetected) is considered a NORMAL CONDITION (see 4.7). Similarly, only the failure of the ventilation, which is undetected, needs to be considered a NORMAL CONDITION. Where a ventilation system's design makes it unlikely that it will be completely blocked in NORMAL USE, such blockages should not be considered. The only way to find the maximum leak rate that needs to be considered is to find the minimum leak rate that can safely be detected by the RESPONSIBLE ORGANIZATION. 本项涉及未检测到的氧气泄漏情况。根据单一故障安全的定义，此类泄漏（因为未被检测到）被视为正常情况（见4.7）。同样，只有通风系统的故障（未被发现）才需要被视为正常情况。如果通风系统的设计不太可能在正常使用中完全堵塞，则不应考虑此类堵塞。找到需要考虑的最大泄漏率的唯一方法是找到责任组织可以安全检测到的最小泄漏率。

Subclause 11.2.2.1 b) 3)

第11.2.2.1 b) 3) 款

The cause of the HAZARDOUS SITUATION is: a leak occurs and is not detected; some time later an electrical failure occurs that starts an ignition. The time interval t_c for checking the seals can be calculated as follows: 造成危险情况的原因是：发生泄漏，但没有检测到；一段时间后，发生电气故障，开始点火。检查密封的时间间隔 t_c 可计算如下：

- estimate the probability per time p_e of an electrical failure that exceeds the values given in 11.2.2.1 a); 估计每次电气故障的概率 p_e 超过中给出的值 11.2.2.1 a) ;
- estimate the probability per time of the oxygen leak p_o ; 估算每次氧泄漏概率 p_o ;
- determine the accepted probability of dangerous failures per time r ; 确定每一次危险故障的可接受概率 r ;
- calculate: $t_c = r / (0,5 \times p_e \times p_o)$. 计算： $t_c = r / (0,5 \times p_e \times p_o)$ 。

Subclause 11.2.2.2 – External exhaust outlets for OXYGEN RICH ENVIRONMENT

第11.2.2.2款-富氧环境的外部排气口

Serious oxygen fires have been reported where the ignition source has been a faulty electrical connector close to an oxygen outlet. 据报道，在氧气出口附近的一个有故障的电气接头的点火源发生了严重的氧气火灾。

Subclause 11.3 – Constructional requirement for fire ENCLOSURES of ME EQUIPMENT

第11.3款——医用电气设备防火外壳的结构要求

The requirements for fire ENCLOSURES from IEC 61010-1 [22] have been included primarily as an alternate to the tests related to SINGLE FAULT CONDITIONS (associated with combustion and its consequences listed in Clause 13). By requiring flame resistance for the ENCLOSURE and materials contained within it, the probability of occurrence of fire escaping such ENCLOSURES is considered minimal. Where the fire ENCLOSURE constitutes only a part of the ME EQUIPMENT, careful analysis should be performed to assure that a reliable barrier to the propagation of fire exists. IEC 61010-1[22]中对防火外壳的要求主要作为单一故障条件（与第13条所列燃烧及其后果相关）相关试验的替代品。通过要求外壳及其所含材料的阻燃性，此类外壳发生火灾的可能性被认为是最小的。如果防火外壳仅构成医用电气设备的一部分，则应进行仔细分析，以确保存在防止火灾蔓延的可靠屏障。

IEC 60950-1:2005 components (i.e. power supplies, modems, network routers, etc.) are allowed to be integrated into ME EQUIPMENT when MOOP insulation has been determined to be adequate and TOUCH CURRENT limits have been satisfied. IEC 60950-1:2005组件（即电源、调制解调器、网络路由器等）可在MOOP绝缘被确定为足够且满足接

触电流限制的情况下集成到医用电气设备中。

The flame resistance requirements for wire insulation, when used inside a fire ENCLOSURE, in accordance with IEC 60950-1:2005, subclause 4.7.3.4, are:

根据IEC 60950-1:2005第4.7.3.4款，在防火外壳内使用时，电线绝缘的阻燃要求如下：

- Minimum of FV-2 when tested in accordance with IEC 60695-11-10, or
根据IEC 60695-11-10进行试验时，FV-2最小值，或
- insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide.
与PVC、TFE、PTFE、FEP、聚氯乙烯或聚酰亚胺绝缘。

While the ME EQUIPMENT flame resistance requirement of FV-1 for wire insulation when used inside a flame enclosure is slightly more stringent than the IEC 60950-1:2005, subclause

当在火焰外壳内使用时，FV-1对电线绝缘的医用电气设备的阻燃性要求比IEC 60950-1:2005子条款稍微严格一些

4.7.3.4 requirement, it would seem reasonable to conclude an equivalent level of risk should IEC 60950-1 compliant wire be integrated into the ME EQUIPMENT or ME SYSTEM either:

4.7.3.4要求，如果符合IEC 60950-1标准的电线被集成到医用电气设备或医用电气系统中，则得出等效的风险水平似乎是合理的：

- indirectly when IEC 60950-1 components have been integrated into the ME EQUIPMENT or
当IEC 60950-1组件已集成到医用电气设备或
ME SYSTEM, or
ME系统，或
- directly as part of a wire selection decision for the ME EQUIPMENT or ME SYSTEM.
直接作为医用电气设备或医用电气系统选线决策的一部分。

IEC 61010-1:2010 [22], subclause 9.3.2, requires wire insulation when used inside a fire enclosure to have a UL 2556 rating of VW-1, or comply with the applicable requirements of IEC 60332-1-2 or IEC 60332-2-2 These wire flame resistance requirements are considered acceptable for ME EQUIPMENT and ME SYSTEMS. IEC 61010-1:2010[22]第9.3.2款要求在防火外壳内使用的电线绝缘等级应达到VW-1的UL 2556等级，或符合IEC 60332-1-2或IEC 60332-2-2的适用要求。这些电线的阻燃性要求被认为是医用电气设备和医用电气系统可接受的。

Subclause 11.4 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics

第11.4款-用于易燃麻醉剂的医用电气设备和医用电气系统

While the use of flammable anaesthetics is uncommon, it was determined during the writing of this edition that some MANUFACTURERS might still want to rate their ME EQUIPMENT as CATEGORY AP or CATEGORY APG. In order to make this edition more usable (by removing the rarely used section on this topic) while maintaining the availability of the CATEGORY AP and CATEGORY APG RATINGS, the material has been moved to an annex and only this clause's brief reference to it remains in the body of the standard.

虽然使用易燃麻醉剂是不常见的，但在编写本版本的过程中，一些制造商可能仍希望将其医用电气设备评定为AP类或APG类。为了使本版更具实用性（删除本主题中很少使用的章节），同时保持AP类和APG类评级的可用性，材料已移至附录中，本标准正文中只保留本条款对其的简要引用。

The final determination of whether ME EQUIPMENT should be RATED CATEGORY AP or CATEGORY APG should be determined by the MANUFACTURER based on the INTENDED USE. Requirements related to CATEGORY AP and CATEGORY APG are found in Annex G (see also the rationale for Annex G). 医用电气设备是否应额定为AP类或APG类的最终确定应由制造商根据预期用途确定。与AP类和APG类相关的要求见附录G（另见附录G的基本原理）。

Subclause 11.5 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable agents

第11.5款-拟与易燃剂一起使用的医用电气设备和医用电气系统

While it was necessary to address cases where ME EQUIPMENT is used with flammable agents (such as some disinfectants) or in areas where they are commonly used and where the MANUFACTURER of the ME EQUIPMENT has given no special handling instructions or precautions, the variety of such agents, their volatility as well as many other determinant factors precludes giving specific instructions. The only reasonable solution in such cases is to assure that the MANUFACTURER evaluates and addresses the associated RISK.

虽然有必要解决医用电气设备与易燃剂（如某些消毒剂）一起使用的情况，或在它们通常使用的区域，并且医用电气设备的制造商没有给出特殊的处理说明或预防措施的情况下，这些药剂的种类，它们的波动性以及许多其他决定因素排除了给出具体指示的可能性。在这种情况下，唯一合理的解决方案是确保制造商评估并解决相关风险。

A mixture of the vapour of a flammable disinfection or cleaning agent with air can be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

根据国家或地方法规，易燃消毒剂或清洁剂的蒸汽与空气的混合物可被视为易燃麻醉剂与空气的混合物。

Subclause 11.6.2 – Overflow in ME EQUIPMENT

第11.6.2款-医用电气设备溢出

The purpose of this test is to assess not only whether the liquid actually wets any parts in a way that would adversely affect a MEANS OF PROTECTION or result in a HAZARD; but also whether a similar amount of liquid that could overflow on another occasion and reach the same parts of the ME EQUIPMENT, but possibly not land in exactly the same way, could adversely affect a MEANS OF PROTECTION or result in a HAZARD. The results of the test should be evaluated to assure they realistically represent conditions that will be experienced when the ME EQUIPMENT is used.

本试验的目的不仅是评估液体是否会对保护装置产生不利影响或导致危险的方式实际浸湿任何部件，而且还评估在另一种情况下可能溢出并到达医用电气设备相同部件的类似数量的液体，但可能不会以完全相同的方式降落，可能会对保护手段造成不利影响或造成危险。应对试验结果进行评估，以确保其真实地代表使用医用电气设备时所经历的条件。

Subclause 11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

第11.6.3款-医用电气设备和医用电气系统溢出

In addition to ME EQUIPMENT that requires the use of fluids, many types are some ME EQUIPMENT is exposed to fluid spills as part of their REASONABLY FORESEEABLE MISUSES. In

such cases spillage is considered NORMAL USE and the associated RISKS are addressed by the requirements of this subclause. Furthermore, as described in 9.4.2, tilting of TRANSPORTABLE ME EQUIPMENT to an angle of 10° is considered NORMAL USE. In such cases (as well as for ME EQUIPMENT requiring fluids) the amount and location where spills can occur vary greatly. Only a proper evaluation of the ME EQUIPMENT being tested can determine an appropriate application of the requirement. Doing such an evaluation is the responsibility of the MANUFACTURER and the results are to be provided to those performing the test (typically in the RISK MANAGEMENT FILE). This requirement would be an appropriate area for evaluation by writers of particular standards. 除了需要使用液体的医用电气设备外，许多类型的医用电气设备暴露于液体泄漏中，这是其合理可预见的误用的一部分。在这种情况下，溢出被视为正常使用，相关风险由本款要求解决。此外，如9.4.2所述，移动式医用电气设备倾斜至10°角视为正常使用。在这种情况下（以及需要液体的医用电气设备），可能发生泄漏的数量和位置有很大的不同。只有对被测医用电气设备进行适当评估，才能确定该要求的适当应用。进行此类评估是制造商的责任，结果将提供给执行测试的人员（通常在风险管理文件中）。这一要求将是特定标准编写者进行评估的适当领域。

In accord with the principles outlined in IEC 62366, where explicit warnings or safety notices (validated as described in IEC 62366) are given, failure to heed such warnings or safety notices is considered abuse of the ME EQUIPMENT that is beyond the responsibility of the MANUFACTURER. Therefore where such warnings or safety notices are given, the liquid reservoir is filled only to the intended fill level before being tilted to 10°. Where they are not given, the liquid reservoir is filled 15% above the intended level.

根据IEC 62366中概述的原则，如果给出了明确的警告或安全通知（如IEC 62366中所述进行验证），未遵守此类警告或安全通知将被视为滥用医用电气设备，这超出了制造商的责任范围。因此，在给出此类警告或安全通知的情况下，在倾斜至10°之前，仅将储液罐加注至预期的加注液位。如果没有给出，则储液罐的填充量为预期液位的15%。

Examination of the NORMAL USE of ME EQUIPMENT should provide an adequate estimate of the amount of fluid that is likely to be spilled on it. 医用电气设备的正常使用检查应提供可能溅到其上的液体量的充分估计。

Spillage for equipment that does not require the use of fluids is considered to be a SINGLE FAULT CONDITION.

不需要使用液体的设备溢出被视为单一故障状态。

Subclause 11.6.4 – Leakage
第11.6.4款-泄漏

Leakage is considered to be a SINGLE FAULT CONDITION.
泄漏被认为是单一故障状态。

Subclause 11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS
第11.6.5款-水和颗粒物进入医用电气设备和ME系统

Although it is unlikely that ME EQUIPMENT would be RATED for protection against particulate matter, IEC 60529 does address the possibility and it should be considered a valid option. The presence of any water or particulate matter inside the ENCLOSURE after testing in accordance with its IEC 60529 classification is regarded as a NORMAL CONDITION. The requirement is therefore to assess the possibility of a HAZARDOUS SITUATION due to such ingress in combination with a possible SINGLE FAULT CONDITION (such as an interrupted PROTECTIVE EARTH CONNECTION). 尽管医用电气设备不太可能被定为防颗粒物的防护等级，但IEC 60529确实提出了这种可能性，并且应将其视为一种有效的选择。按照IEC 60529分类进行试验后，外壳内存在任何水或颗粒物被视为正常情况。因此，要求结合可能的单一故障条件（如保护性接地连接中断）来评估由于此类进入而出现危险情况的可能性。

Subclause 11.6.8 – Compatibility with substances used with the ME EQUIPMENT
第11.6.8款-与医用电气设备所用物质的相容性

ME EQUIPMENT, ACCESSORIES and parts thereof should be designed to be used safely with the substances with which they are intended to come into contact in NORMAL USE. 医用电气设备、附件及其零件的设计应确保其与正常使用中预期接触的物质安全使用。

Where appropriate, particular standards should specify the corresponding requirements.
在适当的情况下，特殊标准应规定相应的要求。

Subclause 11.8 – * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT
第11.8款-*医用电气设备电源/供电干线中断

Interruption of the power supply could result in a HAZARD HAZARDOUS SITUATION due to loss of functionality. This HAZARD HAZARDOUS SITUATION is dealt with in 7.9.2.4. Restoration of the power source can also result in HAZARDOUS SITUATIONS. Examples could include unintended activation of moving parts or resumption of dangerous outputs. These potentially HAZARDOUS SITUATION and the duration of the power interruption that could result in the HAZARDS HAZARDOUS SITUATIONS need to be considered as part of the RISK MANAGEMENT PROCESS. 由于功能丧失，电源中断可能导致危险危险情况。7.9.2.4中处理了这种危险和危险情况。恢复电源也可能导致危险情况。例如，活动部件的意外激活或危险输出的恢复。这些潜在的危险情况和可能导致危险危险情况的断电持续时间需要作为风险管理过程的一部分加以考虑。

IEC 61000-4-11 [21] defines general and reproducible conditions for the operation of electrical and electronic equipment if they undergo voltage dips, short interruptions and voltage variations. The voltage level and duration of short interruptions are defined in Tables 210 and IEC 61000-4-11[21]定义了电气和电子设备在经历电压骤降、短时中断和电压变化时的一般和可复制条件。表210和211 of IEC 60601-1-2:2001. IEC 60601-1-2 treats these short interruptions as a NORMAL CONDITION. IEC 60601-1-2:2001第211条。IEC 60601-1-2将这些短时中断视为正常情况。

For ME EQUIPMENT in which the safety of the PATIENT depends on the continuity of the power, particular standards should include requirements regarding power failure alarms or other precautions. 对于患者安全取决于电源连续性的医用电气设备，特殊标准应包括有关电源故障警报或其他预防措施的

要求。

Clause 12 – Accuracy of controls and instruments and protection against hazardous outputs

第12条-控制装置和仪表的准确性以及对危险输出的防护

IEC 60601-1 is the guideline for all particular standards and, therefore, contain some requirements of a more general character in order to serve this purpose. For this reason, it is necessary to have some generally formulated requirements in Clause 12. IEC 60601-1是所有特定标准的指南，因此，为了达到这一目的，它包含了一些更通用的要求。因此，有必要在第12条中制定一些一般性的要求。

Standardization bodies, including those outside IEC, have adopted the system of this IEC publication in order to have a single uniform system of standards. In such cases it is most important to give a guideline in this clause. 标准化机构（包括IEC以外的机构）采用了本IEC出版物的体系，以形成统一的标准体系。在这种情况下，最重要的是在本条款中给出指导。

This clause introduces the concept of USABILITY. The term was chosen over the commonly used terms of “user error” or “human error” because not all errors are the result of oversight or carelessness on the part of the OPERATOR of the ME EQUIPMENT. All too frequently, use errors are the direct result of poor human interface design that seduces the OPERATOR into an incorrect decision. Use errors caused by inadequate USABILITY have become an increasing cause for concern. The USABILITY ENGINEERING PROCESS described in IEC 60601-1-6 is intended to achieve reasonable USABILITY, which in turn is intended to minimise use errors and to minimise use associated RISKS.

本条款介绍了可用性的概念。之所以选择这个术语，是因为并不是所有的错误都是由于医用电气设备操作人员的疏忽或疏忽造成的。通常，使用错误是糟糕的人机界面设计的直接结果，它诱使操作员做出错误的决定。由于可用性不足而导致的使用错误越来越引起人们的关注。IEC 60601-1-6中描述的可用性工程过程旨在实现合理的可用性，而合理可用性反过来又旨在最大限度地减少使用错误和最小化使用相关风险。

Subclause 12.4.1 – Intentional exceeding of safety limits

第12.4.1款-故意超出安全限值

If the control range of ME EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output that is regarded as non-hazardous, means should be provided that prevent such a setting or that indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock) that the selected setting is in excess of a safety limit.

如果医用电气设备的控制范围使得在一部分范围内交付的输出与被认为是无害的输出有很大的不同，应提供防止此类设置的装置，或向操作员指示（例如，当设置控制装置或绕过联锁装置时，通过明显的附加电阻）所选设置超过安全限值。

Where appropriate, particular standards should specify safe output levels.

在适当的情况下，特定标准应规定安全输出水平。

Subclause 12.4.3 – Accidental selection of excessive output values

第12.4.3款-意外选择过量输出值

Protection for the accidental selection of excessive output values can be obtained by appropriate steps to minimise the possibility to accidentally select excessive output, e.g. by interlocks in order to achieve deliberate action or by separated output terminals. In considering the measures for protection, the standard on human factors could be taken into account.

意外选择过大输出值的保护可通过适当的步骤来实现，以将意外选择过大输出的可能性降到最低，例如通过联锁来实现有意的动作或通过分离的输出端子。在考虑保护措施时，可考虑人为因素标准。

Clause 13 – HAZARDOUS SITUATIONS and fault conditions

第13条-危险情况和故障条件

ME EQUIPMENT or its parts could result in HAZARDS HAZARDOUS SITUATIONS due to abnormal operation or fault conditions, which, therefore, needs to be investigated. While this clause identifies specific fault conditions, 4.7 requires that the RISK ANALYSIS be used to identify other failures which should be investigated.

医用电气设备或其部件可能由于异常操作或故障条件而导致危险和危险情况，因此需要对其进行调查。虽然本条款确定了具体的故障条件，但4.7要求使用风险分析来识别应调查的其他故障。

Subclause 13.1.1 – General

第13.1.1款-概述

While separation requirements (CREEPAGE DISTANCES and AIR CLEARNACES) and insulation requirements are detailed in Clause 8, these requirements should not be viewed as applying only to RISKS associated with electrical HAZARDS. In addition to the potential for electric currents to cause fibrillation (due to electric shock), these currents can also be the root cause of injuries not directly related to electric shock.

虽然隔离要求（爬电距离和空气净空）和绝缘要求在第8条中有详细说明，但这些要求不应被视为仅适用于与电气危险相关的风险。除了电流可能导致纤颤（由于电击），这些电流也可能是与电击无关的伤害的根本原因。

Examples of these other HAZARDS (related to inadequate or faulty insulation or short circuits across physical spacing used as insulation) could include sparks that could become a source of ignition of flammable materials (as discussed in Clause 11) or functional failures that could cause a loss of ESENTIAL PERFORMANCE. In these cases, compliance with the insulation requirements of Clause 8 should always be considered evidence that RISKS arising from the failure of insulation or spacing have been adequately addressed when evaluating the safety of ME EQUIPMENT.

这些其他危险的例子（与绝缘不充分或有缺陷或跨越用作绝缘的物理间距的短路有关）可能包括可能成为易燃材料火源的火花（如第11条所述）或可能导致本质性能损失的功能故障。在这些情况下，在评估医用电气设备的安全性时，应始终将符合第8条绝缘要求的证据视为绝缘或间距故障引起的风险已得到充分解决。

Finally, it should be noted that the requirements for CREEPAGE DISTANCES and AIR CLEARNACES are not intended to be required at the circuit board level where there is no significant

RISK that spacings will be compromised (shorted) by contaminants (from NORMAL USE or the manufacturing PROCESS) such as fluids or particulate matter (see also IEC 60529). In most applications, spacing between (for example) circuit board traces and component leads are not considered likely to fail. In cases where there is doubt as to whether spacing could fail (where the CREEPAGE DISTANCE and AIR CLEARANCE requirements of 8.9 are not met), the MANUFACTURER'S RISK ANALYSIS should evaluate the likelihood of shorting across such gaps, but only where such short-circuiting could directly result in unacceptable RISKS. Where shorting across spacing or insulation failures are clearly not likely to result in unacceptable RISKS, such analysis should not be required.

最后，应注意的是，在电路板级不存在因液体或颗粒物等污染物（来自正常使用或制造过程）而损害（短路）间距的重大风险的电路板级，不需要对爬电距离和空气净空的要求（另见IEC 60529）。在大多数应用中，电路板迹线和元件引线之间的间距被认为不太可能失效。如果对间距是否可能失效存在疑问（不满足8.9中的爬电距离和空气净空要求），制造商的风险分析应评估穿过此类间隙短路的可能性，但仅限于此类短路可能直接导致不可接受的RISK。如果间隔短路或绝缘故障显然不太可能导致不可接受的风险，则不需要进行此类分析。

Subclause 13.1.2 – Emissions, deformation of ENCLOSURE or exceeding maximum temperature

第13.1.2款-排放、外壳变形或超过最高温度

The delivery of unintended hazardous quantities of energy or substances to a PATIENT or into the natural environment could be addressed by particular standards. 向病人或自然环境中输送意外危险量的能量或物质可通过特殊标准加以解决。

Hazardous quantities of poisonous or ignitable gas depend on the type of gas, concentration, place of emission etc.

有毒或可燃气体的危险量取决于气体类型、浓度、排放地点等。

SINGLE FAULT CONDITIONS that might result in a small fire, but where the fire would remain contained within a fire ENCLOSURE, are acceptable because the containment will limit the effects to the area inside of the fire ENCLOSURE. 可能导致小型火灾，但火灾仍被控制在防火外壳内的单一故障条件是可以接受的，因为安全壳将限制对防火外壳内部区域的影响。

At a power dissipation of less than 15 W in the absence of an increased oxygen concentration (see 11.2.2), no fire HAZARD exists. Where circuits could dissipate 15 W or greater, it should be demonstrated that components within such circuits will not cause fire, molten metal, etc. to propagate in such a way as to result in a HAZARD (by setting the surroundings on fire for example). However, as in IEC 61010-1 [22], it is considered that when such components are enclosed in a fire ENCLOSURE as defined in 11.3, adequate protection from such propagation is provided. 在不增加氧气浓度的情况下，功耗小于15W（见11.2.2），不存在火灾危险。如果电路的耗散功率为15W或更大，则应证明此类电路中的组件不会导致火灾、熔融金属等以导致危险的方式传播（例如，通过点燃周围环境）。然而，如IEC 61010-1[22]中所述，认为当此类部件封闭在11.3中定义的防火外壳内时，应提供足够的保护以防止此类传播。

The power level (15 Watts) cited in the original publication of this standard as the threshold below which ignition will not occur in normal ambient concentrations of oxygen was found to be significantly below the level used in IEC 61010-1 [22]. The original 15 W value was not based on any scientific test or research but came from “common practice” at some certification bodies (an anecdotal value only). 在本标准原始出版物中引用的功率水平（15瓦）被发现明显低于IEC 61010-1[22]中使用的水平，低于该阈值时，氧气的正常环境浓度不会发生点火。最初的15W值不是基于任何科学测试或研究，而是来自于一些认证机构的“常见做法”（仅为传闻值）。

However, IEC 60950-1 provides a variety of energy levels based on voltage ranging from 100 VA to 150 VA. For purposes of simplicity, the lowest of these values (100 VA) with minimal restrictions on construction were used as an alternative to the 15 W limit (without construction restrictions) originally used in this standard for ME EQUIPMENT in general. 然而，IEC 60950-1基于电压范围从100 VA到150 VA提供了各种能量水平。为简单起见，这些值中的最低值（100 VA）和最小的结构限制被用作本标准中最初用于医用电气设备的15 W限值（无施工限制）的替代品。

Direct application of the requirements for limited energy circuits in IEC 60950-1 can also be considered to assure that the RISK of fire has been reduced to acceptable levels at higher energies to demonstrate equivalent safety as well. 也可考虑直接应用IEC 60950-1中的有限能量电路要求，以确保在较高能量下，火灾风险已降低至可接受水平，以证明同等安全性。

Since facilities where ME EQUIPMENT compliant with this standard is used will also contain information technology equipment (compliant with IEC 60950-1) and such equipment can be part of ME EQUIPMENT or ME SYSTEMS, it would be unreasonable to require the ME EQUIPMENT to offer a higher level of protection against ignition than does the other equipment used in the same environment.

由于使用符合本标准的医用电气设备的设施也将包含信息技术设备（符合IEC 60950-1），并且这些设备可以是医用电气设备或医用电气系统的一部分，要求医用电气设备提供比在相同环境中使用的其他设备更高水平的点火保护是不合理的。

It is felt that limiting the maximum temperatures for APPLIED PARTS to the NORMAL CONDITION values is appropriate because exceeding them is known to result in HARM and the PATIENT is frequently unable to pull away. 人们认为，将应用部件的最高温度限制在正常条件下是合适的，因为超过这些温度会导致伤害，并且患者经常无法离开。

The restrictions of this subclause are regarded to be sufficient to avoid an enduring fire. A fire is not only dangerous by itself but has side effects such as destroying isolation barriers or destroying mechanical stability. These cannot be taken into account by the above limitations. Therefore, the MANUFACTURER needs to consider the following when coming to a conclusion: 本款的限制被认为足以避免持久火灾。火灾不仅本身是危险的，而且有副作用，例如破坏隔离屏障或破

坏机械稳定性。上述限制不能考虑这些因素。因此，制造商在得出结论时需要考虑以下几点：

- Obviously a limitation of 100 VA cannot guarantee 'no ignition'. Smaller components such as resistors, semiconductors etc. can be exposed to levels of power that could cause ignition. However, standards such as IEC 60950-1 and IEC 61010-1 and experience demonstrate that when such situations arise if the components are mounted on FV1 rated material an enduring fire is very unlikely to occur. 显然，100伏安的限制不能保证“不点火”。较小的部件，如电阻器、半导体等，可能会暴露在可能导致点火的功率水平下。然而，IEC 60950-1和IEC 61010-1等标准和经验表明，如果将部件安装在FV1额定材料上，则不太可能发生持久火灾。
- Ignition could destroy isolation barriers exposing hazardous voltages. A device which is designed according to the requirements of this subclause should still be checked to determine whether such barriers would be affected and whether additional appropriate precautions independent of the requirements of this subclause. 点火会破坏暴露在危险电压下的隔离屏障。根据本款要求设计的装置仍应进行检查，以确定此类屏障是否会受到影响，以及是否有独立于本款要求的其他适当预防措施。

Since no enduring fire will occur, the mechanical stability is regarded as maintained.
由于不会发生持久火灾，因此机械稳定性被视为保持不变。

Subclause 13.2.9 – Interruption and short circuiting of motor capacitors **第13.2.9款-机电电容器的中断和短路**

The effect of functioning centrifugal switches can be taken into account. A locked rotor condition is specified because some capacitor motors might or might not start, causing variable results. Capacitor voltage is checked to assure that its dielectric will not be stressed causing the accumulation of hazardous gases including hydrogen. 可以考虑离心开关的作用。由于某些电容式电动机可能起动，也可能不起动，因此规定了堵转状态，从而导致各种结果。检查电容器电压，以确保其电介质不会受到应力，从而导致危险气体（包括氢气）的积聚。

While the short circuit or open circuit of the capacitor is a SINGLE FAULT CONDITION and locking of the rotor is also a SINGLE FAULT CONDITION (see 13.2.8) this is regarded as an instance of
电容器的短路或开路是单一故障情况，转子锁定也是单一故障情况（见13.2.8），这被视为

the situation referred to in 4.7, where one SINGLE FAULT CONDITION can result unavoidably in another SINGLE FAULT CONDITION and the two failures are considered as one SINGLE FAULT CONDITION.

4.7中提到的情况，其中一个单一故障条件不可避免地会导致另一个单一故障条件，并且这两个故障被视为一个单一故障条件。

Subclause 13.2.10 – Additional test criteria for motor operated ME EQUIPMENT and Table 26, last line

第13.2.10款-电动医用电气设备和试验台的附加试验标准

26, 最后一行

Temperature limits of motor windings in ME EQUIPMENT are determined after the first hour as an arithmetic average because experience of test houses has shown that ME EQUIPMENT for non-CONTINUOUS OPERATION reaches variable values that could temporarily differ from the maximum values. Therefore, lower temperature limits are required. The values in Table 26 are based on the requirements of IEC 60950-1:20012005.

在电机连续运行时，由于电机绕组的平均温度值在电机达到最大值后会暂时不同。因此，需要较低的温度限制。表26中的值基于IEC 60950-1:20012005的要求。

Subclause 13.2.13.1 – General overload test conditions

第13.2.13.1款-一般过载试验条件

The ball pressure test is not intended to represent the exact conditions experienced in use. The test is performed at elevated temperatures to test the robustness (adequate safety factor) of the mechanical properties of the insulation. The principle is not unlike dielectric withstand testing which subjects insulation to voltages far in excess of those seen in use.

钢球压力测试并不代表使用过程中所经历的确切条件。该试验在高温下进行，以测试绝缘材料机械性能的坚固性（足够的安全系数）。这一原理与介电耐压试验不同，绝缘承受的电压远远超过使用中的电压。

Subclause 13.2.13.4 – ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

第13.2.13.4款-额定用于非连续运行的医用电气设备

Where ME EQUIPMENT or parts thereof are RATED for non-CONTINUOUS OPERATION but controls allow OPERATORS to leave it in operation (should a medical or other emergency occur), the CONTINUOUS OPERATION of the ME EQUIPMENT is considered reasonably foreseeable misuse. Where safety is dependent on switching the ME EQUIPMENT or parts thereof off after a prescribed period, steps should be taken to assure that intentional action is not required to do so.

如果医用电气设备或其部件的额定值为非连续运行，但控制允许操作员将其保持运行（如果发生医疗或其他紧急情况），医用电气设备的连续运行被视为可合理预见的误用。如果安全取决于在规定的时间内关闭医用电气设备或其部件，则应采取措施确保不需要故意这样做。

Clause 14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

第14条-可编程电气医疗系统（PEMS）

Computers are increasingly used in ME EQUIPMENT, often in safety-critical roles. The use of computing technologies increases the level of complexity in ME EQUIPMENT. This complexity means that systematic failures can escape the practical limits of testing. Accordingly, this clause goes beyond traditional test and measurement of the finished ME EQUIPMENT and includes requirements for the PROCESSES by which it is developed. Testing of the finished product is not, by itself, adequate to address the safety of PROGRAMMABLE ME EQUIPMENT MEDICAL ELECTRICAL SYSTEMS.

计算机在医用电气设备中的应用越来越广泛，通常在安全方面起着至关重要的作用。计算技术的使用增加了医用电气设备的复杂性。这种复杂性意味着系统故障可以逃脱测试的实际限制。因此，本条款超出了医用电气设备成品的传统测试和测量范围，并包括其开发过程的要求。成品测试本身不足以解决可编程医用电气设备的安全问题。

For these reasons, this clause requires that a PROCESS with specific elements be established and followed. The intention is to establish these specific PROCESS elements, leaving the user of this

clause to determine in detail how to accomplish them. This is similar to the approach taken in the ISO 9000 series. Because users of this clause are expected to be qualified to perform the identified activities, detail has been kept to a minimum. 基于这些原因，本条款要求建立并遵循具有特定要素的流程。其目的是建立这些特定的过程元素，让本条款的用户详细决定如何完成这些元素。这与ISO9000系列中采用的方法类似。由于本条款的使用者被期望有资格执行所确定的活动，所以细节被保持在最低限度。

While iteration of some elements of the PROCESS is expected, no specific requirements to do so have been included. These requirements were omitted because the need to repeat PROCESSES or portions of them is unique to each particular device. In addition, the need for such iteration will arise from the more detailed understanding that emerges during the design PROCESS. 虽然过程的某些元素需要迭代，但是没有包含这样做的具体要求。这些要求被省略了，因为每个特定设备都需要重复这些过程或其中的一部分。此外，这种迭代的需要将产生于在设计过程中出现的更详细的理解。

Because users of this standard are required to establish, maintain and apply a RISK MANAGEMENT PROCESS as part of compliance, this clause establishes those characteristics unique to programmable systems that should be considered as part of that PROCESS. Requirements for development and modification of medical device software have been specified in IEC 62304. The requirements from IEC 62304 that apply to development prior to placing a product in service are included by reference for the PEMS software. 由于本标准的用户需要建立、维护和应用风险管理过程，作为合规的一部分，本条款规定了可编程系统特有的特性，这些特性应被视为该过程的一部分。IEC 62304中规定了医疗器械软件的开发和修改要求。IEC 62304中适用于产品投入使用前开发的要求包含在PEMS软件中。

There are some requirements in IEC 62304 that apply to software maintenance after a product has been placed into service. These requirements have not been included in the reference. IEC 62304中有一些要求适用于产品投入使用后的软件维护。参考文献中未包含这些要求。

The effective application of Clause 14 will require, subject to the task in hand, competence in the following:

根据手头的任务，有效适用第14条将要求具备以下能力：

- application of the specific ME EQUIPMENT with emphasis on safety considerations;
特殊医用电气设备的应用，强调安全考虑；
- ME EQUIPMENT development PROCESS;
医用电气设备开发过程；
- methods by which safety is assured;
确保安全的方法；
- techniques of RISK ANALYSIS and RISK CONTROL.
风险分析和风险控制技术。

Requirements have been minimized to those that are essential to assuring BASIC SAFETY and ESSENTIAL PERFORMANCE. This has been done in recognition of the extensive and growing literature in the fields of software assurance and RISK ASSESSMENT techniques as well as the rapid evolution of this discipline.

要求已减至对确保基本安全和基本性能至关重要的要求。这样做是为了确认软件保证和风险评估技术领域的广泛和不断增长的文献，以及这一学科的快速的发展。

Subclause 第14.1款-概述

14.1

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General

This standard requires the application of a RISK MANAGEMENT PROCESS in accordance with ISO 14971. This is particularly relevant to PEMS, because of the difficulty of showing the correctness of software or complex hardware. Therefore the design of a PEMS has to be performed within a RISK MANAGEMENT PROCESS, in which RISK CONTROL measures are related to the RISKS being controlled. For a software PESS, the software safety requirements from subclause 4.3 of IEC 62304:2006 and the software RISK MANAGEMENT requirements from Clause 7 of IEC 62304:2006 are included. If the application of ISO 14971 RISK MANAGEMENT shows that a PESS has the potential to contribute to a HAZARDOUS SITUATION, and non-software RISK CONTROL measures external to the PESS have not reduced the RISK to an acceptable level, Clause 14 adds extra RISK MANAGEMENT and life-cycle PROCESSES for the PEMS. 本标准要求应用符合ISO 14971的风险管理流程。这与PEMS尤其相关，因为很难显示软件或复杂硬件的正确性。因此，PEMS的设计必须在风险管理过程中进行，其中风险控制措施与所控制的风险相关。对于软件PESS，包括IEC 62304:2006第4.3款的软件安全要求和IEC 62304:2006第7条中的软件风险管理要求。如果ISO 14971风险管理的应用表明PESS有可能导致危险情况，并且PES外部的非软件风险控制措施没有将风险降低到可接受的水平，则第14条增加了PEMS的额外风险管理和生命周期过程。

Compliance VERIFICATION requires the MANUFACTURER'S internal assessment to cover not only the requirements of this clause but also those of ISO 14971 IEC 62304 that have been included by reference.

合规性验证要求制造商的内部评估不仅包括本条款的要求，还包括ISO 14971 IEC 62304中引用的要求。

Compliance with the requirements of Clause 14 is judged by examining the documentation produced by the PROCESSES required in the various subclauses. Clause 14 should be applied as a whole and not selectively. All of this documentation is required to be in the RISK MANAGEMENT FILE. 是否符合第14条的要求是通过检查各子条款中要求的过程产生的文件来判断的。第14条应作为一个整体而不是选择性地适用。所有这些文件都必须在风险管理文件中。

The concept of assessment has been introduced in the compliance statement to allow for methods other than inspection where necessary, such as audit. Thus, although there is no general requirement for the MANUFACTURER to operate a quality management system in accordance with ISO 13485 [30], certain features of such a system are necessary. One feature that is commonly regarded as essential for a quality management system to be effective is a PROCESS of audit and review performed within the organisation to confirm that it is actually following its own PROCEDURES; this

is separate from any external assessment that could be performed to demonstrate compliance with standards or regulatory requirements. This standard, therefore, requires that the MANUFACTURER not only document certain aspects of the design PROCESS but also carry out an assessment to confirm that the requirements of this clause have been followed. 在合规声明中引入了评估的概念，以便在必要时采用检查以外的方法，例如审计。因此，尽管制造商没有按照ISO 13485[30]运行质量管理体系的一般要求，但此类体系的某些特征是必要的。通常认为质量管理体系有效的一个重要特征是在组织内部进行的审核和审核过程，以确认其确实遵循了自己的程序；这与为证明符合标准或监管要求而进行的任何外部评估是分开的。因此，本标准要求制造商不仅记录设计过程的某些方面，还应进行评估，以确认已遵守本条的要求。

Subclause
第14.2款-文件

14.2

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Documentation

The expected way by which compliance with PROCESS requirements can be determined is by assuring that the documentation required for each PROCESS step has been generated. While most of the requirements of ISO 14971 4.2 are crucial components of an adequate software life-cycle, Clause 14 contains many additional PROCESS steps not required by that standard 确定是否符合过程要求的预期方法是确保每个过程步骤所需的文件已生成。虽然ISO 14971 4.2的大多数要求是适当软件生命周期的关键组成部分，但第14条包含了该标准不要求的许多附加过程步骤

4.2. Therefore, the documentation that these additional PROCESS steps (in Clause 14) require is necessary for a certification body to determine that the PROCESS steps have been performed. 4.2条。因此，认证机构有必要提供这些附加工艺步骤（第14条）要求的文件，以确定工艺步骤是否已执行。

Because Clause 14 addresses those RISKS associated with PEMS, this documentation is required to be included in part of the RISK MANAGEMENT FILE. PEMS第14条要求将这些风险纳入文件中，因为这些风险属于文件的一部分。

Since compliance with Clause 14 is determined by inspection and assessment to assure that the required documentation has been generated, the quality and accuracy of these documents 由于符合第14条的情况是通过检查和评估来确定的，以确保所需的文件已经生成，这些文件的质量和准确性

is important. Because demonstration of the safety of a PEMS depends on documentation, an effective system is needed to ensure the integrity of the documentation and, if different versions of a document exist, to identify the applicability of each version. Therefore it is required that the documents be generated, revised and maintained under a formal document control system. MANUFACTURERS should assure that this documentation is clear and comprehensive to assist in the assessment PROCESS.

很重要。由于PEMS安全性的证明取决于文件，因此需要一个有效的系统来确保文件的完整性，如果存在不同版本的文件，则需要确定每个版本的适用性。因此，要求在正式的文件控制系统下生成、修订和维护文件。制造商应确保该文件清晰、全面，以协助评估过程。

Subclause 14.3 – RISK MANAGEMENT plan

第14.3款-风险管理计划

ISO 14971 Subclause 4.2.2 requires that a RISK MANAGEMENT plan be prepared and maintained in the RISK MANAGEMENT FILE.

ISO 14971第4.2.2款要求在风险管理文件中编制和维护风险管理计划。

In addition to elements of the RISK MANAGEMENT plan required by ISO 14971 4.2.2, a PEMS VALIDATION plan is required because validation is seen as a necessary activity when developing a PEMS.

除了ISO 14971 4.2.2要求的风险管理计划要素外，还需要PEMS验证计划，因为在开发PEMS时，验证被视为一项必要的活动。

Subclause 14.4 – PEMS DEVELOPMENT LIFE-CYCLE

第14.4款——PEMS开发生命周期

A documented life-cycle helps ensure that safety issues are considered throughout a product's development. This is important for all products and it is vital for PEMS. Safety cannot be added to a PEMS after it has been developed. Two reasons for this are as follows. 记录的生命周期有助于确保在产品开发过程中考虑到安全问题。这对所有产品都很重要，对质子交换膜至关重要。PEMS开发完成后，不能添加安全性。原因如下。

- a) The actual PROCESSES used in the development of a PEMS, and the quality and rigour of those PROCESSES, are decided as a result of RISK ASSESSMENT. If it is discovered later on that inappropriate PROCESSES were used or that inadequate quality and rigour were applied, then the development will have to be repeated with correct PROCESSES.

PEMS开发过程中使用的实际过程，以及这些过程的质量和严格性，都是由风险评估决定的。如果后来发现使用了不适当的过程，或者应用了不适当的质量和严格性，则必须用正确的过程重复开发。

- b) Changes made at a late stage in the PEMS DEVELOPMENT LIFE-CYCLE are likely to be expensive (both in time and money). This is particularly true if a system requirement is incorrect or missing. System architecture can also be vulnerable to late changes. Often, the architecture is part of the safety case. Late changes can require significant rework in order to maintain the integrity of an architectural solution. 在PEMS开发生命周期的后期阶段所做的更改可能会很昂贵（包括时间和金钱）。如果系统需求不正确或缺失，这一点尤其正确。系统架构也容易受到后期更改的影响。通常，架构是安全案例的一部分。为了保持架构解决方案的完整性，后期更改可能需要大量的返工。

Framework

框架

A life-cycle for the development of a product provides a framework that allows the necessary safety activities to take place in a timely and systematic manner. It should not impose unnecessary restrictions and it should ensure that all the required safety activities take place. The life-cycle needs to be decided early. Different life-cycle models are acceptable. Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLES in more detail. IEC 62304 [26] Clauses 5, 7, 8 and 9 of IEC 62304:2006 describe the PROCESSES to be included in the software development life-cycle for the

development of safe medical device software. 产品开发生命周期提供了一个框架，允许及时和系统地进行必要的安全活动。不应施加不必要的限制，并应确保进行所有必要的安全活动。生命周期需要尽早决定。不同的生命周期模型是可以接受的。第H.2条更详细地解释了PEMS开发生命周期。IEC 62304[26]IEC 62304:2006第5、7、8和9条描述了安全医疗设备软件开发的软件开发生命周期中应包括的过程。

Milestones and activities

里程碑和活动

The requirement for milestones, and activities with inputs and outputs for each, ensures that due consideration is given to:

对里程碑的要求，以及每项活动的输入和输出，确保适当考虑：

- the activities, 活动，
 - what needs to be done before the activity can start, and 在活动开始之前需要做些什么，以及
 - what the activity needs to provide, 活动需要提供什么，
- so that VERIFICATION of the results can be performed. 以便对结果进行验证。

The sequence of activities in the life-cycle is required to be defined in terms of milestones because this offers the greatest flexibility to the MANUFACTURER. No requirement is made concerning the number or nature of the milestones, nor is there any implication that all project activities have to pass through the milestones simultaneously. This standard has not used the term “phases” although this term was used in IEC 60601-1-4 [14]. The term has been avoided because it is difficult to express concurrency and overlap in a phase model. 生命周期中的活动顺序需要根据里程碑来定义，因为这为制造商提供了最大的灵活性。对里程碑的数量或性质没有要求，也没有暗示所有项目活动必须同时通过里程碑。尽管IEC 60601-1-4[14]中使用了术语“相位”，但本标准并未使用该术语。这个术语被避免了，因为在阶段模型中很难表达并发和重叠。

In a good life-cycle:
在良好的生命周期中：

- the necessary activities are defined in advance of their performance;
必要的活动在其执行之前被定义；
- the PROCESSES used in development activities could be specified as an outcome of RISK MANAGEMENT;
开发活动中使用的过程可以被指定为风险管理的结果；
- the sequence of activities is defined so as to ensure that necessary inputs to an activity are available before the activity starts;
活动顺序的定义是为了确保在活动开始之前，对活动的必要输入是可用的；
- criteria are defined for deciding whether the activity has been satisfactorily completed; and
确定了确定活动是否圆满完成的标准；以及
- accountability is facilitated.
促进问责制。

Activities are defined in terms of inputs and outputs because it is simple to measure whether those inputs and outputs exist. The MANUFACTURER is responsible for deciding how the milestones are achieved and how the required documentation is produced. 活动是根据输入和输出定义的，因为测量这些输入和输出是否存在很简单。制造商负责决定如何实现里程碑以及如何生成所需的文件。

In order to determine whether each activity has been satisfactorily completed, it is required that the criteria for VERIFICATION of each activity be defined. VERIFICATION examines whether the inputs have been transformed into the outputs completely, correctly and according to the required PROCESS. No requirement is made concerning the type or extent of VERIFICATION, except for VERIFICATION of RISK CONTROL measures and ESSENTIAL PERFORMANCE (see 14.10). 为了确定每项活动是否圆满完成，需要确定每项活动的验证标准。验证检查输入是否已完全、正确地按照要求的过程转换为输出。除了对风险控制措施和基本性能的验证（见14.10），对验证的类型或范围没有任何要求。

Subclause 14.5 – Problem resolution **第14.5款-问题解决**

Where appropriate, a documented system for problem resolution is required by this standard.

Problems can arise:

在适当的情况下，本标准要求有一个解决问题的文件系统。可能会出现问题：

- with the product;
使用产品；
- within a PROCESS;
在一个过程中；
- between PROCESSES.
进程之间。

Examples

of

problems

are:

问题的例子有：

- inconsistent requirements;
要求不一致；
- ambiguous requirements;
要求不明确；
- missing specifications;
缺少规格；
- coding errors;
编码错误；
- incorrect operation of the PEMS.
PEMS操作不正确。

A system for problem resolution is needed to ensure that when a problem arises, its impact on HAZARDS and their consequent RISK is managed. Ad hoc methods for resolving problems can undermine the benefits obtained by using a systematic life-cycle approach. An appropriate place to document the system for problem resolution is as part of the PEMS DEVELOPMENT LIFE- CYCLE. 当问题出现时，需要对其风险进行管理，以确保问题对系统产生影响。解决问题的临时方法可能会损害使用系统生命周期方法所获得的好处。记录系统解决问题的适当地方是作为PEMS开发生命周期的一部分。

Subclause 14.6.1 – Identification of known and foreseeable HAZARDS
第14.6.1款-已知和可预见危险的识别

PEMS have extra initiating causes for HAZARDS.
质子交换膜对危险有额外的始发原因。

Subclause14.6.2–RISKCONTROL

第14.6.2款-风险控制

As the choice of the PROCEDURES and tools used by a MANUFACTURER for the development of a PEMS will be influenced by many factors, this subclause requires that one of the factors for the choice is the RISK reduction required for the RISK CONTROL measure. A RISK CONTROL measure that is developed using PROCEDURES and tools that are known to be good is more likely to carry out its intended functions than one developed using PROCEDURES and tools that are of unknown quality. 由于制造商用于开发PEMS的程序和工具的选择将受到许多因素的影响，本款要求选择的因素之一是风险控制措施所需的风险降低。使用已知良好的程序和工具制定的风险控制措施比使用质量未知的程序和工具制定的风险控制措施更有可能实现其预期功能。

Subclause14.7–Requirement specification

第14.7款-需求规范

RISK CONTROL measures are used to control the RISK of identified HAZARDS. The requirements for these measures are documented in requirement specifications. The requirement should both specify what the measure does and how well it does it. ISO 14971 Subclause 4.2 does not demand a requirements specification. 风险控制措施用于控制已识别危险源的风险。这些措施的要求记录在需求规范中。需求应该同时说明度量的作用以及度量的效果。ISO 14971子条款4.2不要求要求规范。

Verifiable requirements

可验证要求

Requirements should be verifiable. This applies to both the function of the RISK CONTROL measure and how likely it is to perform correctly. Quantitative VERIFICATION of failure rates is, generally, impractical for software. VERIFICATION of a qualitative approach would be by verifying that the appropriate PROCESSES were used. 需求应该是可验证的。这既适用于风险控制措施的功能，也适用于其正确执行的可能性。对于软件来说，失效率的定量验证通常是不切实际的。定性方法的验证将通过验证是否使用了适当的过程。

Identifiable safety requirements

可识别的安全要求

The requirement to distinguish the RISK CONTROL measures and ESSENTIAL PERFORMANCE is needed to ensure that they are implemented and to ensure that if there is a need to change the ESSENTIAL PERFORMANCE or a RISK CONTROL measure, the impact of the change on the RESIDUAL RISK can be assessed. 需要区分风险控制措施和基本绩效，以确保它们得到实施，并确保如果需要改变基本绩效或风险控制措施，可以评估变更对剩余风险的影响。

Decomposition

分解

Examples of a PEMS structure are shown in Annex H. Requirements to implement the RISK CONTROL measures should be specified for the PEMS and for any PESS that implements or partially implements one or more RISK CONTROL measure. This can be in a single document or in several documents. 附录H中给出了PEMS结构的示例。应为PEMS和实施或部分实施一项或多项风险控制措施的PES规定实施风险控制措施的要求。这可以在一个文档中，也可以在多个文档中。

Subclause14.8–Architecture

第14.8款-建筑

An architecture specification is not required by ISO 14971 4.2. It is an additional requirement for PEMS because: ISO 14971 4.2不要求体系结构规范。这是PEMS的附加要求，因为：

- often the architecture chosen will be part of a RISK CONTROL measure. RISK CONTROL 通常，选择的架构将是风险控制措施的一部分。风险控制 measures need to be explicit for complex systems such as a PEMS;

对于复杂系统，如PEMS，需要明确的措施；

- architecture specifications are recognized as a necessary part of a good software development PROCESS such as is required for a PEMS.

架构（architecture）规范被认为是良好软件开发过程（如PEMS所需）的必要组成部分。

There is a list of architecture features for inclusion in the specification where appropriate. This list has been selected because in particular circumstances one or more of the features could be used to control the RISK of a HAZARD. For example, the use of a COMPONENT WITH HIGH- INTEGRITY CHARACTERISTICS will effectively remove any RISK that would result from the failure of that component.

在适当的情况下，规范中有一个体系结构特性列表。选择此列表是因为在特定情况下，一个或多个特征可用于控制危险的风险。例如，使用具有高完整性特征的组件将有效地消除由于该组件的故障而导致的任何风险。

Subclause 第14.8 e) 款

14.8

e)

Partitioning of functionality can be useful when there is a significant need for rigorous safety validation of PEMS.

当需要对PEMS进行严格的安全验证时，功能分区是有用的。

The software (firmware and application layers) is distinctly divided into critical, non-critical and supervisory sections. Partitioning is used so that the instructions and data of the critical, non-critical and supervisory sections do not interfere with each other and that there is separation of duties among the sections of the software. If there is no separation of duties
软件（固件和应用程序层）分为关键、非关键和监控部分。使用分区，以便关键、非关键和监控部分的指令和数据不会相互干扰，并且软件各部分之间的职责分离。如果没有职责分离

among the sections of the software, all software should be defined as critical, to make sure that the analysis has taken into consideration the critical section of the software.

在软件的各个部分中，所有软件都应定义为关键部分，以确保分析考虑到了软件的关键部分。

Requirements for separating critical code from non-critical code include RISK ASSESSMENT of the entire system, RISK CONTROL strategies employed, analysis of physical resources and an analysis of logical properties (e.g., control and data coupling). In general, partitioning should separate and isolate the safety-related functionality from the non-safety-related functionality in the design and implementation. This PROCESS can minimize, or at least reduce, the VERIFICATION necessary to assure that data shared by or passed to the critical section does not affect the specified operation of the safety critical code.

将关键代码与非关键代码分离的要求包括整个系统的风险评估、采用的风险控制策略、物理资源分析和逻辑属性分析（例如，控制和数据耦合）。一般来说，分区应该在设计和实现中将安全相关功能与非安全相关功能分开并隔离。至少可以减少或不影响关键程序的安全性。

Partitioning includes the following steps:

分区包括以下步骤：

a) identification of critical, non-critical and supervisory sections. The means of identification depends upon the modularity of the code, the programming language, the code design and other specification attributes; 关键、非关键和监管部门的识别。识别方法取决于代码的模块性、编程语言、代码设计和其他规范属性；

b) description of the interfaces between the critical and non-critical sections:

关键和非关键部分之间的接口说明：

1) identification of data or variables global to the critical and non-critical sections, modules, etc., identified in step a); 识别步骤a中确定的关键和非关键部分、模块等的全局数据或变量；

2) identification of any parameters that are passed between critical and non-critical sections, modules, etc., identified in step a); 识别在步骤a中确定的关键和非关键部分、模块等之间传递的任何参数；

3) description of the flow of the data, variables or parameters identified in steps b) 1) and b) 2); 描述步骤b) 1) 和b) 2) 中确定的数据、变量或参数的流程；

4) description of the mechanism which is used to prevent data corruption, overwriting or other errors of the above identified data, variables or parameters which would affect safety critical performance; 用于防止上述数据、变量或参数的数据损坏、覆盖或其他错误，从而影响安全关键性能的机制说明；

c) validation of the integrity of the partition. This can be accomplished by functional testing and stress testing techniques.

验证分区的完整性。这可以通过功能测试和压力测试技术来实现。

Subclause 14.8 g) to n)

第14.8 g) 至n) 款

There is a list of items to be taken into consideration in the architecture specification. This list has been selected because each of these items could influence the choice of architecture.

架构（architecture）规范中有一个要考虑的项目列表。之所以选择此列表，是因为这些项目中的每一项都可能影响体系结构的选择。

Subclause 14.9 – Design and implementation

第14.9款-设计和实施

The technical solutions chosen need to be defined. It is often appropriate to decompose a PEMS

into subsystems. Figure H.1 shows examples of PEMS/ PESS structures with different amounts of decomposition. Reasons for decomposing a PEMS could include the following. 需要确定所选的技术解决方案。将PEMS分解为子系统通常是合适的。图H.1显示了具有不同分解量的PEMS/PESS结构示例。分解PEMS的原因可能包括以下几个方面。

Keeping the complexity of subsystems manageable

保持子系统复杂性的可控性

The less complex the system the easier it is to understand and consequently easier to design and then maintain. The resulting design is more likely to be correct and easier to test. Coding standards should specify limits for complexity. 系统越不复杂，就越容易理解，从而更容易设计和维护。最终的设计更可能是正确的，更容易测试。编码标准应规定复杂性的限制。

Architecture

建筑

The system architecture could make it logical to separate systems e.g. if diverse systems are needed they should be implemented as distinct subsystems.

系统架构可以使分离系统成为逻辑，例如，如果需要不同的系统，它们应该作为不同的子系统来实现。

Modularity

模块化

Modularity can facilitate the provision of different system options, reuse of an existing proven subsystem and the extension of system functionality.

模块化有助于提供不同的系统选项、重用现有的经验证的子系统和扩展系统功能。

Physical
物理部件

components

A sensible division of physical subsystems will help the diagnosis and repair of hardware faults.
物理子系统的合理划分将有助于硬件故障的诊断和修复。

Different
不同的技术

technologies

Often different engineers will implement the hardware and the software design. In this case specifying each as a separate subsystem will enable each to be implemented independently.
通常不同的工程师将实施硬件和软件设计。在这种情况下，将每个子系统指定为单独的子系统将使每个子系统能够独立实现。

The overall system will only function correctly if each of its constituent subsystems has been adequately specified. This leads to the requirement for a design specification for each subsystem. A design specification for a subsystem would typically include a detailed interface specification, and could include implementation details, e.g. algorithms.
只有当每个组成子系统都得到充分规定时，整个系统才能正常工作。这就需要为每个子系统制定设计规范。子系统的设计规范通常包括详细的接口规范，也可能包括实现细节，例如算法。

Each subsystem should be tested to show that the design specification has been correctly implemented. This leads to the requirement for a test specification for each subsystem.
应测试每个子系统，以证明设计规范已正确实施。这就需要为每个子系统制定一个测试规范。

The design and test specifications can be documented in whatever form is practicable, e.g. they can be separate documents or they can be combined in a larger document. The design specification and the test specification for each subsystem should be identifiable.
它们可以单独记录在设计文件中，也可以是更大的文件。每个子系统的设计规范和测试规范应是可识别的。

Examples of the elements of the design environment are given in H.4 a). Such elements will have an influence on the quality and correctness of the design. Some elements will have been identified as the suitably validated tools and PROCEDURES (see 14.6.2). The descriptive data regarding the design environment facilitates VERIFICATION that the suitably validated tools and PROCEDURES have been used.
H.4a) 中给出了设计环境元素的示例。这些元素将对设计的质量和正确性产生影响。一些要素将被确定为经过适当验证的工具和程序（见14.6.2）。有关设计环境的描述性数据有助于验证是否使用了适当验证的工具和程序。

Subclause
第14.10款-验证

14.10

—

VERIFICATION

ISO 14971 Subclause 4.2 requires VERIFICATION of RISK CONTROL measures. There are additional requirements for PEMS. These are that:
ISO 14971子条款4.2要求验证风险控制措施。PEMS还有其他要求。这些是：

- the ESSENTIAL PERFORMANCE is verified; and
基本性能得到验证；以及
- there is a VERIFICATION plan.
有一个验证计划。

ESSENTIAL PERFORMANCE is significant for PEMS because the PEMS uses a PESS to control its functions. ESSENTIAL PERFORMANCE will often depend on the PEMS functions being carried out correctly.
由于PEMS使用PESS来控制其功能，因此PEMS的基本性能非常重要。基本性能通常取决于PEMS功能的正确执行。

A VERIFICATION plan leaves it up to the MANUFACTURER how to achieve the requirements of this clause. This is a better and more flexible approach than specifying how to verify a PEMS in this clause. The MANUFACTURER is responsible for planning the VERIFICATION so that it is adequately

thorough and then to implement the plan.
验证计划由制造商决定如何达到本条款的要求。这是一种比在本条款中指定如何验证PEMS更好、更灵活的方法。制造商负责计划验证，使其充分彻底，然后实施计划。

The requirement lists activities that affect the thoroughness of the VERIFICATION and which need to be planned.
需求列出了影响验证的彻底性和需要计划的活动。

Subclause 14.11 — PEMS VALIDATION
第14.11款——PEMS验证

The final phase of any PEMS DEVELOPMENT LIFE-CYCLE model is PEMS VALIDATION. PEMS VALIDATION is intended to assure that the right product is built. Validation is important for PEMS because unexpected interactions between functions might occur that can only be discovered by validation.
任何PEMS开发生命周期模型的最后一个阶段是PEMS验证。PEMS验证旨在确保制造出正确的产品。验证对于PEMS很重要，因为函数之间可能会发生只有验证才能发现的意外交互。

PEMS VALIDATION can include tests for a high volume of data, heavy loads or stresses, human factors, security, performance, configuration compatibility, fault testing, documentation and safety. PEMS验证可以包括对大量数据、重载或压力、人为因素、安全性、性能、配置兼容性、故障测试、文档和安全性的测试。

Independence is needed to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the PEMS VALIDATION. Examples of level of independence include:

独立性是避免利益冲突的必要条件，因为设计者的假设不应影响或限制PEMS验证的范围。独立程度的例子包括：

- separate person;
独立人员；

- separate management;
分开管理;
- separate organization.
独立组织。

Subclause 14.12 - Modification
第14.12款-修改

Typically the design of a PEMS is not completely new but is partly or even largely derived from earlier design(s). Nevertheless, it might be possible to treat the design as if it were completely new and to establish the RISK MANAGEMENT report and demonstrate compliance with the requirements of this standard without reference to previous documentation. If however the RISK MANAGEMENT report does need to include some information from the documentation of the previous design(s), it is then necessary to confirm that all such information remains valid despite the changes introduced in the new design.

通常，PEMS的设计并不是全新的，而是部分甚至大部分源于早期的设计。然而，可以将设计视为全新设计，并建立风险管理报告并证明符合本标准的要求，而无需参考先前的文件。但是，如果风险管理报告确实需要包括先前设计文件中的一些信息，则有必要确认，尽管新设计中引入了变更，但所有此类信息仍然有效。

Subclause 14.13 – Connection of a PEMS by NETWORK/DATA COUPLING to other equipment PEMS intended to be incorporated into an IT-NETWORK
第14.13款-通过网络/数据耦合将PEMS连接至拟并入IT网络的其他设备PEMS

Many hospitals are operating ME EQUIPMENT in a networked environment today. Originally, these networks IT-NETWORKS were installed to optimize business economic and technical area. For this, a fast electronic data interchange is required. Today, these networks IT- NETWORKS are used for medical applications within the hospital, between hospitals, and from home.

如今，许多医院都在网络环境中操作医用电气设备。最初，这些网络的安装是为了优化商业经济和技术领域。为此，需要快速的电子数据交换。今天，这些网络IT网络被用于医院内部、医院之间和家庭中的医疗应用。

Initially, the use was only the exchange of laboratory data. Now there are large amounts of data transported over the networks IT-NETWORKS, such as medical image data. There are further requests from the user to get “real time” solutions (e.g. control of operation robots via network an IT-NETWORK).

最初，这种用途只是交换实验室数据。现在有大量的数据通过IT网络传输，比如医学图像数据。用户还要求获得“实时”解决方案（例如，通过网络和IT网络控制操作机器人）。

Additional guidance on NETWORK/DATA COUPLING incorporation of a PEMS into an IT-NETWORK is found in Annex H.

关于将PEMS并入IT网络的网络/数据耦合的附加指南见附录H。

Subclause 15.1– Arrangements of controls and indicators of ME EQUIPMENT
第15.1款-医用电气设备控制装置和指示器的布置

Controls, instruments, indicating lamps, etc. that are associated with a specific function of the ME EQUIPMENT should be grouped together.

与特定功能相关的控制装置、仪表、指示灯等医用电气设备应组合在一起。

Subclause 15.2 - Serviceability
第15.2款-可用性

The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not create a HAZARD result in a HAZARDOUS SITUATION. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

这种零件的交换预计很容易进行，最好不用特殊工具。此外，拆卸磨损零件或预防性更换零件和装配备

用零件时，不应造成危险，导致危险情况。为确保这一点，执行此类活动的说明必须易于理解和遵循，而不会带来任何混淆的风险。

Subclause
第15.3.2款-推压试验

15.3.2

–

Push

test

ENCLOSURES need to have adequate rigidity if they are to maintain a level of protection from internal live parts. This requirement is harmonized with the force test of IEC 60950-1. The force is dependent on the person handling the ME EQUIPMENT, not the weight of the ME EQUIPMENT. In most cases, the application of a force of 250 N is considered reasonably foreseeable. However there can be cases where a RISK ASSESSMENT finds that the 45 N force applied over an area of 625 mm², as required by the second edition of this standard, would continue to be an acceptable VERIFICATION method for determining an acceptable level of RISK. For example, ultrasound transducers and similar small HAND-HELD APPLIED PARTS, which balance the needs of robustness with other needs relating to efficacy and biocompatibility, have established track RECORDS of safety and effectiveness over many years, and therefore could continue to use the older VERIFICATION test.

如果外壳要保持内部带电部件的防护等级，则需要有足够的刚度。本要求与IEC 60950-1的力试验一致。力取决于操作医用电气设备的人员，而不是医用电气设备的重量。在大多数情况下，施加250 N的力被认为是可以合理预见的。然而，风险评估发现，按照本标准第二版的要求，施加在625 mm²面积上的45 N力将继续是确定可接受风险水平的可接受验证方法。例如，超声换能器和类似的小型手持应用部件，在稳健性需求与其他功效和生物相容性相关需求之间取得了平衡，多年来已经建立了安全性和有效性的跟踪记录，因此可以继续使用较旧的验证测试。

Internal components are not subjected to the force test of IEC 60950-1 because their robustness is verified per the tests of 15.3.4 and 15.3.5.
内部组件不需要进行IEC 60950-1的力测试，因为其坚固性根据15.3.4和15.3.5的测试进行了验证。

Subclause	15.3.3	-	Impact	test
第15.3.3款-冲击试验				

An ENCLOSURE'S resistance to impact is required to prevent unacceptable RISK during reasonably foreseeable misuse. The energy of the test impact approximates ME EQUIPMENT being accidentally struck by an object in the hand of a passer-by or by a broomstick or mop handle during cleaning of the floor. The test equipment has been simplified and harmonized with other standards containing ENCLOSURE impact requirements, including IEC 60950-1. 外壳应具有抗冲击性，以防止在合理可预见的误用期间出现不可接受的风险。试验冲击的能量相当于设备在清洁地板时被过路人手中的物体或扫帚或拖把柄意外击中。试验设备已简化并与包含外壳冲击要求的其他标准（包括IEC 60950-1）协调一致。

Where a MANUFACTURER feels the requirements of this subclause are not necessary to mitigate an unacceptable RISK, justification is documented in the RISK MANAGEMENT FILE per 4.5, along with an identification of alternate requirements met. For example, FIXED ME EQUIPMENT can have one side of the ENCLOSURE protected by the floor, wall or ceiling. The MANUFACTURER documents the evaluation of the probability that the ME EQUIPMENT could be moved or installed incorrectly. The MANUFACTURER also evaluates and identifies, through the RISK MANAGEMENT PROCESS, what resistance to impact the protected side of the ENCLOSURE needs to have to ensure no unacceptable RISKS are generated by failure to comply with the original requirements of this subclause. 如果制造商认为本款的要求对于降低不可接受的风险是不必要的，则应按照4.5的规定，在风险管理文件中记录理由，并确定满足的替代要求。例如，固定式医用电气设备外壳的一侧可由地板、墙壁或天花板保护。制造商记录医用电气设备移动或安装不正确的可能性评估。制造商还通过风险管理过程评估和确定外壳受保护侧的抗冲击能力，以确保不因未遵守本子条款的原始要求而产生不可接受的风险。

Subclause	15.3.4	-	Drop	test
第15.3.4款-跌落试验				

The tests for HAND-HELD ME EQUIPMENT or its parts that are hand held are different from the test for PORTABLE and MOBILE ME EQUIPMENT because of the difference in practical application. 手持式医用电气设备或其部件的试验因其实际应用的不同而不同于便携式和移动式医用电气设备的试验。

A drop surface of wood of density > 600 kg/m³ allows selection of most common hardwoods. Oak, beech, birch, ash and maple are acceptable. These varieties have similar hardness while hardwoods of density < 600 kg/m³ (e.g. mahogany, elm, sweet gum, cherry) and softwoods have greatly decreased hardness in comparison. 密度>600 kg/m³的木材下落面允许选择最常见的硬木。橡树、山毛榉、桦树、白蜡和枫木均可。这些品种具有相似的硬度，而密度<600 kg/m³的硬木（如红木、榆树、甜胶、樱桃木）和软木的硬度则大大降低。

Subclause	15.3.4.2	-	PORTABLE	ME	EQUIPMENT
第15.3.4.2款-便携式医用电气设备					

This test represents NORMAL USE, as explained in the rationale for 15.3.5. This test is not intended to represent reasonably foreseeable misuse. There is not currently a test that directly addresses free fall type reasonably foreseeable misuse, however it is felt the ball impact test in 15.3.3 represents foreseeable misuse, albeit indirectly. As stated in 4.2, if the RISK MANAGEMENT PROCESS concludes that a more severe test is appropriate, this should be done. 如15.3.5的基本原理所述，本试验代表正常使用。本试验不代表可合理预见的误用。目前还没有一个测试可以直接解决自由落体类型的合理可预见的误用，但是可以认为15.3.3中的球击测试代表了可预见的误用，尽管是间接的。如4.2所述，如果风险管理过程得出结论认为更严格的测试是适当的，则应这样做。

Subclause	15.3.5	-	Rough	handling	test
第15.3.5款-粗暴搬运试验					

Contrary to what is often assumed, ME EQUIPMENT can be used in a hostile environment. In case of emergency, ME EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators

and subjected to bumps and vibration. Such conditions can in fact typify NORMAL USE for some ME EQUIPMENT. Encountering obstacles is considered commonplace and quite reasonably foreseeable misuse. Not all obstacles are clearly marked and the OPERATOR cannot always stop the ME EQUIPMENT in time after having become aware of the obstacle
与通常的假设相反，医用电气设备可以在恶劣的环境中使用。在紧急情况下，医用电气设备被用手推车抬过门阶和电梯，并受到撞击和振动的影响。这种情况实际上可以代表某些医用电气设备的正常使用。遇到障碍被认为是司空见惯的，而且相当可预见的滥用。并非所有的障碍物都有明确的标记，而且操作员在意识到障碍物后不能及时停止医用电气设备

The test requirements of 15.3.5 are meant to judge resistance to rough handling, and not stability. Stability test requirements for MOBILE ME EQUIPMENT are in 9.4.
15.3.5中的试验要求旨在判断对粗暴操作的耐受性，而不是稳定性。移动医用电气设备的稳定性试验要求见9.4。

The 0,8 m/s speed together with the severity of the obstacles chosen, are considered to represent worst case reasonably foreseeable misuse levels of stress/shock energies. The intent of tis test is to ascertain the risks from damage caused by rough handling shock/stress. Instability is evaluated in 9.4.
0.8 m/s的速度和所选障碍物的严重程度被认为是最坏情况下可合理预见的应力/冲击能量误用水平。tis试验的目的是确定粗暴搬运冲击/应力引起的损坏风险。不稳定性在9.4中进行了评估。

The meaning of “in its normal direction of travel” is the direction(s) the ME EQUIPMENT is likely to travel at the maximum normal speed. For most cases, this would be the forward direction. Some ME EQUIPMENT, such as a bed, is likely to travel in a forward or backward direction, at normal speed, and therefore each test should be considered for each direction.
“正常行驶方向”是指医用电气设备可能以最大正常速度行驶的方向。在大多数情况下，这将是前进的方向。一些医用电气设备（如床）可能以正常速度向前或向后移动，因此应考虑每个方向的每次试验。

Subclause 15.3.6 – Mould stress relief test**第15.3.6款-模具应力消除试验**

Many thermoforming PROCESSES can leave residual stresses in plastics. Because polymer chains are held together by weak van der Waals bonds, these residual stresses can result in viscous flow (deformation). Elevated temperature results in weakening of van der Waals bonds and an increase in the rate of viscous flow. Thermoplastics with low melting temperatures, such as polyethylene and polypropylene, are more susceptible to stress relief deformation than polymers with higher melting temperatures, such as polycarbonate and polyetheramide. 许多热成型工艺会在塑料中留下残余应力。因为聚合物链是由弱范德华键连接在一起的，这些残余应力会导致粘性流动（变形）。温度升高导致范德华键减弱，粘性流动速率增加。熔融温度较低的热塑性塑料（如聚乙烯和聚丙烯）比熔融温度较高的聚合物（如聚碳酸酯和聚醚酰胺）更容易发生应力消除变形。

Compliance should be verified by analysis of the polymer properties, when possible. This VERIFICATION should consist of a documented comparison of the maximum temperature the polymer will be exposed to in NORMAL USE and the polymer manufacturer's recommended temperature use range.

如有可能，应通过分析聚合物性能来验证合规性。该验证应包括对聚合物在正常使用过程中暴露于的最高温度和聚合物制造商建议的温度使用范围进行记录比较。

Subclause 15.3.7 – Environmental influences**第15.3.7款-环境影响**

a) ME EQUIPMENT is often used or stored in environmental conditions that are within the INTENDED USE as declared by the MANUFACTURER. In such cases no HAZARD is expected. However the environmental conditions could differ from those declared and still the ME EQUIPMENT is expected to remain safe. To ensure this, the RESPONSIBLE ORGANISATION has to perform the periodic inspection and maintenance prescribed by the MANUFACTURER. These activities are expected to prevent any deterioration of the safety level and also detect signs of commencing of any such deterioration. To ensure this, the instructions for preventive maintenance have to be easy to understand and to follow, without introducing any RISK for mix-ups or for overlooking of safety-relevant symptoms. 医用电气设备通常在制造商声明的预期用途内的环境条件下使用或储存。在这种情况下，预计不会有危险。然而，环境条件可能与声明的不同，医用电气设备仍有望保持安全。为确保这一点，责任组织必须执行制造商规定的定期检查和维修。这些活动预计能防止安全水平的任何恶化，并能检测到任何此类劣化开始的迹象。为了确保这一点，预防性维护的说明必须易于理解和遵循，而不引入任何混淆风险或忽视安全相关症状。

b) The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not create a HAZARD. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up. 这种零件的交换预计很容易进行，最好不用特殊工具。此外，拆卸磨损零件或预防性更换零件和装配备用零件不应造成危险。为确保这一点，执行此类活动的说明必须易于理解和遵循，而不会带来任何混淆的风险。

c) Corrosion of metal to metal interfaces should be taken into account.
应考虑金属对金属界面的腐蚀。

Subclause 15.4.3 – Batteries**第15.4.3款-电池**

If a HAZARDOUS SITUATION might develop as a result of exhaustion of the battery, means should be provided to forewarn of this condition.

如果电池耗尽可能导致危险情况的发生，则应提供对这种情况进行预警的方法。

Where appropriate, particular standards should specify the corresponding requirement.

在适当的情况下，特殊标准应规定相应的要求。

Subclause 15.4.3.5 – Excessive current and voltage protection
5.5.4.3过电压保护

Subclause 4.7 requires the ME EQUIPMENT to be SINGLE FAULT SAFE. One possible fault could be the bridging of a CREEPAGE DISTANCE between the positive and negative terminals of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE and any protective device (see Figure A.23).
子条款4.7要求医用电气设备是单一故障安全的。一个可能的故障是内部电源正极和负极端子之间的爬电距离桥接
电源和任何保护装置（见图A.23）。

IEC 1426/12
IEC 1426/12标准

Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between
the
图A.23—操作员在
terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device
内部电源和后续保护装置的端子

A short circuit test would be required to demonstrate that this area is SINGLE FAULT SAFE
需要进行短路测试，以证明该区域是单一故障安全的
unless two MEANS OF OPERATOR PROTECTION are present. In that case, the test can be omitted.
除非有两种操作员保护措施。在这种情况下，可以省略测试。

Subclause 15.4.4 – Indicators
第4.4.15款

It is important for an OPERATOR and SERVICE PERSONNEL to be able to determine the functional status of ME EQUIPMENT. In NORMAL USE, the OPERATOR needs to be able to distinguish between ME EQUIPMENT in stand-by and ME EQUIPMENT in a fully functional state. Some ME EQUIPMENT has an extended warm-up period. Other ME EQUIPMENT has standby or battery charging modes.
操作员和维修人员能够确定医用电气设备的功能状态是很重要的。在正常使用中，操作员需要能够区分处于备用状态的医用电气设备和处于全功能状态的医用电气设备。一些医用电气设备的预热时间较长。其他医用电气设备有备用或电池充电模式。

It can be hazardous for ME EQUIPMENT to be left unattended in the wrong state. SERVICE PERSONNEL need to be able to determine when ME EQUIPMENT is energized to avoid HAZARDS.

在错误的状态下无人看管可能会对医用电气设备造成危险。维修人员需要能够确定医用电气设备何时通电以避免危险。

Subclause 15.4.7.3 – Entry of liquids
第15.4.7.3款-液体进入

The former IPX8 rating requirement for foot switches amounts to no more than “greater protection than IPX7.” By making this requirement IPX6 minimum, the requirement sets a defined level of protection while allowing higher levels where appropriate.
以前对脚踏开关的IPX8额定值要求不超过“比IPX7更高的保护”。通过将此要求设为最低IPX6，该要求规定了定义的保护等级，同时允许在适当的情况下提高防护等级。

For equipment used on the floor in areas where liquids are usually not found, the IPX1 requirement is included because it is considered extremely likely that some wetting will occur.

对于在通常找不到液体的区域地板上使用的设备，IPX1要求包括在内，因为它被认为极有可能发生一些湿润。

Subclause 15.5 – MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

第15.5款-医用电气设备的电源变压器和根据8.5提供隔离的变压器

The addition of “and transformers providing separation in accordance with 8.5” to the original title that only identified “Mains transformers” is intentional. The tests for transformers should be utilized any time that the transformer is used to establish separation between OPERATORS, PATIENTS, etc. and a HAZARD.

在原标题中添加“和根据第8.5条提供分离的变压器”是有意添加的，仅标识“电源变压器”。在使用变压器确定操作员、患者等与危险之间的隔离时，应使用变压器测试。

Revisions to 15.5 do not change significantly current methods (including those of the second edition of this standard) of testing. The methods and requirements were simplified and now include all different types of protectors like: PTCs, feedback control (switch mode power supplies), primary or secondary over-current devices, etc. Those transformers that have not been tested in accordance with the 5X frequency and 5X voltage tests of 15.5.2 to establish the adequacy of insulation between the turns of a winding that are shorted at the terminals (rather than external to the transformer) to assure that failure of that insulation will not cause maximum allowable temperatures to be exceeded. 对15.5的修订不会显著改变现行的试验方法（包括本标准第二版的方法）。方法和要求被简化，现在包括所有不同类型的保护器，如：PTC、反馈控制（开关电源）、一次或二次过电流装置，未按照15.5.2中的5倍频率和5倍电压试验进行试验的变压器，以确定在端子处（而不是变压器外部）短路的绕组匝间绝缘的充分性，以确保绝缘故障不会导致最大允许值超过温度。

Because of the difficulties that would be encountered when trying to test transformers that are RATED for high frequencies (such as those used in switch mode power supplies), the 2X frequency and voltage tests are specified in those cases as well. The second edition only applied this test where the voltage exceeded 500 V.
由于在测试额定高频变压器（如开关电源中使用的变压器）时会遇到困难，因此在这些情况下还规定了2X频率和电压测试。第二版只在电压超过500V的情况下进行此测试。

Subclause 15.5.1.1 – Transformers
第15.5.1.1款-变压器

Output windings are required to be “tested in turn” because under overload conditions, testing all windings simultaneously can cause over temperature devices to operate which would not operate if only one winding was being overloaded. A single output winding being overloaded is actually quite likely. Therefore this combination of conditions is considered the likely worst case scenario.
要求对输出绕组进行“轮流测试”，因为在过载条件下，同时测试所有绕组会导致过热装置运行，如果只有一个绕组过载，则不会运行。一个单一的输出绕组过载实际上是很有可能的。因此，这种情况组合被认为是最坏的情况。

The intent of the requirement is to test under the worst-case condition (nearly always with either a full load or no-load). Such a worst case can be determined through evaluation of the transformer design or by performing a few spot tests. Generally, testing all possible conditions to determine worst case is unnecessary.
要求的目的是在最坏情况下进行测试（几乎总是满载或空载）。这种最坏情况可以通过评估变压器设计或进行一些现场测试来确定。一般来说，不需要测试所有可能的条件来确定最坏的情况。

The limits of Table 31 are applied at a 25 °C ambient because of the impracticality of performing the overload and short tests inside of a thermal chamber.
表31中的限值适用于25°C的环境，因为在热室内进行过载和短期试验是不现实的。

Subclause 15.5.2 – Dielectric strength
第15.5.2款-介电强度

It is necessary to raise the frequency of the test voltage in proportion to the voltage to prevent saturation of the magnetic core and consequent very high current.
有必要提高试验电压的频率，使之与电压成比例，以防止磁芯饱和，从而产生非常高的电流。

The electrical insulation between the primary winding and other windings, screens and the core of a MAINS SUPPLY TRANSFORMER is presumed to have been investigated by the dielectric strength tests performed on the assembled ME EQUIPMENT as described in 8.8.3. The dielectric strength tests of 8.8.3 need not be repeated.
一次绕组和其他绕组、屏蔽和电源变压器铁芯之间的电气绝缘假定已通过8.8.3中所述组装的医用电气设备的介电强度试验进行了研究。8.8.3中的介电强度试验无需重复。

Subclause 15.5.3 – Construction of transformers used to provide separation as required by 8.5
第15.5.3款-按照8.5的要求，用于提供隔离的变压器的结构

The requirements specified in IEC 61558-1, Subclause 5.12 are generally similar to those in the second edition of this standard but transformers complying with them are likely to be more readily available.
IEC 61558-1第5.12款中规定的要求通常与本标准第二版中的要求相似，但符合这些要求的变压器可能更容易获得。

The original citation of subclause 5.12 of IEC 61558-1 was made incorrect by modifications to the 61558 series. In reviewing the revised IEC 61558 standards, it was determined that citation of the standard would not reduce the cost of transformers or provide any other benefits since the spacing and dielectric requirements of IEC 60601-1 would be required to be applied to provide MEANS OF PATIENT PROTECTION. For this reason, the citation was deleted, and the principles of the second edition of IEC 60601-1 were employed with reference to spacing and dielectric requirements of the third edition. Where only MEANS OF OPERATOR PROTECTION is required, transformers constructed for use in IEC 60950-1 equipment should be considered acceptable.
IEC 61558-1第5.12款的原始引用因对61558系列的修改而不正确。由于IEC 606-01标准中的任何要求都不适用于减少变压器保护的​​成本，因此IEC 606-01标准中的任何要求都不适用。因此，删除了引文，

并参考第三版的间距和介电要求，采用了第二版IEC 60601-1的原则。如果只需要操作员保护装置，则应认为用于IEC 60950-1设备的变压器是可接受的。

Additionally, Annex U of IEC 60950-1:20012005 includes requirements relating to the use of triple-insulated winding wire in transformers instead of a separate layer of insulation between windings (as would be traditionally be provided by bobbins for example). Transformers which use this method of separation between windings and which comply with all other requirements of this standard should generally be considered to provide an adequate level of BASIC SAFETY. 此外，IEC 60950-1:20012005的附录U包括了有关在变压器中使用三重绝缘绕组线而不是绕组之间的单独绝缘层（例如传统上由线轴提供）的要求。使用这种绕组间分离方法并符合本标准所有其他要求的变压器通常应考虑提供足够的基本安全水平。

Clause16条-医用电气系统

16

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ME

SYSTEMS

Increasingly, ME EQUIPMENT is being combined with other pieces of equipment that might not have originally been intended for medical application to create systems where one or more of the elements of the system come into contact with the PATIENT. Clause 16 provides requirements to ensure the safety of the PATIENT who could come into contact with ME SYSTEMS. 越来越多地，医用电气设备与原本可能不用于医疗应用的其他设备组合在一起，以创建一个或多个系统元素与患者接触的系统。第16条规定了确保可能接触医用电气系统的患者安全的要求。

Clause 16 on ME SYSTEMS is intended to be used by MANUFACTURERS of combinations of electrical equipment that include one or more items of ME EQUIPMENT. The equipment can be separate items or can be in a single ENCLOSURE or a combination of these cases. 关于医用电气系统的第16条旨在供电气设备组合制造商使用，包括一个或多个医用电气设备。设备可以是单独的项目，也可以是一个单独的外壳，也可以是这些案例的组合。

Clause 16 is also intended to be used by personnel from institutions for medical practice who assemble or adapt ME SYSTEMS, as they can become the MANUFACTURER by that action. In this case, engineering expertise in the application of the electrical equipment design standards is required to ensure that the ME SYSTEM complies with all requirements of Clause 16. 第16条也适用于装配或改造医用电气系统的医疗机构的人员，因为他们可以通过该行动成为制造商。在这种情况下，需要电气设备设计标准应用方面的工程专业知识，以确保医用电气系统符合第16条的所有要求。

More and more, such ME SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, that are connected with each other in a direct or indirect way. ME EQUIPMENT complying with this standard can be connected with other, non-ME EQUIPMENT. The latter equipment might fully meet the requirements in the safety standards applicable in their specific application field. However, they do not always comply with the safety requirements for ME EQUIPMENT and, thereby, influence the safety of the whole ME SYSTEM. It is for this reason that the MANUFACTURER is required to apply RISK MANAGEMENT to the whole ME SYSTEM. One example of an additional HAZARD is the ignition of fire when an ME SYSTEM containing non-ME EQUIPMENT is used in an OXYGEN RICH ENVIRONMENT, possibly accidentally.

越来越多地，这种医用电气系统包括最初制造用于不同特定应用领域（不一定是医疗领域）的设备，这些设备以直接或间接的方式彼此连接。符合本标准的医用电气设备可与其他非医用电气设备连接。后一种设备可能完全符合适用于其特定应用领域的安全标准的要求。然而，它们并不总是符合医用电气设备的安全要求，从而影响整个医用电气系统的安全。因此，要求制造商对整个医用电气系统进行风险管理。附加危险的一个例子是，当包含非医用电气设备的医用电气系统在富氧环境中使用时，可能意外发生火灾。

The electrical equipment can be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is performed. Within a medically used room, electrical equipment might be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT. 电气设备可以位于用于诊断、治疗或监视患者的医用房间，也可以位于不进行医疗实践的非医疗用房间内。在医疗用房内，电气设备可以放置在定义为患者环境的体积的内部或外部。

There are two situations possible in medical practice.
在医疗实践中有两种可能的情况。

a) Where Clause 16 does not apply
第16条不适用

Simultaneously operated ME EQUIPMENT, i.e. different ME EQUIPMENT connected at the same time to a PATIENT but not connected to each other. Such ME EQUIPMENT can influence each other. For example, high-frequency surgical equipment in the operating theatre can influence PATIENT monitoring. 同时操作的医用电气设备，即不同的医用电气设备同时与患者相连，但彼此不相连。这样的设备可以互相影响。例如，手术室中的高频手术设备会影响病人的监护。

NOTE Assistance can be available from the instructions for use for each ME EQUIPMENT.
注：可从每个医用电气设备的使用说明中获得帮助。

b) Where Clause 16 applies
如果第16条适用

ME SYSTEMS, consisting of ME EQUIPMENT and possibly also non-ME EQUIPMENT, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: ME SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed

tomography or magnetic resonance imaging.
医用电气系统，由医用电气设备和可能的非医用电气设备组成，为特定目的（如病人的诊断或治疗）永久或临时互连。例如：用于诊断性X射线检查的ME系统、带摄像机的内窥镜、患者监控、带个人电脑的超声波设备、计算机断层扫描或磁共振成像。

The various parts of such an ME SYSTEM could be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room, or parts of the ME SYSTEM could be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.
医用电气系统的各个部分可以位于患者环境内或外部，但仍在医疗用房内，或者医用电气系统的各个部分可以位于非医疗用房间内，例如，配电或数据处理设备。

Subclause 16.1 – General requirements for the ME SYSTEMS
第16.1款-医用电气系统的一般要求

The basic requirement for the safety of ME SYSTEMS is that, after installation or subsequent modification, an ME SYSTEM does not result in an unacceptable RISK. Compliance with the requirements imposed on ME SYSTEMS in this standard will imply that the RESIDUAL RISK is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.
医用电气系统安全性的基本要求是，在安装或后续修改后，医用电气系统不会导致不可接受的风险。遵守本标准中对医用电气系统的要求将意味着剩余风险被认为是可接受的，除非有相反的客观证据。

The MANUFACTURER of ME SYSTEMS that can be reconfigured by the OPERATOR or the RESPONSIBLE ORGANIZATION could be challenged to provide information on all possible combinations of the equipment, which could represent an unreasonable burden. RISK MANAGEMENT methods provide a very adequate means of determining which combination of items constitutes the largest RISKS, and which measures need to be taken to provide for the adequate level of safety. Ultimately, compliance testing can be done after assembly of the complete ME SYSTEM.
可由操作员或责任机构重新配置的医用电气系统制造商可能会被要求提供关于所有可能的设备组合的信息，这可能是不合理的负担。风险管理方法提供了一种非常充分的方法来确定哪些项目组合构成了最大的风险，以及需要采取哪些措施来提供足够的安全水平。最终，合规性测试可以在组装完整个ME系统之后完成。

Appropriate documentation concerning the standards compliance can be a declaration of conformity by the MANUFACTURER or a certificate from a test house.

有关标准合规性的适当文件可以是制造商的符合性声明或测试机构的证书。

ME SYSTEMS, by their nature, can be frequently modified; Clause 16 does not apply to the modification of individual items in an ME SYSTEM

医用电气系统，根据其性质，可以经常修改；第16条不适用于医用电气系统中单个项目的修改

Subclause 16.2 – ACCOMPANYING DOCUMENTS of an ME SYSTEM 第16.2款-医用电气系统随附文件

The documents that accompany an ME SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as:

用于心脏直接应用的医用电气系统附带的文件应提供以下项目的数据：

- use of rubber gloves;
使用橡胶手套；
- use of stop-cocks made of insulating material;
使用绝缘材料制成的截止阀；
- minimum distances between PATIENT and equipment being part of the ME SYSTEM (PATIENT ENVIRONMENT);
患者与医用电气系统（患者环境）一部分的设备之间的最小距离；
- instructions about how to use the ME EQUIPMENT in the typical medical application, for example, use of a catheter.
关于如何在典型医疗应用中使用医用电气设备的说明，例如导管的使用。

For safety reasons, particular attention should be paid to the different levels of RISK when, within the PATIENT ENVIRONMENT, electrodes or other body sensors are used on the PATIENT, externally and internally, including direct connections to the heart.
出于安全原因，当在患者环境中，在患者的外部和内部使用电极或其他身体传感器时，应特别注意不同的风险水平，包括与心脏的直接连接。

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.
与患者心脏的可能连接应与设备保持隔离。

The warning not to place MULTIPLE SOCKET-OUTLETS on the floor is to prevent the ingress of liquids and to prevent mechanical damage.

警告不要在地板上放置多个插座，以防止液体进入并防止机械损坏。

Furthermore, measures should be taken to ensure that, when assembling or modifying an ME SYSTEM incorporating MULTIPLE SOCKET-OUTLETS, these are mounted in such a way as to prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation. 此外，应采取措施，以确保在装配或修改包含多个插座的医用电气系统时，这些插座的安装方式应能防止液体进入，并避免在正常使用和运输过程中发生机械损坏。

Relevant safety standards for non-ME EQUIPMENT could specify or require disclosure of permissible environmental conditions. Accordingly, the environmental conditions permitted for various items in an ME SYSTEM can be different. The permissible environmental conditions for the ME SYSTEM is to be specified so that no HAZARD HAZARDOUS SITUATION will arise when operating it within these specified limits.

非医用电气设备的相关安全标准可规定或要求披露允许的环境条件。因此，医用电气系统中各种项目允许的环境条件可能不同。应规定医用电气系统的允许环境条件，以便在这些规定范围内操作时不会出现危险和危险情况。

Subclause 16.3 – Power supply 第16.3款-电源

This requirement is to ensure the safety according to IEC 60601-1 at the ME SYSTEM level.
此要求是为了确保符合IEC 60601-1的医用电气系统级的安全性。

BASIC SAFETY after assembly is maintained, for example, by one or more of the following measures:
例如，通过以下一项或多项措施来维护组装后的基本安全：

- measures that are built-in within the ME EQUIPMENT, for example, separation of relevant circuits;
医用电气设备内的内置措施，例如，相关电路的分离；
- SEPARATION DEVICES provided as ACCESSORIES to the ME EQUIPMENT (see 16.5);
作为医用电气设备附件提供的分离装置（见16.5）；
- SEPARATION DEVICES provided as ACCESSORIES to the ME SYSTEM;
作为医用电气系统附件提供的分离装置；
- separating transformer;
隔离变压器；
- additional PROTECTIVE EARTH CONDUCTORS.
附加保护接地导体。

Non-ME EQUIPMENT can provide the specified power supply for ME EQUIPMENT in accordance with 5.5 f), 7.9.2.14 and 8.2.1.

非医用电气设备可按照5.5f)、7.9.2.14和8.2.1为医用电气设备提供规定的电源。

Subclause 16.5 – SEPARATION DEVICES

第16.5款-分离装置

The BASIC SAFETY of some ME EQUIPMENT depends on the precondition that any SIGNAL INPUT/OUTPUT PARTS are connected only to equipment that is specified for this purpose, otherwise LEAKAGE CURRENTS could be increased by unwanted currents flowing through signal cables.

某些医用电气设备的基本安全性取决于以下前提条件：任何信号输入/输出部件仅连接到为此目的而指定的设备上，否则，流经信号电缆的不必要电流会增加泄漏电流。

HAZARDOUS SITUATIONS could occur if the SIGNAL INPUT/OUTPUT PART of ME EQUIPMENT is 如果医用电气设备的信号输入/输出部分 connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit. 连接到医疗用房外的设备，可能在另一栋楼，因此连接到另一个主电源分支电路。

A SEPARATION DEVICE prevents a HAZARD HAZARDOUS SITUATION to the PATIENT or OPERATOR. 隔离装置可防止对患者或操作员造成危险的情况。 Additionally, the inclusion of the SEPARATION DEVICE helps to avoid HAZARDS HAZARDOUS SITUATIONS through malfunction of equipment caused by unwanted currents flowing through cables. 此外，隔离装置的加入有助于避免危险的危险情况，通过通过电缆的有害电流引起设备故障。

The need for a SEPARATION DEVICE depends on the configuration of the ME SYSTEM. 是否需要分离装置取决于医用电气系统的配置。

Subclause16.6—LEAKAGECURRENTS第16.6款-泄漏电流

Relevant standards for some non-ME EQUIPMENT can have limits for TOUCH CURRENTS that are higher than required by Clause 16; these higher limits are acceptable only outside the PATIENT ENVIRONMENT. It is essential to reduce TOUCH CURRENTS when non-ME EQUIPMENT is to be used within the PATIENT ENVIRONMENT. LEAKAGE CURRENT reduction measures can include: 一些非医用电气设备的相关标准可能会有高于第16条要求的接触电流限值；这些更高的限值仅在患者环境之外才可接受。在病人环境中使用非医用电气设备时，必须降低接触电流。减少泄漏电流的措施包括：

- additional PROTECTIVELY EARTHED parts; 附加保护接地部件；
- a separating transformer; 隔离变压器；
- an additional non-conductive ENCLOSURE. 一个附加的非导电外壳。

Interconnecting cables and their connector housings are parts of the ENCLOSURE and therefore the LEAKAGE CURRENT limits within the PATIENT ENVIRONMENT, as required in 16.6.1, are applicable. 互连电缆及其连接器外壳是外壳的一部分，因此16.6.1中要求的患者环境中的泄漏电流限值适用。

If a MULTIPLE SOCKET-OUTLET without a separating transformer is used, the interruption of its protective earthing could result in TOUCH CURRENTS equal to the sum of the individual EARTH LEAKAGE CURRENTS. 如果使用不带隔离变压器的多个插座，其保护接地中断可能导致接触电流等于单个接地漏电流之和。

Subclause16.6.3—PATIENTLEAKAGECURRENT第16.6.3款-患者漏电流

For ME EQUIPMENT, the maximum allowed values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT (applicable with several APPLIED PARTS connected to the ME EQUIPMENT) are given in Table 3 and Table 4; see also 8.7.3. An ME SYSTEM is to provide the equivalent level of safety as provided by ME EQUIPMENT within the PATIENT ENVIRONMENT (see 16.1). Therefore, the same maximum values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT apply, regardless

whether the APPLIED PARTS are connected to the same element of the ME SYSTEM or not. This holds for the operation of the ME SYSTEM in NORMAL CONDITION, as the single fault concept is not applicable to an ME SYSTEM. 对于医用电气设备，患者泄漏电流和总患者泄漏电流的最大允许值（适用于连接到医用电气设备的几个应用部件）见表3和表4；另见8.7.3。医用电气系统应提供与医用电气设备在患者环境中提供的同等安全等级（见16.1）。因此，无论应用部件是否连接到医用电气系统的同一元件上，患者漏电电流和总患者漏电电流的最大值相同。这适用于医用电气系统在正常情况下的运行，因为单一故障概念不适用于医用电气系统。

It should be noted that combinations of equipment or of APPLIED PARTS, made by the RESPONSIBLE ORGANIZATION or OPERATOR, that are outside the range of combinations indicated by the MANUFACTURER, could lead to HAZARDOUS SITUATIONS. This warning holds in particular when combinations of equipment are used for medical purposes on the same PATIENT, which have not been intended by their MANUFACTURER(S) to be used in such combinations. 应注意的是，由负责组织或操作员制造的设备或应用部件的组合超出制造商指示的组合范围，可能导致危险情况。当设备组合用于同一患者的医疗目的时，此警告尤其有效，而制造商并未打算将其用于此类组合。

Subclause 16.7 – Protection against MECHANICAL HAZARDS
第16.7款-机械危险防护

Attention should be paid to the effects of interruptions causing unplanned movements, removal of compression forces, and the safe removal of PATIENTS from the PATIENT ENVIRONMENT when a HAZARDOUS SITUATION occurs. 当发生危险情况时，应注意导致意外移动的中断、压缩力的消除以及将患者安全地从患者环境中移除的影响。

Subclause 16.9.2.1 – MULTIPLE SOCKET-OUTLET
第16.9.2.1款-多个插座

The second edition of this standard used the defined term “auxiliary mains socket-outlet (AMSO)” to describe a socket-outlet intended for provision of mains supply to other ME EQUIPMENT or to other separate parts of the ME EQUIPMENT. The systems collateral standard, IEC 60601-1-1 [13], defined a term “multiple portable socket-outlet (MPSO)”. The two terms have been combined into a new term, “MULTIPLE SOCKET-OUTLET (MSO).” Subclause 本标准第二版使用了定义的术语“辅助电源插座（AMSO）”来描述为其他医用电气设备或医用电气设备的其他独立部件提供电源的插座。系统并行标准IEC 60601-1-1[13]定义了一个术语“多个便携式插座（MPSO）”。这两个术语已合并为一个新术语“多插座（MSO）”

57.2 e) of the second edition required that an AMSO be designed so that it could not accept a MAINS PLUG. An exception for emergency trolleys was allowed. With the combination of the two definitions and the change to 8.11.2 to require any MSO on ME EQUIPMENT to comply with 第二版第57.2 e) 条要求AMSO的设计不能接受电源插头。紧急手推车例外。结合这两个定义，并修改为8.11.2，要求医用电气设备上的任何MSO符合

16.9.2.1, the need for rapid exchange in an emergency situation is reconciled with the need to restrict LEAKAGE CURRENT.

16.9.2.1, 紧急情况下快速交换的需要与限制泄漏电流的需要相协调。

Reassignment of the mains connection for the ME SYSTEM is a dangerous practice and beyond the scope of this clause. See 16.2 for disclosure requirements.

重新分配医用电气系统的电源连接是一种危险的做法，超出了本条款的范围。披露要求见16.2。

Excessive TOUCH CURRENTS can occur unless casual access for additional equipment connections is impeded or prevented.

除非妨碍或阻止额外设备连接的偶然访问，否则会出现过大的接触电流。

Subclause 16.9.2.1 c), 3rd dash

第16.9.2.1 c) 款第3个破折号

ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD has an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that does not exceed 200 m Ω . Similarly, the MULTIPLE SOCKET-OUTLET has an impedance that does not exceed 200 m Ω between its MAINS PLUG and its socket-outlets. This results in an impedance that does not exceed 400 m Ω between the MULTIPLE SOCKET-OUTLET MAINS PLUG and any part of ME EQUIPMENT that is PROTECTIVELY EARTHED.

带有不可拆卸电源线的医用电气设备在电源插头的保护接地引脚和任何保护性接地部件之间的阻抗不超过200 m Ω 。同样，多个插座的电源插头和插座之间的阻抗不超过200 m Ω 。这会导致多个插座电源插头和任何保护性接地医用电气设备部件之间的阻抗不超过400 m Ω 。

The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed 200 m Ω when the relevant circuits have limited current capability (see 8.6.4 b)). In such cases in ME EQUIPMENT, this results in an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that exceeds 400 m Ω . 当相关电路的电流容量有限时，保护接地连接的阻抗允许超过200 m Ω （见8.6.4 b））。在这种情况下，在医用电气设备中，电源插头中的保护接地引脚与任何保护性接地部件之间的阻抗超过400 m Ω 。

Subclause

16.9.2.1

第16.9.2.1 d) 款

d)

The TOUCH CURRENT of the ME SYSTEM must be less than 500 μ A in SINGLE FAULT CONDITION. A separating transformer can be used as a measure to reduce that TOUCH CURRENT. Therefore a separating transformer with BASIC INSULATION is sufficient. The DOUBLE or REINFORCED INSULATION as required for isolating transformers is not needed.

在单一故障条件下，医用电气系统的接触电流必须小于500 μ A。隔离变压器可作为减少接触电流的措施。因此，具有基本绝缘的隔离变压器就足够了。不需要隔离变压器所需的双重或加强绝缘。

Transformers providing a greater degree of safety e.g. ones constructed to IEC 60601-1 requirements or to the isolating transformer requirements in other parts of the IEC 61558 series, e.g. IEC 61558-2-4 or IEC 61558-2-23 are also acceptable. 提供更高安全等级的变压器，如根据IEC 60601-1要求或IEC 61558系列其他部分中的隔离变压器要求（如IEC 61558-2-4或IEC 61558-2-23）制造的变压器也是可以接受的。

The CLASS I requirement for the transformer assembly is necessary to provide connected equipment with a PROTECTIVE EARTH CONNECTION. 变压器组件的I级要求是为连接的设备提供保护接地连接所必需的。

Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and the occurrence of two

independent SINGLE FAULT CONDITIONS is of no concern. The transformer construction can be of a type with or without a PROTECTIVELY EARTHED centre tapped secondary winding.

不需要对隔离变压器进行隔离监测。在日常维护过程中，可以检测到单一故障状态，两个独立的单一故障状态的发生不受关注。变压器结构可以是带或不带保护接地中心抽头二次绕组的类型。

Subclause 16.9.2.2 – PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS 第16.9.2.2款-医用电气系统中的保护接地连接

All PROTECTIVE EARTH CONDUCTORS and POWER SUPPLY CORDS should be routed together.
所有保护接地导线和电源线应一起布线。

When a MULTIPLE SOCKET-OUTLET is used to construct an ME SYSTEM, each individual item of equipment plugged in to the MULTIPLE SOCKET-OUTLET needs to meet the relevant ME EQUIPMENT or non-ME EQUIPMENT requirements. The total protective earth impedance when tested as a complete system according to 8.6.4 needs to meet the highest impedance requirement from 8.6.4. a) (i.e. shall not exceed 200 m Ω). This might require measures such as using short power supply cords within the ME SYSTEM and using a system POWER SUPPLY CORD of greater cross sectional area than is necessary for current carrying purposes to reduce its protective earth impedance. It is unacceptable practice to connect MULTIPLE SOCKET-OUTLETS in series. 当使用多个插座构建医用电气系统时，插入多个插座的每个单独设备项目都需要满足相关的医用电气设备或非医用电气设备的要求。当按照8.6.4作为一个完整系统进行测试时，总保护接地阻抗需要满足8.6.4中的最高阻抗要求。a)（即不应超过200 m Ω ）。这可能需要采取措施，如在医用电气系统内使用短电源线，以及使用横截面积大于载流目的所需的系统电源线，以降低其保护接地阻抗。串联多个插座是不可接受的做法。

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of an ME SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the ME SYSTEM. 在病人环境中，限制医用电气系统不同部分之间的电位差是很重要的，与保护接地系统的充分连接在限制电位差方面起着重要作用。因此，重要的是要防止该保护装置对医用电气系统的任何部分造成中断。

- The additional protective earthing could be used when the TOUCH CURRENT in SINGLE FAULT CONDITION exceeds the allowable limits.
当单一故障状态下的接触电流超过允许限值时，可采用附加保护接地。
- The additional protective earthing is not necessary for ME EQUIPMENT complying with this standard. However, in the case of non-ME EQUIPMENT this will prevent TOUCH CURRENTS exceeding allowable limits.
符合本标准的医用电气设备不需要额外的保护接地。但是，对于非医用电气设备，这将防止接触电流超过允许限值。
- The use of a TOOL is not required to disconnect the MAINS PLUG because the MAINS PLUG disconnect power plug does not require use of a tool, because the power plug will disconnect both the mains and the protective earth.
会断开电源和保护接地。

Clause 17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 第17条-医用电气设备和医用电气系统的电磁兼容性

IEC 60601-1-2 specifies electromagnetic immunity test levels to minimize the effect of the electromagnetic environment on the ME EQUIPMENT and ME SYSTEMS covered by this standard. It specifies electromagnetic emissions limits to minimize the effect on other equipment of electromagnetic disturbances that could be emitted, intentionally or unintentionally, by ME EQUIPMENT and ME SYSTEMS. It also specifies requirements for identification, marking and documents so that the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM provides information to the RESPONSIBLE ORGANIZATION that is essential in determining the suitability of the ME EQUIPMENT or ME SYSTEM for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the ME EQUIPMENT or ME SYSTEM to maintain BASIC SAFETY and provide its ESSENTIAL PERFORMANCE without disturbing other equipment.

IEC 60601-1-2规定了电磁抗扰度试验水平，以尽量减少电磁环境对本标准所涵盖的医用电气设备和医用电气系统的影响。它规定了电磁辐射限值，以尽量减少医用电气设备和医用电气系统有意或无意发射的电磁干扰对其他设备的影响。它还规定了标识、标记和文件的要求，以便医用电气设备或医用电气系统的制造商向责任组织提供信息，这些信息对于确定医用电气设备或医用电气系统在使用的电磁环境中的适用性以及管理允许医用电气设备或医用电气系统保持基本安全并在不干扰其他设备的情况下提供其基本性能的电磁环境。

Electromagnetic emission requirements are necessary for the protection of:
电磁发射要求对于保护：

- safety services (e.g. police, fire and ambulance communications);
安全服务（如警察、消防和救护车通讯）；
- other ME EQUIPMENT and ME SYSTEMS;
其他医用电气设备和医用电气系统；
- non-ME EQUIPMENT (e.g. computers);
非医用电气设备（如计算机）；
- telecommunications (e.g. radio/TV, telephone, radio-navigation).
电信（如无线电/电视、电话、无线电导航）。

More importantly, electromagnetic immunity requirements are necessary to assure that ME EQUIPMENT and ME SYSTEMS maintain BASIC SAFETY and continue to provide their ESSENTIAL PERFORMANCE in the presence of the electromagnetic disturbances to which they can be expected to be exposed during NORMAL USE. 更重要的是，电磁抗扰度要求是必要的，以确保医用电气设备和医用电气系统保持基本安全，并在正常使用期间可能暴露在电磁干扰下继续提供其基本性能。

Annex G – Protection against HAZARDS of ignition of flammable anaesthetic mixtures (see also the rationale for 11.4)

附录G-易燃麻醉混合物引燃危险防护（另见11.4的基本原理）

Section six of the second edition of this standard has been moved to a normative annex. This was done in recognition of the fact that flammable anaesthetics are rarely used and their use is expected to cease entirely within a short period. However, it is also recognized that the practice of medicine changes frequently and that even now some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications. In order to assure that the material contained in Section six along with the associated CATEGORY AP and CATEGORY APG RATINGS remain available while improving the readability of the standard for most users, the material has been moved to Annex G. 本标准第二版第六节已移至规范性附录。这样做是因为认识到易燃麻醉剂很少使用，而且预计在短时间内将完全停止使用。然而，人们也认识到，医学实践经常发生变化，即使是现在，一些制造商仍可能希望为此类应用提供设备。为了确保第六节中包含的材料以及相关的AP类和APG类评级保持可用，同时提高大多数用户对本标准的可读性，已将材料移至附录G中。

Subclause G.1.3 – Requirements for ME EQUIPMENT

子条款G.1.3-医用电气设备要求

The most devastating accidents with flammable anaesthetic agents occur when the mixture of the agent with oxygen normally used is that which will cause the most rapid combustion, a state that sometimes is described as “detonation optimum.” The worst example of such an agent is cyclopropane, while the oxygen/ether mixture normally used is far below that point. 最具破坏性的易燃麻醉剂事故发生在通常使用的麻醉剂与氧气的混合物会引起最迅速的燃烧，这种状态有时被描述为“最佳爆震”。这种麻醉剂最坏的例子是环丙烷，而通常使用的氧/醚混合物是远低于这一点。

Subclause G.5.3 – Low-energy circuits

子条款G.5.3-低能电路

The graphs of Figure G.1, Figure G.2 and Figure G.3 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY AP ME EQUIPMENT without performing the ignition test. 图G.1、图G.2和图G.3中的图表有助于在不进行点火试验的情况下，设计满足AP ME类设备允许限值要求的电路。

Extrapolation for higher voltages is not valid because the ignition condition of gases changes at higher voltages. The limit for inductances is introduced because high inductance values generally produce higher voltages.

对于更高电压的推断是无效的，因为气体的点火条件在更高的电压下会发生变化。引入电感极限是因为高电感值通常会产生更高的电压。

Subclause G.5.4 – External ventilation with internal overpressure

子条款G.5.4-内部超压的外部通风

The amount of air or inert gas escaping from the ME EQUIPMENT by leakage is assumed to be limited so that hygienic conditions in the medically used room are not disturbed appreciably.

假设由于泄漏而从医用电气设备中逸出的空气或惰性气体的量是有限的，这样医疗用房的卫生条件不会受到明显的影响。

For the purposes of G.5.4 and G.5.5 the term “enclosure” can represent either the ENCLOSURE

在G.5.4和G.5.5中，“附件”一词可表示外壳

as defined in 3.26 or a distinct compartment or housing.

如第3.26节所述，或单独的隔间或外壳。

Subclause G.5.5 – ENCLOSURES with restricted breathing

Subclause G.5.5 a)

子条款G.5.5-限制呼吸的外壳子条款G.5.5 a)

This requirement is regarded as sufficient to prevent ignition in NORMAL USE during an operational period of several hours since average conditions in NORMAL USE are less stringent.

由于正常使用的平均条件不那么严格，因此这一要求被认为足以防止在数小时的运行期间在正常使用中着火。

Subclause G.6.2 – Power supply

第G.6.2款-电源

This requirement prevents the introduction of voltages higher than those permitted by G.6.3. Such voltages can exist on earth wiring.

该要求防止引入高于G.6.3允许的电压。这种电压可能存在于接地线路上。

Subclause G.6.3 – Temperatures and low-energy circuits

子条款G.6.3-温度和低能电路

The graphs of Figure G.4, Figure G.5 and Figure G.6 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY APG ME EQUIPMENT, without performing the ignition test.

图G.4、图G.5和图G.6中的图表用于帮助设计满足APG ME类设备规定的允许限值要求的电路，而无需进行点火试验。

Annex B

附件B

(informative)

（资料性）

Sequence of testing

试验顺序

B.1

General

总则

Tests should, if applicable, be performed in the sequence indicated below, unless otherwise stated by particular standards. See also 5.8.
除非特殊标准另有规定，否则应按以下顺序进行试验（如适用）。另见5.8。

However, this does not preclude the possibility of conducting a test that preliminary inspection suggests might cause failure.
然而，这并不排除进行初步检查可能导致失败的试验的可能性。

The tests for radiation HAZARDS in Clause 10, biocompatibility in 11.7, USABILITY in 12.2, ALARM SYSTEMS in 12.3, PEMS in Clause 14 and electromagnetic compatibility in Clause 17 can be performed independently from the tests in the following sequence.
第10条中的辐射危害试验、第11.7条中的生物相容性试验、第12.2条中的可用性试验、第12.3条中的报警系统试验、第14条中的PEMS试验和第17条中的电磁兼容性试验可以独立于以下顺序进行。

The tests specified for ME SYSTEMS in Clause 16 should be performed in the same sequence as the tests for ME EQUIPMENT.
第16条中规定的医用电气系统试验应按照与医用电气设备试验相同的顺序进行。

B.2

RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS and ESSENTIAL PERFORMANCE

医用电气设备或医用电气系统的风险管理流程和基本性能

See

4.2

and

4.3.

见4.2和4.3。

B.3

General

一般要求

requirements

See

4.1,

4.5

to

4.10

(inclusive)

and

5.1

to

5.7(inclusive).

见4.1、4.5至4.10（含）和5.1至5.7（含）。

B.4

Classification of ME EQUIPMENT and ME SYSTEMS

医用电气设备和医用电气系统的分类

See

Clause

6.

见第6条。

B.5

Determination of APPLIED PARTS and ACCESSIBLE PARTS

应用部件和可触及部件的确定

See

5.9.

见5.9。

B.6	ME EQUIPMENT 医用电气设备标识、标记和文件	identification,	marking	and	documents
See	7.2	to	7.8.2	(inclusive),	Annex C.
见附录C第7.2至7.8.2条（含7.2条）。					
B.7	Energy consumption 能耗（功率输入）		(power		input)
See					4.11.
见4.11。					
B.8	Limitation of 电压、电流或能量的限制	voltage,	current	or	energy
See					8.4.
见8.4。					
B.9	Separation 零件分离		of		parts
See	8.5.1	to	8.5.4		(inclusive).
见8.5.1至8.5.4（含）。					

B.10 CREEPAGE DISTANCES and AIR CLEARANCES

爬电距离和空气间隙

See 8.9.

见8.9。

B.11 HAZARDS associated with moving parts

与活动部件相关的危险

See 9.2 except 9.2.2.4.1.

见9.2，9.2.2.4.1除外。

B.12 HAZARD associated with surfaces, corners and edges

与表面、角落和边缘相关的危险

See 9.3.

见9.3。

B.13 Serviceability

适用性

See 15.2.

见15.2。

B.14 Accuracy of controls and instruments and protection against hazardous outputs

控制装置和仪表的准确性以及对危险输出的防护

See 12.1 and 12.4.

见12.1和12.4。

B.15 Instability HAZARDS

不稳定危害

See 9.4.

见9.4。

B.16 Noise, vibration and acoustic energy

噪声、振动和声能

See 9.6.

见9.6。

B.17 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

医用电气设备电源/供电干线中断

See 11.8.

见11.8。

B.18 Protective earthing, functional earthing and potential equalization of

保护接地、功能接地和电位均衡

ME EQUIPMENT

医用电气设备

See 8.6.

见8.6。

B.19 Excessive temperatures in ME EQUIPMENT
医用电气设备温度过高

See 11.1.
见11.1。

B.20 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength at steady-state operating temperature
稳态工作温度下的泄漏电流、病人辅助电流和介电强度

See 8.4.2 and 8.7 and 8.8.3.
见8.4.2、8.7和8.8.3。

B.21 Humidity preconditioning treatment
湿度预处理

See 5.7.
见5.7。

B.22 Dielectric strength (COLD CONDITION) LEAKAGE CURRENTS and PATIENT
介电强度（冷态）泄漏电流和患者
AUXILIARY CURRENTS and dielectric strength after humidity preconditioning
实验室环境温度下湿度预处理后的辅助电流和介电强度

See 8.4.2 and 8.7 and 8.8.3.

见8.4.2、8.7和8.8.3。

B.23 Defibrillation protection
除颤保护

See 8.5.5.

见8.5.5。

B.24 Expelled parts HAZARD
排出部件危险

See 9.5.

见9.5。

B.25 Pressure vessels and parts subject to pneumatic and hydraulic pressure
承受气压和液压压力的压力容器和零件

See 9.7.

见9.7。

B.26 HAZARDS associated with support systems
与支持系统相关的危险

See 9.8.

见9.8。

B.27 Mechanical strength
机械强度

See 15.3 and 9.2.2.4.1.

见15.3和9.2.2.4.1。

B.28 HAZARDOUS SITUATIONS and fault conditions
危险情况和故障条件

See Clause 13.

见第13条。

B.29 MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers
providing separation in accordance with 8.5
医用电气设备的电源变压器和按照8.5提供隔离的变压器

See 15.5.

见15.5。

B.30 ME EQUIPMENT components and general assembly

医用电气设备部件和总成

See 15.4 and 8.10.
见15.4和8.10。

B.31 MAINS PARTS, components and layout 电源部件、组件和布局

See 8.11.
见8.11。

B.32 Insulation other than wire insulation 电线绝缘以外的绝缘

See 8.8.4.
见8.8.4。

**B.33 Fire prevention and constructional requirements for fire ENCLOSURES of
防火外壳的防火和构造要求
ME EQUIPMENT
医用电气设备**

See 11.2 and 11.3.

见11.2和11.3。

**B.34 Overflow, spillage, leakage, ingress of water, cleaning, disinfection,
溢流、溢出、泄漏、进水、清洗、消毒，
sterilization and compatibility with substances used with the ME EQUIPMENT
灭菌和与医用电气设备所用物质的相容性**

See 11.6.

见11.6。

**B.35 CATEGORY AP and CATEGORY APG ME EQUIPMENT
AP类和APG类ME设备**

See 11.4 and Annex G.

见11.4和附录G。

**B.36 VERIFICATION of markings
标记的验证**

See 7.2 to 7.8.2 (inclusive), Annex C and 7.1.

见7.2至7.8.2（含）附录C和7.1。

Annex C
附件C
(informative)
（资料性）

Guide to marking and labelling requirements for ME EQUIPMENT and
医用电气设备和
ME SYSTEMS
ME系统

C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts
医用电气设备、医用电气系统或其部件外部的标记

The requirements for marking on the outside of ME EQUIPMENT and its parts are found in 7.2. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.1. Symbols and safety signs used in marking on the outside of ME EQUIPMENT are found in Annex D. 医用电气设备及其部件外部的标记要求见7.2。医用电气设备、医用电气系统及其部件外部标记的附加要求见表C.1所列子条款。医用电气设备外部标记所用的符号和安全标志见附录D。

Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts)
表C.1—医用电气设备、医用电气系统或其部件外部的标记)

Description of marking 标记说明	Subclause 子条款
CATEGORY APG ME EQUIPMENT: marking of APG ME类设备：标记	G.3.1 G、3.1 条
CATEGORY AP ME EQUIPMENT: marking of AP ME类设备：标记	G.3.2 G、3.2 条
CATEGORY AP and APG: marking of major parts AP和APG类：主要零件的标记	G.3.3 G、3.3 条
CATEGORY AP and APG ME EQUIPMENT: marking of parts AP和APG ME类设备：零件标记	G.3.5 G、3.5 款
Depressurizing pressure system elements: warning about 减压系统元件：警告	9.7.2 9.7.2款
Emergency stop device actuator: marking of 紧急停止装置执行机构：标记	9.2.4 9.2.4条
Hazardous voltage: warning of 危险电压：警告	8.11.1 i) 8.11.1 i)
Mass of PATIENT, if designed for less than 135 kg: marking of 病人质量（如果设计小于135 kg）：标记	9.8.3.1 9.8.3.1
Moving parts: warning of 运动部件：警告	9.2.1 9.2.1条

MULTIPLE SOCKET-OUTLET: marking of 多插座：标记	16.9.2.1 b) 16.9.2.1 b) 条)
Overbalancing during transport: warning about 运输过程中失衡：警告	9.4.2.2 9.4.2.2
POTENTIAL EQUALIZATION CONDUCTOR terminal: marking of 电位均衡导体端子：标记	8.6.7 8.6.7
Prohibition against pushing, leaning, resting: warning of 禁止推搡、倾斜、休息：警告	9.4.2.3 a) 9.4.2.3 a) 条)
Prohibition against sitting or stepping: warning of 禁止坐或踩：警告	9.4.2.3 b) 9.4.2.3 b)
Reservoir or liquid storage chamber: marking of overflow HAZARD 储液罐或储液室：溢出危险标志	11.6.2 11.6.2 款
MECHANICAL PROTECTIVE DEVICE intended to function only once: marking of 仅起作用一次的机械保护装置：标记	9.8.4.3 9.8.4.3
Separating transformer assembly: marking of 分离变压器组件：标记	16.9.2.1 d) 16.9.2.1 d)
Surfaces where application of force results in a RISK of overbalancing: marking of 施加力会导致失衡风险的表面：标记	9.4.2.3 9.4.2.3
Transport conditions: warning for 运输条件：警告	9.4.2.2 9.4.2.2

C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts 医用电气设备、医用电气系统或其部件内部的标记

The requirements for marking on the inside of ME EQUIPMENT and its parts are found in 7.3. Additional requirements for marking on the inside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.2. Symbols used in marking on the inside of ME EQUIPMENT are found in Annex D.
医用电气设备及其部件内部的标记要求见7.3。医用电气设备、医用电气系统及其部件内部标记的附加要求见表C.2所列子条款。医用电气设备内部的标记符号见附录D。

²²⁾ See 7.2.1 for the minimum requirements for marking on ME EQUIPMENT and on interchangeable parts
医用电气设备和可互换部件上标记的最低要求见7.2.1。

Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts
表C.2——医用电气设备、医用电气系统或其部件内部的标记

Description of marking	Subclause
Hazardous energies: marking of capacitors or the connected circuit parts	8.4.4
Hazardous voltage: marking of parts	8.11.1 i)
MAINS TERMINAL DEVICES: marking of terminals other than terminal blocks	8.11.4.1
Marking of pressure vessels and pipes: national certification mark	9.7.5
Separating transformer assembly: marking of	16.9.2.1 d)

C.3 Marking of controls and instruments 控制装置和仪器的标记

The requirements for marking of controls and instruments are found in 7.4. Additional requirements for marking of controls and instruments are found in the subclauses listed in Table C.3.
控制装置和仪表的标记要求见7.4。控制装置和仪表标记的附加要求见表C.3中列出的子条款。

Table C.3 – Marking of controls and instruments
表C.3——控制装置和仪表的标记

Description of marking 标记说明	Subclause 子条款
Controls: scale marking of 控件：比例标记	15.4.6.1 b) 15.4.6.1 b) 条)
Varying the temperature setting of THERMOSTATS: clear indication of 改变恒温器的温度设置：明确指示	15.4.2.2 a) 15.4.2.2 a) 条)

C.4 ACCOMPANYING DOCUMENTS, general 随附文件，概述

The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in 7.9.1. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table C.4.
随附文件中包含的一般信息要求见7.9.1。表C.4中列出的子条款中列出了附加的一般信息要求。

Table C.4 – ACCOMPANYING DOCUMENTS, general
表C.4——随附文件，概述

Description of requirement 需求描述	Clause 条款
CATEGORY AP and CATEGORY APG ME EQUIPMENT and parts AP类和APG类ME设备和零件	G.3.4 G、3.4 条
CLASS II ME EQUIPMENT with isolated internal screens: explanation of 带隔离内部屏蔽的II类医用电气设备：说明	8.6.9 8.6.9
Defibrillation voltage, any necessary recovery time 除颤电压，任何必要的恢复时间	8.5.5.1 b) 8.5.5.1 b)

Fixing of structures to floor, wall, ceiling, etc. 将结构固定在地板、墙壁、天花板等上。	9.8.1 9.8.1条
Instability excluding transport: placement and loading of doors, drawers and shelves 不稳定（不包括运输）：门、抽屉和架子的放置和装载	9.4.2.2 e) 9.4.2.2 e)
IT-NETWORK: instructions for connecting ME EQUIPMENT IT网络：连接医用电气设备的说明	14.13 14.13
Isolation device: requirements for 隔离装置：要求	8.11.4.4 8.11.4.4
Lifting points: indication of 吊点：指示	9.4.4 a) 9.4.4 a) 条)
Mass of PATIENT, if support systems designed for less than 135 kg 如果支撑系统的设计重量小于135 kg	9.8.3.1 9.8.3.1
Mass of PATIENT, if support systems designed for more than 135 kg 如果支撑系统的设计重量超过135 kg	9.8.3.1 9.8.3.1
MECHANICAL PROTECTIVE DEVICE intended to function only once: instruction to call SERVICE PERSONNEL 仅起一次作用的机械保护装置：呼叫维修人员的说明	9.8.4.3 9.8.4.3
ME EQUIPMENT: placement of SAFE WORKING LOAD 医用电气设备：安全工作负荷的放置	9.4.2.4.3 c) 9.4.2.4.3 c)
ME SYSTEMS: addition requirements ME系统：附加要求	16.2 16.2
Noise: protective means 噪声：防护措施	9.6.2.1 b) 9.6.2.1 b) 条)
Passing over an obstruction: instructions for 越过障碍物：说明	9.4.2.4.3 9.4.2.4.3
SAFETY DEVICE intended to function only once: instruction to call SERVICE PERSONNEL 仅起一次作用的安全装置：呼叫维修人员的说明	9.8.4.3 9.8.4.3
Working conditions 工作条件	5.4 a) 5.4 a)

C.5 ACCOMPANYING DOCUMENTS, Instructions for use

随附文件、使用说明

The requirements for information to be included in the instructions for use are found in 7.9.2. Additional requirements for information to be included in the instructions for use are found in the subclauses listed in Table C.5. 使用说明中包含的信息要求见7.9.2。表C.5中列出的子条款中列出了使用说明中包含的信息的附加要求。

Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use
表C.5—随附文件、使用说明

Description of requirement	Subclause
ACCESSIBLE PARTS: instruction not to touch them and the PATIENT simultaneously	8.4.2 c)
ACCESSIBLE PARTS: instructions to the OPERATOR to open ACCESS COVERS	8.4.2 c)
APPLIED PARTS (hot or cold): temperatures and clinical effects of	11.1.2.1
APPLIED PARTS not intended to deliver heat: temperature exceeding 41 °C	11.1.2.2
Cleaning or disinfection PROCESSES: specification of	11.6.6
Effect of multiple cleanings/disinfections	11.6.6
Foot-operated controls: intended for use in areas where liquids are likely to be found	15.4.7.3 b)
Mass of ACCESSORIES	9.8.3.21
ME SYSTEMS: other equipment intended to provide power to ME EQUIPMENT	16.3
MOBILE ME EQUIPMENT: requirement that more than one person is needed to move	9.4.2.4.2 a)
Moving parts: warning of	9.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal: information on the function and use of	8.6.7
Reservoir or liquid storage chamber: information on overflow HAZARD	11.6.2
Transport conditions: warning for	9.4.2.2

C.6 ACCOMPANYING DOCUMENTS, technical description

随机文件、技术说明

The requirements for information to be included in the technical description are found in 7.9.3. Additional requirements for information to be included in the technical description are found in the subclauses listed in Table C.6. 技术说明中包含的信息要求见7.9.3。表C.6中列出的子条款中列出了技术说明中所含信息的附加要求。

Table C.6 – ACCOMPANYING DOCUMENTS, technical description
表C.6——随附文件、技术说明

Description of requirement 需求描述	Clause 条款
CLASS II ME EQUIPMENT with isolated internal screens: explanation of 带隔离内部屏蔽的II类医用电气设备：说明	8.6.9 8.6.9
External means of isolation: description of 外部隔离方式：说明	8.11.1 b) 8.11.1 b)
ME SYSTEM large transient currents: disclosure of 医用电气系统大瞬态电流：披露	16.3 16.3
Non-automatic discharging device for internal capacitors: specification of 内电容器非自动放电装置规范	8.4.4 8.4.4条

Network requirements for PEMS intended to be connected to an outside network 拟连接到外部网络的PEMS的网络要求	14.13 14.13

Annex D
附件D
(informative)
（资料性）

Symbols on marking
标记符号
(see Clause 7)
（见第7条）

Symbols are frequently used on ME EQUIPMENT in preference to words with the intention of obviating language differences and permitting easier comprehension of a marking or indication, sometimes in a restricted space. New and improved symbols and safety signs have been introduced since the publication of the second edition of IEC 60601-1 which necessitates changes in the list of approved symbols and safety signs for use on ME EQUIPMENT. 通常在医用电气设备上使用符号，而不是文字，目的是为了减少语言差异，使人们更容易理解标记或指示，有时在有限的空间内。自从第二版IEC 60601-1出版以来，新的和改进的符号和安全标志已经被引入，这使得医用电气设备上使用的认可符号和安全标志的列表必须更改。

Chief among these changes is the revision of the usage of symbol 24 in Table D.1. This symbol was formally used to indicate a warning as well as an informative marking (e.g. this is where the HIGH VOLTAGE is connected). A new safety sign (3) in Table D.2 has been added to indicate, “Warning: Dangerous Voltage.” In this edition of the standard, the safety signs of Table D.2 are required where a warning is intended while the symbols in Table D.1 are used when the intention is solely to inform. 这些变化中最主要的是修改了表D.1中符号24的用法。此符号正式用于表示警告和信息性标记（例如，高压连接在此处）。在表D.2中增加了一个新的安全标志（3），以表明“警告：危险电压”。在本标准版本中，如果打算发出警告，则需要使用表D.2中的安全标志，而在仅用于通知的情况下使用表D.1中的符号。

Similarly is the revision of the usage of symbol 10 in Table D.1, which was formerly used to indicate “attention: consult ACCOMPANYING DOCUMENTS”. That symbol is now used to indicate caution. A new symbol (11) in Table D.1 has been added to indicate, “follow operating instructions”. Additionally, a new safety sign (10) in Table D.2 has been added to mark ME EQUIPMENT where failure to follow operating instructions could place the PATIENT or OPERATOR at RISK. 同样，对表D.1中符号10的用法进行了修订，该符号以前用于表示“注意：查阅随附文件”。这个符号现在用来表示小心。表D.1中增加了一个新符号（11），表示“遵循操作说明”。此外，在表D.2中增加了一个新的安全标志（10），以标记不遵守操作说明可能使患者或操作员处于危险中的医用电气设备。

Consistent use of these symbols and safety signs in all fields of use (e.g., medical, consumer products, and general transportation) will help ME EQUIPMENT OPERATORS to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize safety. 在所有使用领域（如医疗、消费品和一般运输）中一致使用这些符号和安全标志将有助于设备操作员熟悉其含义。反之，任何不一致的使用都会导致混乱和错误，危及安全。

IEC 60878 provides a useful compendium of graphical symbols and safety sign used on electrical equipment in medical practice that were complied from relevant ISO and IEC standards. See also 7.5 and 7.6. **iec60878**提供了一个有用的图形符号和安全标志概要，这些符号和安全标志符合相关的ISO和IEC标准。另见7.5和7.6。

For symbol requirements not met by the symbols in IEC 60878, refer in the first instance to published IEC or ISO symbols, noting that, where necessary, two or more symbols can be grouped together to convey a particular meaning and that, provided the essential communicative characteristics of the basic symbol are maintained, some latitude in graphic design is permissible. The colours of symbols are not specified, except for the background of the AP and APG symbols (see Clause G.3). The colours of safety signs are specified in ISO 3864-1. 对于IEC 60878中的符号不满足的符号要求，首先应参考已发布的IEC或ISO符号，注意，如有必要，可将两个或多个符号组合在一起，以传达特定的含义，并且只要基本符号的基本通信特性保持不变，在平面设计上有一些自由度是允许的。除AP和APG符号的背景外，未规定符号的颜色（见第G.3条）。ISO

3864-1中规定了安全标志的颜色。

In the following tables, the symbol graphic and title are provided for information.
下表提供了符号图形和标题以供参考。

Table D.1 – General symbols

表D.1——通用符号

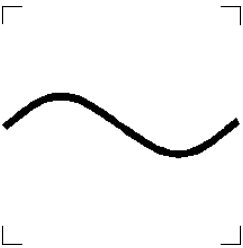
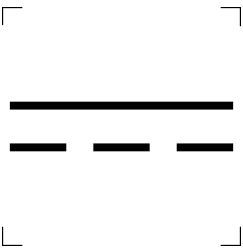
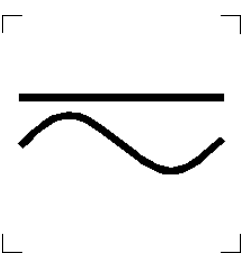
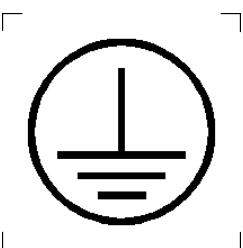
No · 不 。	Symbol 符号	Reference 参考文献	Titl e 标 题
1 1		IEC 60417-5032 IEC 60417-5032标准	Alternating current 交流电
2 2		IEC 60417-5032-1 IEC 60417-5032-1标准	Three-phase alternating current 三相交流电
3 三		IEC 60417-5032-2 IEC 60417-5032-2标准	Three-phase alternating current with neutral conductor 中性线三相交流电
4 4		IEC 60417-5031 IEC 60417-5031标准	Direct current 直流电
5 5		IEC 60417-5033 IEC 60417-5033标准	Both direct and alternating current 直流和交流
6 6		IEC 60417-5019 IEC 60417-5019标准	Protective earth (ground) 保护接地

Table D.1 (continued)
表D.1（续）

No · 不 。	Symbol 符号	Reference 参考文献	Titl e 标 题
7 7		IEC 60417-5017 IEC 60417-5017标准	Earth (ground) 地（地）
8 8		IEC 60417-5021 IEC 60417-5021	Equipotentiality 等电位
9 9		IEC 60417-5172 IEC 60417-5172标准	CLASS II equipment 二类设备
10 10	ISO 7000-0434A标准 注意安全	ISO 7000-0434A 如果作为安全标志使用，规则	Caution 应遵守ISO 3864-1。看到了吗 In case of application as a safety sign, the rules 安全标志ISO 7010-W001（表D.2，安全标志2）。 according to ISO 3864-1 are to be adhered to. See 11 safety sign ISO 7010-W001 (Table D.2, safety sign 2). ISO 7000-1641标准
11 操作说明		ISO 7000-1641 12	Operating instructions IEC 60417-5007标准

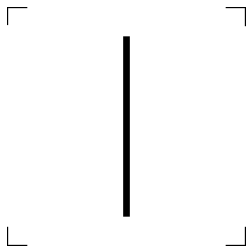
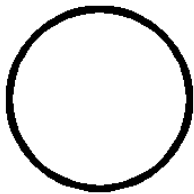
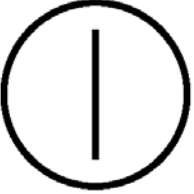
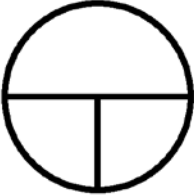
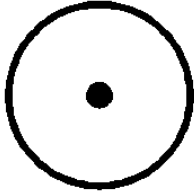
12 “开” （电 源）		IEC 60417- 5007 不。	“ON” (power) 符号

Table D.1 (continued)
表D.1（续）

No · 参 考 文 献	Symbol 标题	Reference 13	Titl e IEC 604 17- 500 8标 准
13 “关” （电 源）		IEC 60417- 5008 14	“OFF” (power) IEC 60417-5010标准
14 “开”/“ 关” （按- 推）		IEC 60417- 5010 注意每个位 置，“开”或 “关”都是一个 稳定的位置。	“ON” / “OFF” (push-push) 15 NOTE Each position, "ON" or "OFF", is a stable position. IEC 60417-5011标准
15 15		IEC 60417- 5011 IEC 60417- 5011	“ON” / “OFF” (push button) “开”/“关”（按钮） NOTE "OFF" is a stable position, whilst the "ON" position only remains during the time the button is depressed. 注：“关”是一个稳定的位置，而“开”位置仅 在按下按钮期间保持不变。
16 16		IEC 60417- 5264 IEC 60417- 5264标准	“ON” for part of equipment 部分设备“开”

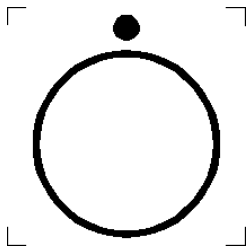
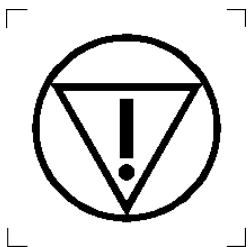
17 17		IEC 60417-5265 IEC 60417-5265标准	“OFF” for part of the equipment 部分设备“关”
18 18		IEC 60417-5638 IEC 60417-5638标准	Emergency stop 紧急停止

Table D.1 (continued)
表D.1（续）

No · 不 。	Symbol 符号	Reference 参考文献	Titl e 标 题
19 19		IEC 60417-5840 IEC 60417-5840标准	TYPE B APPLIED PART B型应用部件 NOTE Subclause 7.2.10 requires that, for clear differentiation with symbol 20, symbol 19 is not to be applied in such a way as to give the impression of being inscribed within a square. 与符号20、符号19的区别不应使人产生被刻在正方形内的印象。
20 20		IEC 60417-5333 IEC 60417-5333标准	TYPE BF APPLIED PART BF型应用部件
21 21		IEC 60417-5335 IEC 60417-5335标准	TYPE CF APPLIED PART CF型应用部件
22 22		IEC 60417-5331 IEC 60417-5331标准	CATEGORY AP equipment AP类设备
23 23		IEC 60417-5332 IEC 60417-5332标准	CATEGORY APG equipment APG类设备

24 24		IEC 60417-5036 IEC 60417-5036标准	Dangerous voltage 危险电压

Table D.1 (continued)
表D.1（续）

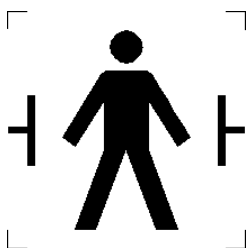
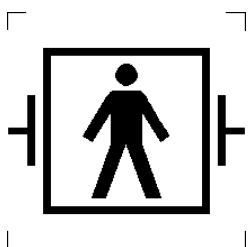
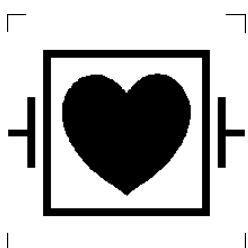
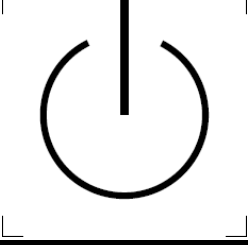
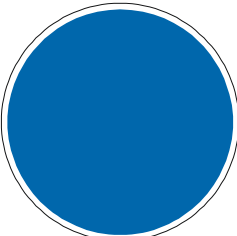
No. 不。	Symbol 符号	Reference 参考文献	Titl e 标 题
25 25		IEC 60417- 5841 IEC 60417- 5841标准	DEFIBRILLATION-PROOF TYPE B APPLIED PART 防除颤B型应用部件
26 26		IEC 60417- 5334 IEC 60417- 5334标准	DEFIBRILLATION-PROOF TYPE BF APPLIED PART BF型除颤应用部件
27 27		IEC 60417- 5336 IEC 60417- 5336标准	DEFIBRILLATION-PROOF TYPE CF APPLIED PART 防除颤型CF应用部件
28 28		ISO 7000- 1051 ISO 7000- 1051标准	Do not reuse 请勿重复使用
29 29		IEC 60417- 5009 IEC 60417- 5009标准	Stand-by 待命

Table D.2 – Safety signs
表D.2-安全标志

No · 不 。	Safety sign 安全标志	Reference 参考文献	Titl e 标 题
1 1		ISO 3864-1, ISO 3864-1标 准, Figure 3 图3	Template for constructing a warning sign 警告标志制作模板 NOTE Background colour: yellow Triangular band: Black 注背景颜色：黄色 三角形带：黑色 Symbol or text: Black 符号或文字：黑色
2 2		ISO 7010- W001 ISO 7010- W001	General warning sign 一般警告标志
3 三		IEC 60878 ISO 3864-B.3.6 a ISO 7010- W012 IEC 60878 ISO 3864- B.3.6 a ISO 7010-W012	Warning: dangerous voltage Warning, electricity 警告：危险电压警告，电
4 4		ISO 7010- P001 ISO 7010- P001 and ISO 3864-1, 以及ISO 3864-1, Figure 1 图1	General prohibition sign and 一般禁止标 志和 Template for constructing a prohibition sign 禁止标志制作模板 NOTE Background colour: white 备注背景颜色：白色 Circular band and slash: red Symbol or text: black 圆圈和斜线：红色

			符号或文本：黑色
5 5		ISO 7010-P017 ISO 7010-P017 标准	No pushing 不要推搡
6 6		ISO 7010-P018 ISO 7010-P018 标准	No sitting 不要坐着

Table D.2 (continued)
表D.2（续）

No · 不 。	Safety sign 安全标志	Reference 参考文献	Titl e 标 题
7 7		ISO 7010-P019 ISO 7010-P019 标准	No stepping on surface 禁止踩踏地面
8 8		ISO 3864-1 ISO 3864-1标 准 Figure 2 图2	Template for constructing a mandatory action sign 用于构造强制行动标志的模板 NOTE Background colour: blue Symbol or text: white 注背景颜色：蓝 色符号或文字： 白色
9 9		ISO 7010- M001 ISO 7010- M001	General mandatory action sign 一般强制性行动标志
10 10		ISO 7010- M002 ISO 7010- M002标准	Refer to instruction manual/ booklet 参考使用手册/手册 NOTE On ME EQUIPMENT "Follow instructions for use" 医用电气设备注释“遵循使用说明”

a The description of this commonly used safety sign appeared in Annex B of ISO 3864:1984. When the safety signs were collected in ISO 7010, this sign was not migrated to the new standard. ISO 3864:1984 was superseded by ISO 3864-1 and ISO 7010 in January 2003. It is expected that this safety sign will be added to ISO 7010 in an upcoming amendment.
a该常用安全标志的说明见ISO 3864:1984附录B。在ISO 7010中收集安全标志时，该标志未迁移到新标准中。ISO 3864:1984于2003年1月被ISO 3864-1和ISO 7010取代。预计该安全标志将在即将到来的修订版中添加到ISO 7010中。

Table D.3 – General codes
表D.3——通用代码

1 1	N N	IEC 60445 IEC 60445 标准	Connection point for the neutral conductor on 中性导线的连接点 PERMANENTLY INSTALLED equipment 永久安装设备
2 2	IPN1N2 IPN1N2型	IEC 60529 IEC 60529 标准	N1 = 0 Non-protected N1=0 无保护 1 Protected against solid foreign objects of 50 mm □ and greater 防止50 mm□及以上的固体异物 2 Protected against solid foreign objects of 12.5 mm □ and greater 防止12.5 mm□厚的固体异物进入以及更大的 3 Protected against solid foreign objects of 2,5 mm □ and greater 防止2.5 mm厚的固体异物进入以及更大的 4 Protected against solid foreign objects of 1.0 mm □ and greater 防止1.0 mm□的固体异物以及更大的 5 Dust-protected 防尘 6 Dust-tight 防尘的 N2 = 0 Non-protected 非保护N2=0 1 Protection against vertically falling water drops 防止垂直下落的水滴 2 Protection against vertically falling water drops when ENCLOSURE tilted up to 15° 防止垂直下落的水滴 外壳倾斜达15° 3 Protected against spraying water 防止喷水 4 Protected against splashing water 防止溅水 5 Protected against water jets 防止喷水 6 Protected against powerful water jets 防止强大的水射流 7 Protected against the effects of temporary immersion in water 防止临时浸入水中的影响 8 Protected against the effects of continuous immersion in water 防止连续浸入水中的影响 NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter “X” (“XX” if both numerals are omitted). 注：当不要求指定特征数字时，用字母“X”代替（如果两个数字都省略了，“XX”）。

Annex E
附件E
(informative)
（资料性）

Examples of the connection of the measuring device (MD) for measurement of
the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY
用于测量病人漏电流和病人辅助装置的测量装置（MD）的连接示例

CURRENT
当前
(see 8.7)
（见8.7）

ME EQUIPMENT with TYPE B APPLIED PART
带B型应用部件的医用电气设备
From all PATIENT
CONNECTIONS
connected together.

从所有连接在一起的病人
身上。

For legends, see Table 5
图例见表5 IEC 2442/05

IEC 2442/05

Figure E.1 – TYPE B APPLIED PART
图E.1-B类应用部件

ME EQUIPMENT with
TYPE BF APPLIED
PART
带有BF型应用部件的医用
电气设备
From and to all
PATIENT
CONNECTIONS of a
single function
connected together. For
legends, see Table 5
一个单一功能的所有患者
连接连接在一起。图例见
表5

IEC 2443/05
IEC 2443/05标准

Figure E.2 – TYPE BF APPLIED PART
图2.E型应用零件

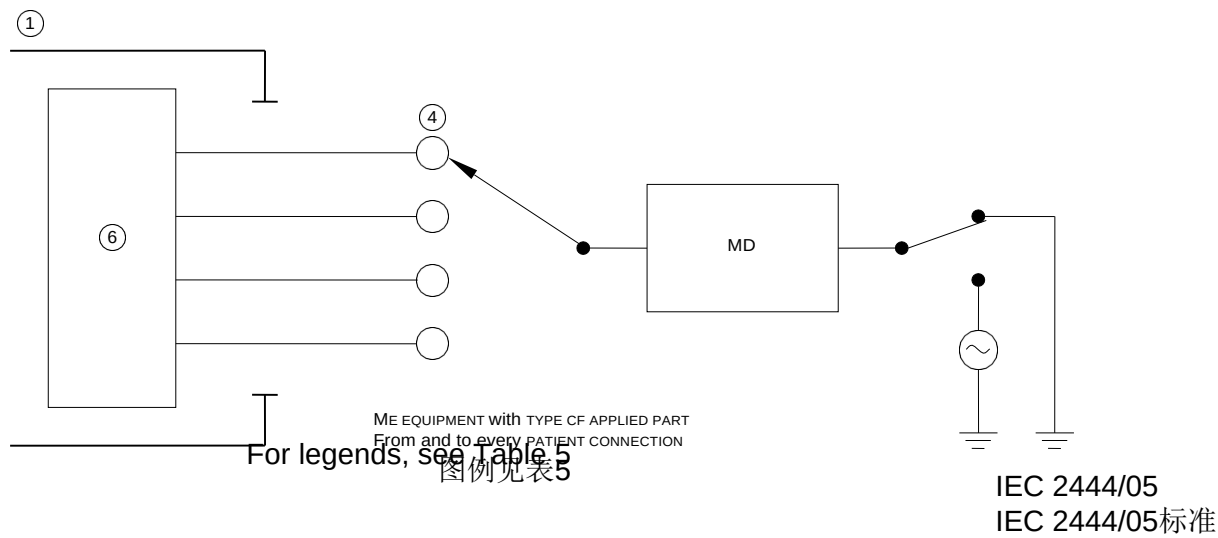


Figure E.3 – TYPE CF APPLIED PART
图E.3-CF型应用部件

4
4

6

MD

ME EQUIPMENT with TYPE
B APPLIED PART, TYPE BF
APPLIED PART or TYPE CF
APPLIED PART
带有B型应用部件、BF型应用
部件或CF型应用部件的医用
电气设备
Between any single PATIENT CONNECTION
and all other PATIENT CONNECTIONS
任何一个病人之间的联系
以及所有其他的病人关系
For legends, see Table 5
图例见表5 IEC 2445/05

IEC 2445/05

Figure E.4 – PATIENT AUXILIARY CURRENT
图E.4—患者辅助电流

①

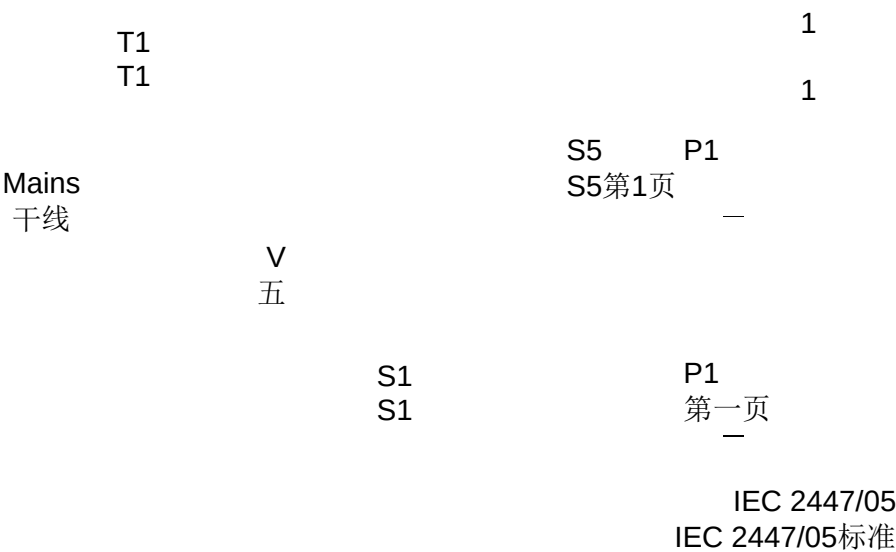
of the APPLIED PART
应用部分的
From and to every
PATIENT
CONNECTION
每个病人的联系
For legends, see Table
5
图例见表5

— —
IEC
2446/0
5
IEC
2446/0
5标准

Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER
图E.5-如果制造商指定，患者连接件的荷载

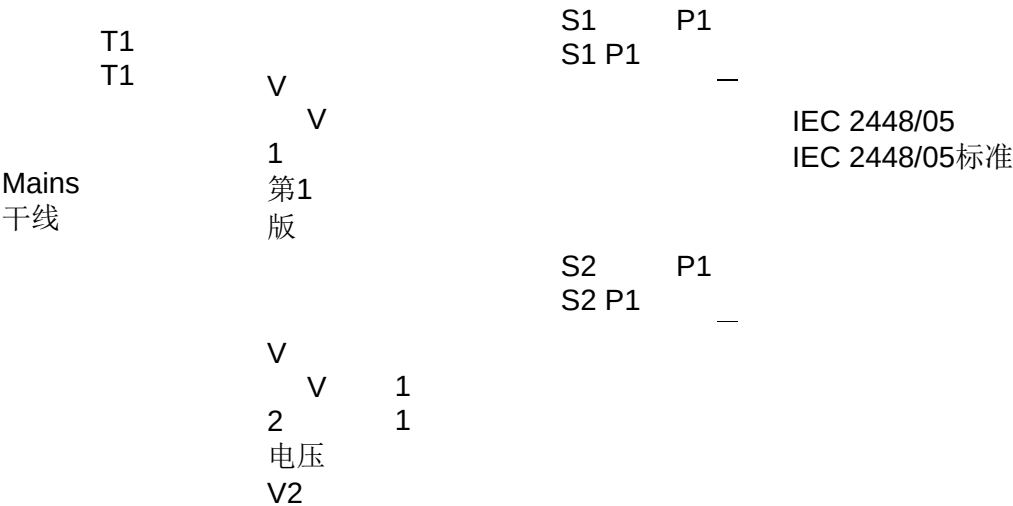
Annex F
高级预测模式
(informative)
(资料性)

Suitable measuring supply circuits
合适的测量电源电路



For legends, see Table 5.
图例见表5。

Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS
图F.1–测量电源线一侧的电源电路
at approximately earth potential
在近似地电位下
(see 8.7.4.2)
(见8.7.4.2)



For legends, see Table 5.

图例见表5。

Figure F.2 – Measuring supply circuit with SUPPLY MAINS

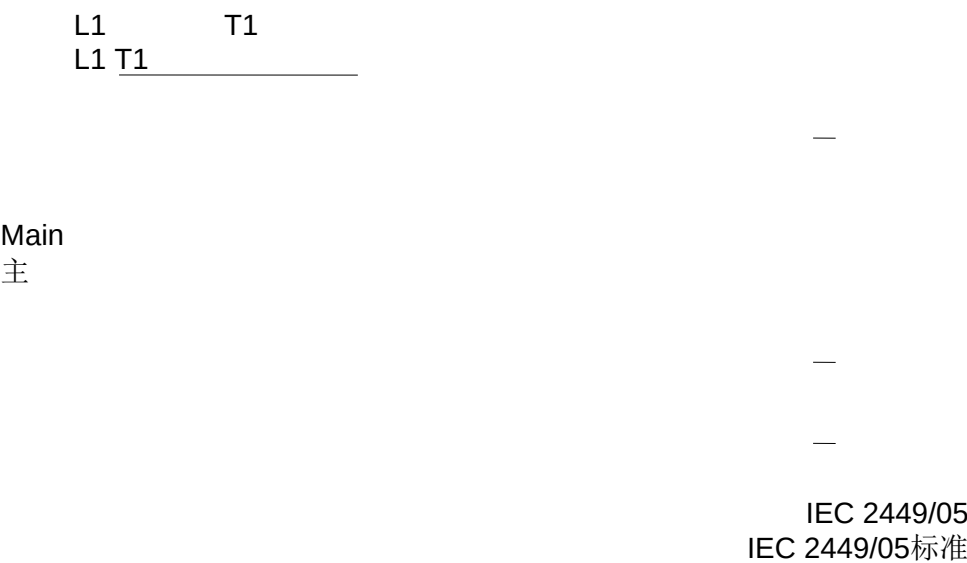
图F.2—测量带电源的供电电路

approximately symmetrical to earth potential

与地电位近似对称

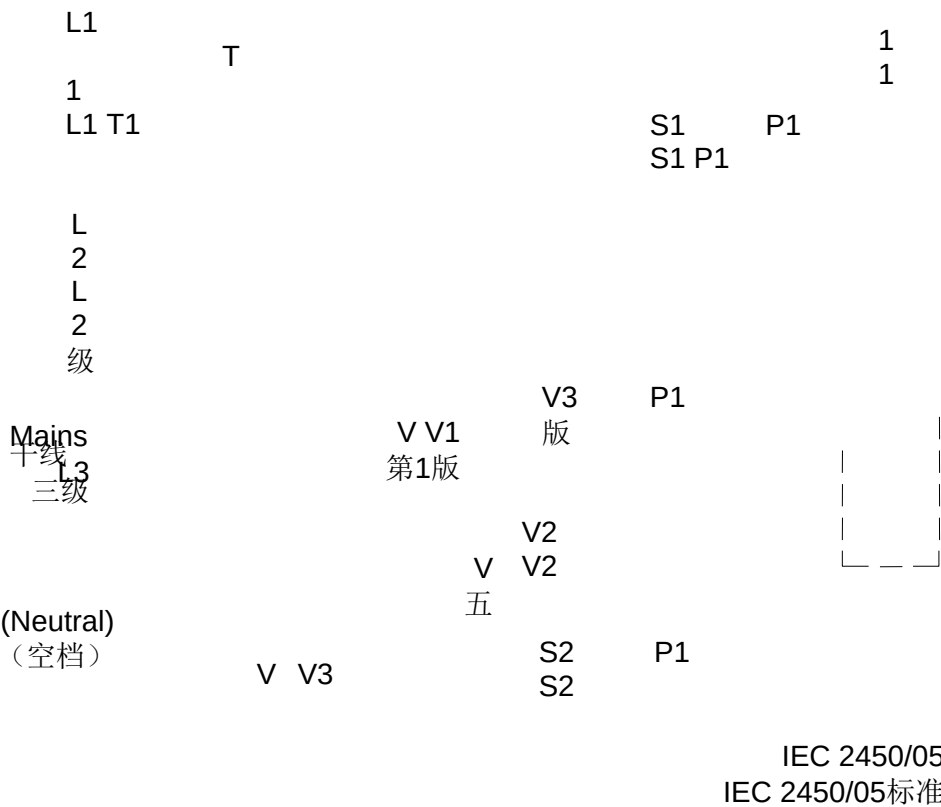
(see 8.7.4.2)

(见8.7.4.2)



For legends, see Table 5.
图例见表5。

Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT
图F.3-多相医用电气设备的测量电源电路
specified for connection to a polyphase SUPPLY MAINS
指定用于连接多相电源
(see 8.7.4.2)
(见8.7.4.2)



For legends, see Table 5.
图例见表5。

Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT

图F.4-单相医用电气设备的测量电源电路
specified for connection to a polyphase SUPPLY MAINS
指定用于连接多相电源
(see 8.7.4.2)
(见8.7.4.2)

T1
T1

For legends, see Table 5.
图例见表5。

Figure F.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM

图F.5–医用电气设备的测量电源电路，该设备具有独立的电源单元，或打算从医用电气系统中的另一个设备接收电源
(see 8.7.4.2)
(见8.7.4.2)

Annex G
附件G
(normative)
（规范性）

**Protection against HAZARDS of ignition of
flammable anaesthetic mixtures**
易燃麻醉混合物引燃危险防护

NOTE This annex replaces the former Section Six: “Protection against HAZARDS of ignition of flammable anaesthetic mixtures” of the second edition.

注：本附录取代第二版第六节：“易燃麻醉混合物引燃危险防护”。

G.1 Introduction
介绍

G.1.1 Applicability
适用性

Where ME EQUIPMENT is used in areas in which flammable anaesthetics or flammable agents for disinfection or skin cleaning are applied, an explosion RISK can exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.
如果医用电气设备用于使用易燃麻醉剂或用于消毒或皮肤清洁的易燃剂的区域，如果此类麻醉剂或药剂与空气、氧气或氧化亚氮混合，则可能存在爆炸危险。

Ignition of such a mixture can be caused by sparks or by contact with parts having a high surface temperature.

这种混合物的着火可能是由火花或与具有高表面温度的零件接触引起的。

Sparks can be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

当通过开关、连接器、保险丝或过电流释放装置等的操作打开或关闭电路时，可能会产生火花。

In HIGH VOLTAGE parts, sparks can be caused by corona. Static discharges can cause sparks.

在高压部件中，电晕会引起火花。静电放电会产生火花。

The probability of occurrence of the ignition of such anaesthetic mixtures depends on their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures and the energy of sparking.
这种麻醉剂混合物发生着火的可能性取决于其浓度、适当的最小点火能量、存在的高表面温度和火花能量。

G.1.2 Industrial equipment and components
工业设备和部件

The constructional requirements of IEC 60079-0 are generally not appropriate for IEC 60079-0的结构要求通常不适用于

ME EQUIPMENT for several reasons:

医用电气设备有以下几个原因：

- a) they lead to constructions of a size, weight or design that are not applicable for medical reasons or that cannot be sterilizable;
它们导致建筑的尺寸、重量或设计因医学原因不适用或不能灭菌；
- b) some constructions allow an explosion inside an ENCLOSURE, but prevent propagation outside it. Such a construction, which might be inherently safe, would be unacceptable in an operating theatre where continuity of operation of ME EQUIPMENT is essential;
有些建筑允许在外壳内爆炸，但防止爆炸在外壳外传播。这种结构可能本质上是安全的，但在医用电气设备的连续运行至关重要的手术室中，这种结构是不可接受的；

- c) industrial requirements were made for flammable agents mixed with air. They cannot be applied to mixtures with oxygen or nitrous oxide used in medical practice;
工业要求对可燃物与空气混合。它们不能用于医疗实践中与氧气或一氧化二氮的混合物;
- d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.
在医疗实践中, 易燃的麻醉剂混合物只出现在相对较少的数量。

However some of the constructions described in IEC 60079-0 are acceptable for CATEGORY AP ME EQUIPMENT (see G.5.1).

然而, IEC 60079-0中描述的一些结构可用于AP-ME类设备(见G.5.1)。

G.1.3 * Requirements for ME EQUIPMENT

***医用电气设备要求**

In this annex, the location of flammable anaesthetic mixtures is described:

在本附录中, 易燃麻醉混合物的位置描述如下:

- as much as necessary for the construction of ME EQUIPMENT, as minimum for specified conditions of exhaust and absorption;
医用电气设备施工所需, 至少在规定的排气和吸收条件下;
- as much as necessary for the allocation of ME EQUIPMENT and the construction of the electrical installation in the IEC 60364 series.

根据IEC 60364系列的要求, 为医用电气设备的配置和电气装置的施工提供必要的材料。

The recommendations, limits and tests of this annex are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in Clause G.7. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

本附录中的建议、限值和试验是基于使用第G.7条中所述的试验装置，对乙醚蒸汽与空气和氧气的最易燃烧混合物进行试验所得统计考虑的结果。这是合理的，因为与乙醚的混合物具有最低的点火温度和最低的点火能量常用的药剂。

Where temperatures or circuit parameters of ME EQUIPMENT used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR exceed allowable limits and sparking cannot be avoided the relevant parts and circuits can be enclosed in ENCLOSURES with pressurized inert gas or clean air or in ENCLOSURES with restricted breathing.

如果医用电气设备在与空气混合的易燃麻醉剂中使用的温度或电路参数超过允许范围，并且无法避免火花，则相关部件和电路可封闭在带有加压惰性气体或清洁空气的外壳内，或封闭在呼吸受限的外壳内。

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which ME EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

呼吸受限的密封室可延迟可燃浓度的积聚。它们之所以被认可，是因为假定医用电气设备在可燃麻醉混合物中与空气混合使用的一段时间后，会有一段通风时间，在此期间，这种浓度将消失。

For ME EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR

对于医用电气设备，包含或用于易燃麻醉混合物的氧气或

NITROUS OXIDE, requirements, limits and tests are far more stringent.

一氧化二氮，要求，限制和测试要严格得多。

These recommendations apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in 4.7. Only two exemptions from an actual ignition test are recognized, these being either the absence of sparks and limited temperature or limited temperature and restricted circuit parameters.

这些建议不仅适用于正常情况，而且适用于4.7中所述的单一故障情况。在实际点火试验中，只有两种豁免被认可，即没有火花和有限温度，或有限温度和受限电路参数。

G.2

Locations

and

basic

requirements

位置和基本要求

G.2.1

Parts of

CATEGORY

APG

ME

EQUIPMENT

APG ME类设备的零件

Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

哪种麻醉设备中含有易燃气体

occurs shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clause G.3, G.4 and G.5.

发生应为AP或APG ME类设备，并应符合第G.3、G.4和G.5条的要求。

G.2.2

FLAMMABLE

ANAESTHETIC

MIXTURE

WITH

AIR

与空气混合的易燃麻醉剂

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or discharge of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE from an ENCLOSURE, it is

如果可燃性麻醉剂混合物与氧气或一氧化二氮从外壳中泄漏或排出，则

considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point.

被认为传播到泄漏点或排放点周围5 cm到25 cm距离处的体积。

G.2.3 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
含氧或一氧化二氮的易燃麻醉剂混合物

A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a 易燃的麻醉剂混合物中可能含有氧气或一氧化二氮
completely or partly enclosed ME EQUIPMENT part and in the PATIENT'S respiratory tract. Such a
mixture is considered to propagate to a distance of 5 cm from an ENCLOSURE part where leakage
or discharge occurs.
完全或部分封闭医用电气设备部件和病人的呼吸道。这种混合物被认为传播到距离发生泄漏或放电的外
壳部件5 cm的距离。

G.2.4 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR
医用电气设备，指定用于与空气混合的易燃麻醉剂

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC
MIXTURE WITH AIR (in a location defined in G.2.2) shall be CATEGORY AP or APG ME
EQUIPMENT and shall comply with the requirements of Clause G.4 and G.5.
指定用于与空气混合的易燃麻醉混合物（在G.2.2中定义的位置）使用的医用电气设备或其部
件应为AP或APG ME类设备，并应符合第G.4和G.5条的要求。

G.2.5 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

医用电气设备，指定用于与氧气或一氧化二氮混合的易燃麻醉混合物

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (in a location defined in G.2.2) shall be CATEGORY APG ME EQUIPMENT and shall comply with the requirements of G.4 and G.6.

指定用于含氧或一氧化二氮的易燃麻醉混合物的医用电气设备或其部件（在G.2.2中规定的位置）应为APG ME类设备，并应符合G.4和G.6的要求。

Compliance with the requirements of G.2.3 through G.2.4 and G.2.5 (inclusive) is checked by inspection and by the appropriate tests of Clause G.3, G.4 and G.5. 通过检验和第G.3、G.4和G.5条（包括第G.2.3条至第G.2.4条和第G.2.5条（包括第G.2.3至G.2.4和G.2.5条）要求的符合性进行检查。

These tests shall be performed after applicable tests according to 11.6.6 and 11.6.7. 这些试验应在根据11.6.6和11.6.7进行的适用试验之后进行。

G.3 Marking, ACCOMPANYING DOCUMENTS

标记、随附文件

G.3.1 CATEGORY APG marking

类别APG标记

CATEGORY APG ME EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters “APG” (see symbol IEC 60417-5332 (DB:2002-10) (Table D.1, symbol 23)). The length of the green-coloured band should be at least 4 cm. The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use. APG类医用电气设备应在显眼位置用至少2 cm宽的绿色色带标记“APG”（见符号IEC 60417-5332（DB:2002-10）（表D.1，符号23））。绿色带子的长度至少应为4厘米。对于特定情况，标记的尺寸应尽可能大。如果无法进行此标记，则应在使用说明中给出相关信息。

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

通过试验和7.1.3中的检验和标准检验。

G.3.2 CATEGORY AP marking

AP类标记

CATEGORY AP ME EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters “AP” (see symbol IEC 60417- 5331 (DB:2002-10) (Table D.1, symbol 22)). AP类医用电气设备应在显眼位置用直径至少为2 cm的绿色圆圈标记，并刻有“AP”字样（见IEC 60417-5331（DB:2002-10）（表D.1，符号22））。

The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

对于特定情况，标记的尺寸应尽可能大。如果无法进行此标记，则应在使用说明中给出相关信息。

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

通过试验和7.1.3中的检验和标准检验。

G.3.3 Placement of markings

标记的放置

The marking according to G.3.1 and G.3.2 and G.3.3 shall be present on the major part of the ME

EQUIPMENT if this part is CATEGORY AP or CATEGORY APG. It need not be repeated on detachable parts that can only be used together with the marked ME EQUIPMENT. 如果医用电气设备的主要部件为AP类或APG类，则该部件应具有G.3.1、G.3.2和G.3.3的标记。不必在只能与标记的ME设备一起使用的可拆卸部件上重复。

Compliance is checked by inspection.
通过检查检查合规性。

G.3.4 ACCOMPANYING DOCUMENTS 随附文件

ACCOMPANYING DOCUMENTS shall contain an indication to enable the RESPONSIBLE ORGANIZATION to distinguish the parts of ME EQUIPMENT (see G.3.5) that are CATEGORY AP and CATEGORY APG. 随附文件应包含一个指示，以使责任机构能够区分医用电气设备（见G.3.5）的AP类和APG类部件。

Compliance is checked by inspection.
通过检查检查合规性。

G.3.5 Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG 医用电气设备部件为AP类或APG类时的标记

On ME EQUIPMENT in which only certain ME EQUIPMENT parts are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

在仅某些医用电气设备部件为AP类或APG类的医用电气设备上，标记应清楚地表明哪些部件属于AP类或APG类。

Compliance is checked by inspection.
通过检查检查合规性。

G.4 Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT AP类和APG类医用电气设备的通用要求

G.4.1 Electrical connections 电气连接

- a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORD shall be according to THE Table 12 values for one MEANS OF PATIENT PROTECTION.
电源线连接点之间的爬电距离和空气间隙应符合表12中的一种患者保护方法的值。
- b) Connections, except those in the circuits described in G.5.3 and G.6.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection or disconnection can be performed only with the use of a TOOL.
除G.5.3和G.6.3所述电路中的连接外，应在正常使用中防止意外断开，或应设计成只能使用工具进行连接或断开。
- c) CATEGORY AP and CATEGORY APG ME EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of G.5.3 and G.6.3.
除非电路符合G.5.3和G.6.3的要求，否则AP类和APG类ME设备不得配备可拆卸电源线。

Compliance is checked by inspection or measurement.
通过检查或测量来检查符合性。

G.4.2 Construction details 施工详图

- a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the ME EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.
只有借助工具才能打开外壳，以防止气体或蒸汽渗入医用电气设备或其部件。

Compliance is checked by inspection.
通过检查检查合规性。

- b) To minimize arcing and sparking due to foreign objects penetrating the ENCLOSURE:
为尽量减少因异物穿透外壳而产生的电弧和火花：
- top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;
外壳顶盖不得有开口；如果控制旋钮盖住了控制装置的开口，则允许使用这些开口；
 - openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;
侧盖开口的尺寸应能防止直径大于4mm的实心圆柱形物体穿透；
 - openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.
底板开口的尺寸应能防止直径大于12 mm的实心圆柱形物体穿透。

Compliance is checked by means of a cylindrical test rod of 4 mm diameter for side-covers and 12 mm diameter for base plates. The test rod is not to enter the ENCLOSURE when applied in all possible directions without appreciable force.
通过直径为4 mm（侧盖）和直径为12 mm（底板）的圆柱形试验棒检查合规性。在没有明显力的情况下，在所有可能的方向上施加试验棒时，不应进入外壳。

- c) Where insulation of electrical conductors equal to one MEANS OF PATIENT PROTECTION may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature or in a HAZARD in such a part (see G.6.3 a)) or in any HAZARDOUS SITUATION.

当等同于一种病人保护手段的导体绝缘可能会接触含有易燃麻醉混合物的部件，该混合物与氧气或一氧化二氮或可燃气体或氧气接触，这些导体的短路或一根导体对含有气体或混合物的导电部件的短路不得导致该部件的完整性丧失，也不得导致不允许的温度或在该部件中造成危险（见G.6.3A）），或处于任何危险情况。

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) should be performed and the temperature in the relevant part should be measured if possible. The short-circuit test need not be performed if the product of the open-circuit voltage in volts and the short-circuit current in amperes does not exceed 10. 通过检查检查合规性。如有疑问，应进行短路试验（无爆炸性气体），并尽可能测量相关零件的温度。如果开路电压（伏特）与短路电流（安培）之积不超过10，则无需进行短路测试。

G.4.3 Prevention of electrostatic charges **防止静电电荷**

- a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG ME EQUIPMENT
应防止AP类和APG类医用电气设备产生静电
by a combination of appropriate measures such as:
采取适当措施，如：

- the use of antistatic materials with a limited electrical resistance as specified in
使用具有有限电阻的抗静电材料
G.4.3 b), and
b) , 和
- provision of electrically conductive paths from ME EQUIPMENT or its parts to a
conductive floor or to the protective earth system or the potential equalization system
or via wheels to an antistatic floor of the medically used room.
提供从医用电气设备或其部件到导电地板或保护接地系统或电位均衡系统的导电路径，
或通过轮子到医用房间的防静电地板。

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO 2882.
麻醉管、床垫和垫、脚轮和其他抗静电材料的电阻限值应符合ISO 2882。

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 1853, ISO 2878 and ISO 23529.

根据ISO 1853、ISO 2878和ISO 23529，通过测量检查是否符合ISO 2882中给出的允许电阻限值。

G.4.4 Corona **光晕**

Parts and components of ME EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. that are not included in ENCLOSURES in compliance with G.5.4 or G.5.5 shall be so designed that corona cannot be produced.
按照G.5.4或G.5.5的要求，在2000 V a.c.或2 400 V d.c.下运行的医用电气设备的零件和部件的设计应确保不会产生电晕。

Compliance is checked by inspection and measurement.
通过检查和测量来检查符合性。

G.5 Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof **AP类医用电气设备及其零部件的要求和试验**

G.5.1 General **总则**

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.
医用电气设备及其零部件在正常使用和正常条件下不得与空气一起点燃易燃麻醉混合物。

ME EQUIPMENT, its parts or components complying with one of Subclauses G.5.2 to G.5.5 (inclusive) are considered to comply with the requirement of this subclause.
医用电气设备，其零件或部件符合子条款G.5.2至G.5.5（含）之一的要求，视为符合本条款的要求。

ME EQUIPMENT, its parts or components complying with the requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2), for sand-filled ENCLOSURES (IEC 60079-5) or for oil-immersed equipment (IEC 60079-6) as well as with the requirements of this standard (excluding those of G.5.2 to G.5.5), are considered to comply with the requirements for CATEGORY AP ME EQUIPMENT.

医用电气设备，其零件或部件符合IEC 60079-0《承压外壳》（IEC 60079-2）、《充砂外壳》（IEC 60079-5）或《油浸设备》（IEC 60079-6）的要求，以及本标准的要求（不包括G.5.2至G.5.5的要求），视为符合要求适用于AP ME类设备。

G.5.2 Temperature limits **温度限值**

ME EQUIPMENT, its parts or components not producing sparks and not producing operating temperatures of surfaces, in contact with gas mixtures in NORMAL USE and NORMAL CONDITION, exceeding 150 °C in case of restricted vertical air circulation by convection, or exceeding 200 °C in case of unrestricted vertical air circulation, if measured at an ambient temperature of 25 °C, are considered to comply with the requirements of G.5.1.

医用电气设备及其零件或部件，在正常使用和正常条件下，与气体混合物接触，不会产生火花，也不会产生表面工作温度，如果通过对流限制垂直空气循环，超过150°C，如果垂直空气循环不受限制，则超过200°C，如果在25°C的环境温度下测量，则认为符合G.5.1的要求。

The operating temperatures are measured during the tests mentioned in 11.1.

在11.1所述试验期间测量工作温度。

G.5.3 * Low-energy circuits

***低能量电路**

ME EQUIPMENT, its parts or components that may produce sparks in NORMAL USE and NORMAL CONDITION of the ME EQUIPMENT (for example, switches, relays, plug connections that can be detached without the use of a TOOL, including connections inside ME EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of G.5.2 and additionally the voltage U_{max} and the current I_{max} , which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following:

医用电气设备，在医用电气设备的正常使用和正常状态下可能产生火花的零件或部件（例如，开关、继电器、不使用工具即可拆卸的插头，包括医用电气设备内部未充分锁定或固定的连接，以及电刷电机）应符合G.5.2的温度要求，此外，考虑到电容 C_{max} 和电感 L_{max} ，其电路中可能出现的电压 U_{max} 和电流 I_{max} 应符合以下要求：

$U_{max} \square U_{zR}$ with a given current I_{zR} , see Figure G.1,
 给定电流 I_{zR} 的 $U_{max} \square U_{zR}$ ，见图G.1，

$U_{max} \square U_c$ with a given capacitance C_{max} , see Figure G.2,
 $U_{max} \square U_c$ ，给定电容 C_{max} ，见图G.2，

$I_{max} \square I_{zR}$ with a given voltage U_{zR} , see Figure G.1, and
 $I_{max} \square I_{zR}$ ，给定电压 U_{zR} ，见图G.1，以及

$I_{max} \square I_{zL}$ with a given inductance L_{max} and a $U_{max} \square 24 \text{ V}$, see Figure G.3.
 $I_{max} \square I_{zL}$ ，具有给定的电感 L_{max} 和 $U_{max} \square 24 \text{ V}$ ，见图G.3。

- The graphs of Figure G.1, Figure G.2 and Figure G.3 have been obtained with the test apparatus according to G.6 Figure G.7 with the most readily flammable mixtures of ether vapour with air (ether volume percentage $4,3 \pm 0,2 \%$) for an ignition probability (without safety factor) of 10-3.
 图G.1、图G.2和图G.3中的图是使用G.6图G.7中的试验装置获得的，其中乙醚蒸汽与空气的最易燃烧混合物（乙醚体积百分比为 $4.3 \pm 0.2\%$ ），着火概率（无安全系数）为10-3。
- Extrapolation of the graph of Figure G.1 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \square U_{zR} \square 50 \text{ W}$.
 在 $I_{zR} \square U_{zR} \square 50 \text{ W}$ 的限制范围内，允许对图G.1的图形进行外推。

Extrapolation for voltages of more than 42 V is not valid.
 电压超过42V的外推法无效。

- Extrapolation of the graph of Figure G.2 is allowed for combinations of capacitances and corresponding voltages within the limitations:
 允许对限值内的电容和相应电压的组合进行图G.2图的外推：

$$\begin{aligned} C U^2 &\square 1,2 \\ \text{mJ}^2 \\ C U^2 &\square 1,2 \text{ 兆} \\ \text{焦耳}^2 \end{aligned}$$

Extrapolation for voltages of more than 242 V is not valid.
 超过242 V的电压外推无效。

If the equivalent resistance R is less than $8\,000 \square$, U_{max} is additionally determined with the actual resistance R .
 如果等效电阻 R 小于 $8000 \square$ ，则 U_{max} 与实际电阻 R 另外确定。

- Extrapolation of the graph of Figure G.3 is allowed for combinations of currents and corresponding inductances within the limitations
 允许对限值内的电流和相应电感的组合进行图G.3图的外推

$$\begin{aligned} L I^2 &\square 0,3 \text{ mJ} \\ L I^2 &\square 0,3 \text{ 兆焦耳} \\ &\frac{2}{2} \end{aligned}$$

Extrapolation for inductances larger than 900 mH is not valid.
 大于900 mH的电感外推无效。

- Voltage U_{max} is taken as the highest supply voltage occurring in the circuit under investigation with the sparking contact open, taking into account the MAINS VOLTAGE variations required in 4.10.
 考虑到4.10中要求的电源电压变化，电压 U_{max} 被视为火花触点开路时所调查电路中的最高电源电压。
- Current I_{max} is taken as the highest current flowing in the circuit under investigation with the sparking contact closed, taking into account the MAINS VOLTAGE variations required in 4.10.
 考虑到4.10中要求的电源电压变化，在火花触点闭合的情况下，电流 I_{max} 被视为所研究电

路中的最高电流。

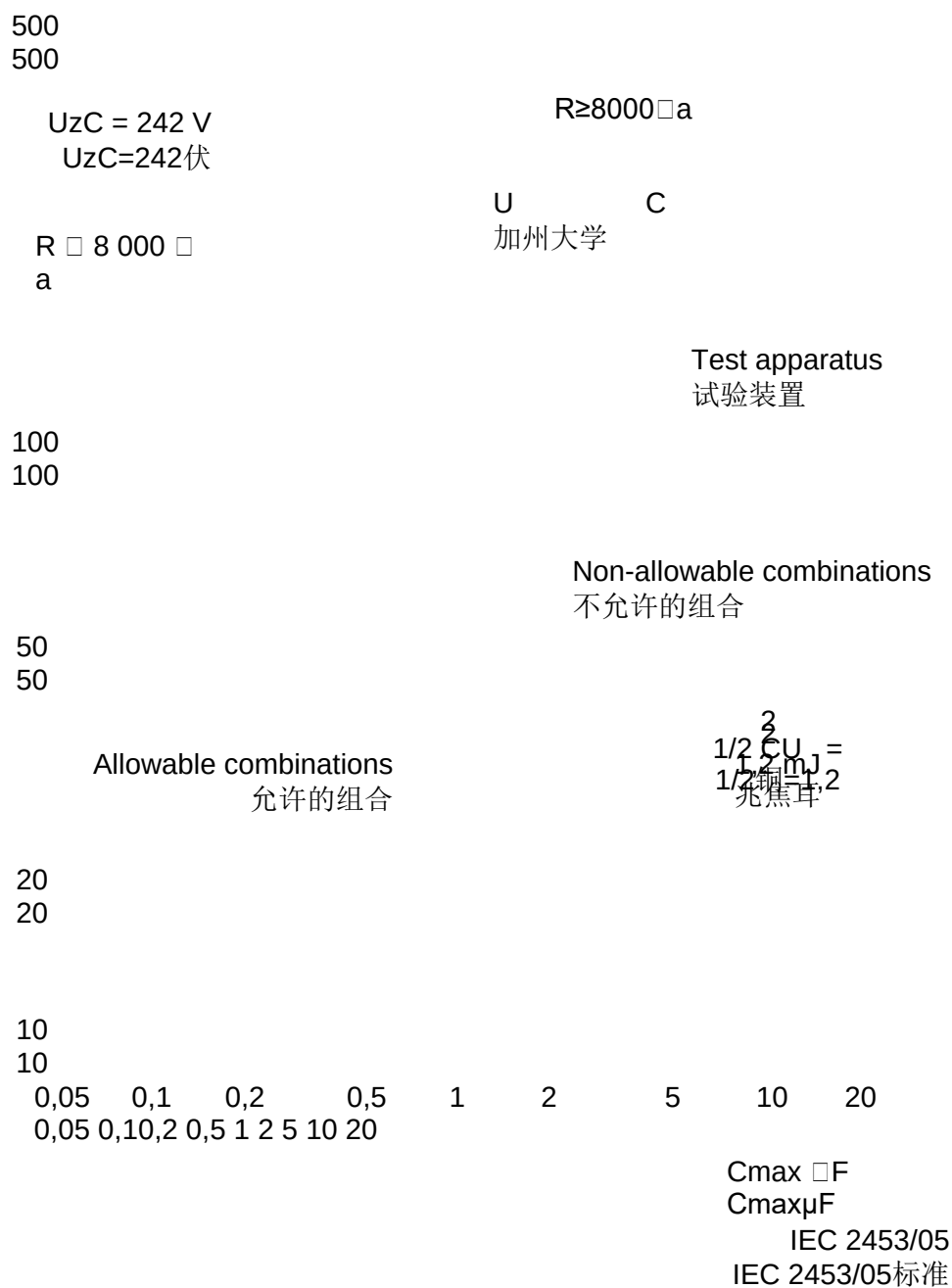
- Capacitance C_{max} and inductance L_{max} , are taken as the values that occur at the component under investigation that produces sparks in the ME EQUIPMENT.
电容 C_{max} 和电感 L_{max} 取在医用电气设备中产生火花的被调查部件上的值。
- If the circuit is supplied with a.c., the peak value is taken into account.
如果电路有交流电源，则应考虑峰值。
- If the circuit is complicated and consists of more than one capacitance, inductance and resistance, or a combination thereof, an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and additionally the equivalent U_{max} and I_{max} , either as d.c. values or as a.c. peak values.
或者等效于电路的最大电感值。

Compliance is checked either by temperature measurement and determination of U_{max} , I_{max} , R , L_{max} and C_{max} and application of Figure G.1, Figure G.2 and Figure G.3, or by examination of the design data.
通过温度测量和 U_{max} 、 I_{max} 、 R 、 L_{max} 和 C_{max} 的测定以及图G.1、图G.2和图G.3的应用，或通过检查设计数据来检查合规性。

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IEC 2452/05
IEC 2452/05标准

Figure G.1– Maximum allowable current I_{ZR} as a function of the maximum allowable voltage U_{ZR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with air
图G.1–在纯电阻电路中测量的最大允许电流 I_{ZR} 与最大允许电压 U_{ZR} 的函数
含空气的乙醚蒸汽



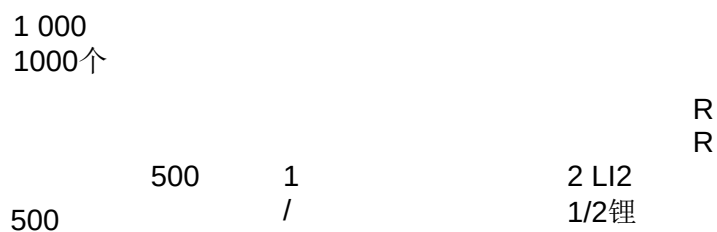
a 8 000 $\square$ or the actual resistance, if R is less than 8 000 $\square$
8000 $\square$ 或实际电阻, 如果R小于8000 $\square$

Figure G.2 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max}

图G.2-最大允许电压 U_{ZC} 与电容 C_{max} 的函数

measured in a capacitive circuit with the most flammable mixture of
ether vapour with air

在含有乙醚蒸汽与空气最易燃混合物的电容电路中测量



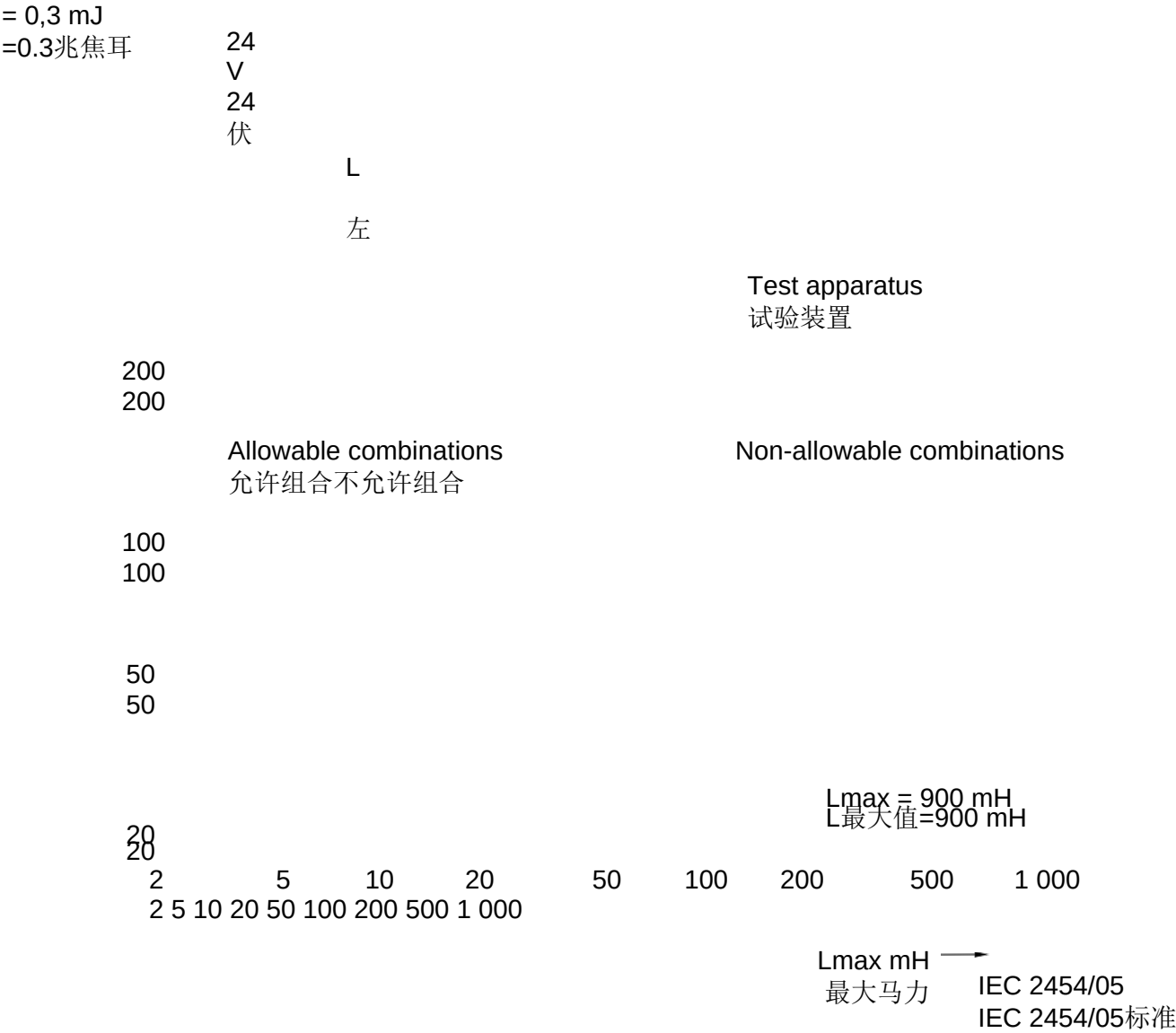


Figure G.3 – Maximum allowable current IZL as a function of the inductance Lmax
图G.3——最大允许电流IZL与电感Lmax的函数
measured in an inductive circuit with the most flammable mixture of
ether vapour with air
在含有最易燃乙醚蒸汽与空气混合物的感应电路中测量

G.5.4 * External ventilation with internal overpressure***外部通风和内部过压**

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with external ventilation by means of internal overpressure the following requirements shall apply.

如果医用电气设备、其零件或部件通过内部过压密封在具有外部通风的外壳内，则应适用以下要求。

- a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR that might have penetrated into the ENCLOSURE of ME EQUIPMENT or of an ME EQUIPMENT part shall be removed by ventilation before the ME EQUIPMENT or the ME EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the ME EQUIPMENT or the ME EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen). 在医用电气设备或医用电气设备部件通电之前，应通过通风清除可能渗入医用电气设备或医用电气设备部件外壳的易燃麻醉混合物，随后，应通过使用不含易燃气体或蒸汽的空气或生理上可接受的惰性气体（例如氮气）维持医用电气设备或医用电气设备部件内的超压，防止此类混合物在运行期间渗透。

- b) The overpressure inside the ENCLOSURE shall be at least 75 Pa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the ENCLOSURE that are necessary for the normal operation of ME EQUIPMENT or its parts. 正常情况下，外壳内的超压应至少为75 Pa。即使空气或惰性气体可以通过外壳上的开口逸出，而这些开口是医用电气设备或其部件正常运行所必需的，也应将超压保持在潜在着火的位置。

Energizing ME EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant ENCLOSURE so that the displaced volume of air or of inert gas is at least five times the volume of the ENCLOSURE. (However, ME EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

只有在所需的最小超压出现一段时间后，才能给医用电气设备通电，使相关外壳通风，以使置换的空气或惰性气体体积至少为外壳体积的五倍。（但是，如果持续存在超压，医用电气设备可随时通电或反复通电。）

- c) If the overpressure drops below 50 Pa during operation, ignition sources shall be de-energized automatically by means that either shall be located in a place where the requirements and tests of Clause G.4 do not apply, or comply with the requirements of Clause G.5.

如果操作过程中超压降至50 Pa以下，应通过将点火源置于第G.4条的要求和试验不适用的地方或符合第G.5条的要求的方式自动断电。

- d) The external surface of the ENCLOSURE in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C. 保持内部超压的外壳外表面在正常条件和正常使用条件下不得达到超过150°C的工作温度（在25°C的环境温度下测量）。

Compliance with the requirements of G.5.4 a) to G.5.4 d) is checked by temperature, pressure and flow measurements and inspection of the pressure monitoring device. 通过温度、压力和流量测量以及压力监测装置的检查，检查是否符合G.5.4 a) 至G.5.4 d) 的要求。

G.5.5 ENCLOSURES with restricted breathing**呼吸受限的外壳**

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with restricted breathing the following requirements shall apply:

如果医用电气设备、其零件或部件封闭在呼吸受限的外壳内，则应适用以下要求：

- a) * ENCLOSURES with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the ENCLOSURE does not occur whilst the ENCLOSURE is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any pressure difference to the space inside the ENCLOSURE.
*呼吸受限的密封室的设计应确保当密封室被易燃麻醉剂混合物和高浓度空气包围至少30分钟，但对空间没有任何压差时，不会在密封室内形成可燃麻醉混合物在外壳内。

- b) If the required tightness is obtained by gaskets or sealing, the material used shall therefore be resistant to ageing.
如果通过垫圈或密封获得所需的紧密性，则所用材料应耐老化。

Compliance is checked by application of test B-b of IEC 60068-2-2, Clause 15, temperature $70^{\circ}\text{C} \pm 2^{\circ}\text{C}$, duration 96 h.
通过应用IEC 60068-2-2第15条中的试验B-B，温度 $70^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ，持续96 h来检查是否合格。

- c) If the ENCLOSURE contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see 8.11.3.5).
如果外壳包含软线入口，当软线受到弯曲或拉动时，应保持软线的气密性。绳索应配备足够的锚固，以限制这些应力（见8.11.3.5）。

Compliance with the requirements of G.5.5 a), G.5.5 b) and G.5.5 c) is checked by application of the following tests:
通过以下试验检查是否符合G.5.5 a)、G.5.5 b)和G.5.5 c)的要求：

After completion of the test of G.5.4 b) if relevant, an internal overpressure of 400 Pa is created and 30 pulls of the value shown in Table G.1 are applied to each flexible cord alternately, in the axial direction of the cord inlet and in the least favourable perpendicular direction, each pull without jerks and of 1 s duration. At the end of the test the overpressure is not be reduced to less than 200 Pa.
完成G.5.4 b)中的试验后（如相关），将产生400 Pa的内部过压，并在软线入口的轴向和最不利的垂直方向交替地向每条软线施加表G.1中所示数值的30次拉力，每次拉力无抖动，持续1s。试验结束时，超压不得降至200 Pa以下。

Table G.1 – Gas-tightness of cord inlets
表G.1—软线入口的气密性

Mass (m) of ME EQUIPMENT 医用电气设备质量 (m) kg 公斤	Pul I 拉 N N
m □ 1 1月1日	30 30
1 < m □ 4 1<m□4	60 60
m > 4 m>4个	10 0 10 0

When the ENCLOSURE of ME EQUIPMENT parts or components is sealed or gas-tight and no doubt exists that the ENCLOSURE complies with the aforementioned requirement, the ENCLOSURE is tested by inspection only.
当医用电气设备零件或部件的外壳密封或气密，且毫无疑问外壳符合上述要求时，仅通过检查对外壳进行测试。

The operating temperature of the external surface of the ENCLOSURE shall not exceed 150 □C measured at an ambient temperature of 25 □C. The steady state operating temperature of the ENCLOSURE is also measured.
在25℃的环境温度下测量的外壳外表面的工作温度不得超过150℃。还应测量外壳的稳态工作温度。

G.6 Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof
APG类医用电气设备及其零部件的要求和试验

G.6.1 General
总则

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE. This requirement applies both in NORMAL USE and in the event of any applicable SINGLE FAULT CONDITION, as described in 4.7.
医用电气设备及其零部件不得点燃与氧气或一氧化二氮混合的易燃麻醉剂。如4.7所述，本要求适用于正常使用和任何适用的单一故障情况。

ME EQUIPMENT, its parts or components that do not comply with the requirements of G.6.3 are tested by a CONTINUOUS OPERATION test over a period of 10 min in an ether/oxygen mixture (ether volume percentage $12,2 \% \pm 0,4 \%$) after the thermal steady state condition has been attained, but not longer than 3 h after switching on.
不符合G.6.3要求的医用电气设备及其零件或部件，在达到热稳定状态后，在乙醚/氧气混合物（乙醚体积百分比 $12,2\% \pm 0,4\%$ ）中进行10 min的连续运行试验，但在接通后不超过3 h。

G.6.2 * Power supply
***电源**

Parts or components of CATEGORY APG ME EQUIPMENT that operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source that is isolated from earth by at least insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation equal to two MEANS OF PATIENT PROTECTION.

在与氧气或一氧化二氮混合的易燃麻醉混合物中工作的APG ME类设备的零件或部件，应采用至少等于一种病人保护措施绝缘与接地隔离的电源供电，并通过等于两种病人保护手段的绝缘与电气部件隔离。

Compliance is checked by inspection of circuit diagrams and measurement.
通过检查电路图和测量检查合规性。

G.6.3 * Temperatures and low-energy circuits
***温度和低能电路**

ME EQUIPMENT, and its parts or components are considered to comply with the requirements of
医用电气设备及其零部件应符合

G.6.1 without being tested according to G.6.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see 4.7):

G、6.1在正常使用、正常条件和单一故障条件下（见4.7），未按G.6.1进行试验：

a) no sparks are produced and no temperatures exceeding 90 °C occur, or
不产生火花，温度不超过90°C，或

b) a temperature limit of 90 °C is not exceeded, ME EQUIPMENT or its parts contain components that may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but the voltage U_{max} and the current I_{max} that can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} , comply with the following:

不超过90°C的温度限制，医用电气设备或其部件包含在正常使用、正常条件和适用的单一故障条件下可能产生火花的部件，但考虑到电容 C_{max} 和电感 L_{max} ，其电路中可能出现的电压 U_{max} 和电流 I_{max} 符合以下内容：

$U_{max} \square LU_zR$ with a given I_zR , see Figure G.4, and
带有给定 I_zR 的 $U_{max} \square LU_zR$ ，见图G.4，以及

$U_{max} \square UzC$ with given C_{max} , see Figure G.5, as well as
给定 C_{max} 的 $U_{max} \square UzC$ ，见图G.5，以及

$I_{max} \square IzR$ with a given voltage U_zR , see Figure G.4, and
 $I_{max} \square IzR$ ，具有给定电压 U_zR ，见图G.4，以及

$I_{max} \square IzL$ with a given inductance L_{max} and $U_{max} \square 24\text{ V}$, see Figure G.6.
 $I_{max} \square IzL$ ，具有给定电感 L_{max} 和 $U_{max} \square 24\text{ V}$ ，见图G.6。

- The graphs in Figure G.4, Figure G.5 and Figure G.6 have been obtained with the test apparatus according to F.8 Figure G.7 with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage $12,2 \pm 0,4\%$ $4,3 \square 0,2\%$) for an ignition probability of 10-3. The maximum allowable values of I_zR (Figure G.4), U_zC (Figure G.5) and I_zL (Figure G.6) include a safety factor of 1,5.
图G.4、图G.5和图G.6中的图表是使用F.8图G.7中的试验装置获得的，其中乙醚蒸汽与氧气的最易燃烧混合物（乙醚体积百分比 $12,2 \pm 0,4\%$ $4,3 \pm 0,2\%$ ），着火概率为10-3。
 I_zR （图G.4）、 U_zC （图G.5）和 I_zL （图G.6）的最大允许值包括1.5的安全系数。
- Extrapolation of the curves of Figure G.4, Figure G.5 and Figure G.6 is limited to the areas indicated.
图G.4、图G.5和图G.6的曲线外推仅限于所示区域。
- Voltage U_{max} is taken as the highest no-load voltage occurring in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.
考虑到4.10中要求的电源电压变化，电压 U_{max} 被视为所调查电路中出现的最高空载电压。
- Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.
考虑到4.10中要求的电源电压变化，电流 I_{max} 被视为所研究电路中的最高电流。
- Capacitance C_{max} and inductance L_{max} are taken as values that occur in the relevant circuit.
电容 C_{max} 和电感 L_{max} 作为相关电路中出现的值。
- If the equivalent resistance R in Figure G.5 is less than 8 000 $\square$, U_{max} is additionally determined with the actual resistance R .
如果图G.5中的等效电阻 R 小于8000 $\square$ ，则 U_{max} 与实际电阻 R 另外确定。
- If the circuit is supplied with a.c., the peak value is taken into account.
如果电路有交流电源，则应考虑峰值。
- If the circuit is complicated and consists of more than one capacitance, inductance and resistance or a combination thereof an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and, additionally, the equivalent U_{max} and I_{max} either as d.c. values or a.c. peak values.

如果电路很复杂，并且由一个以上的电容、电感和电阻或其组合组成，则计算等效电路，以确定等效最大电容、等效最大电感以及等效 U_{max} 和 I_{max} （直流值或交流峰值）。

- If the energy produced in an inductance or capacitance in a circuit is limited by voltage- limiting or current-limiting devices preventing the limits of Figure G.4, Figure G.5 and Figure G.6 being exceeded, two independent components shall be applied, so that the required limitation of voltage or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components. 如果电路中电感或电容产生的能量受到限压或限流装置的限制，以防止超过图G.4、图G.5和图G.6中的限值，则应使用两个独立的元件，因此，即使在其中一个部件出现第一个故障（短路或开路）的情况下，也能达到所需的电压或电流限制。

This requirement does not apply to transformers designed and made according to this standard and to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in the event of rupture. 本要求不适用于根据本标准设计和制造的变压器，也不适用于为防止导线在断裂时展开而提供保护的绕线限流电阻器。

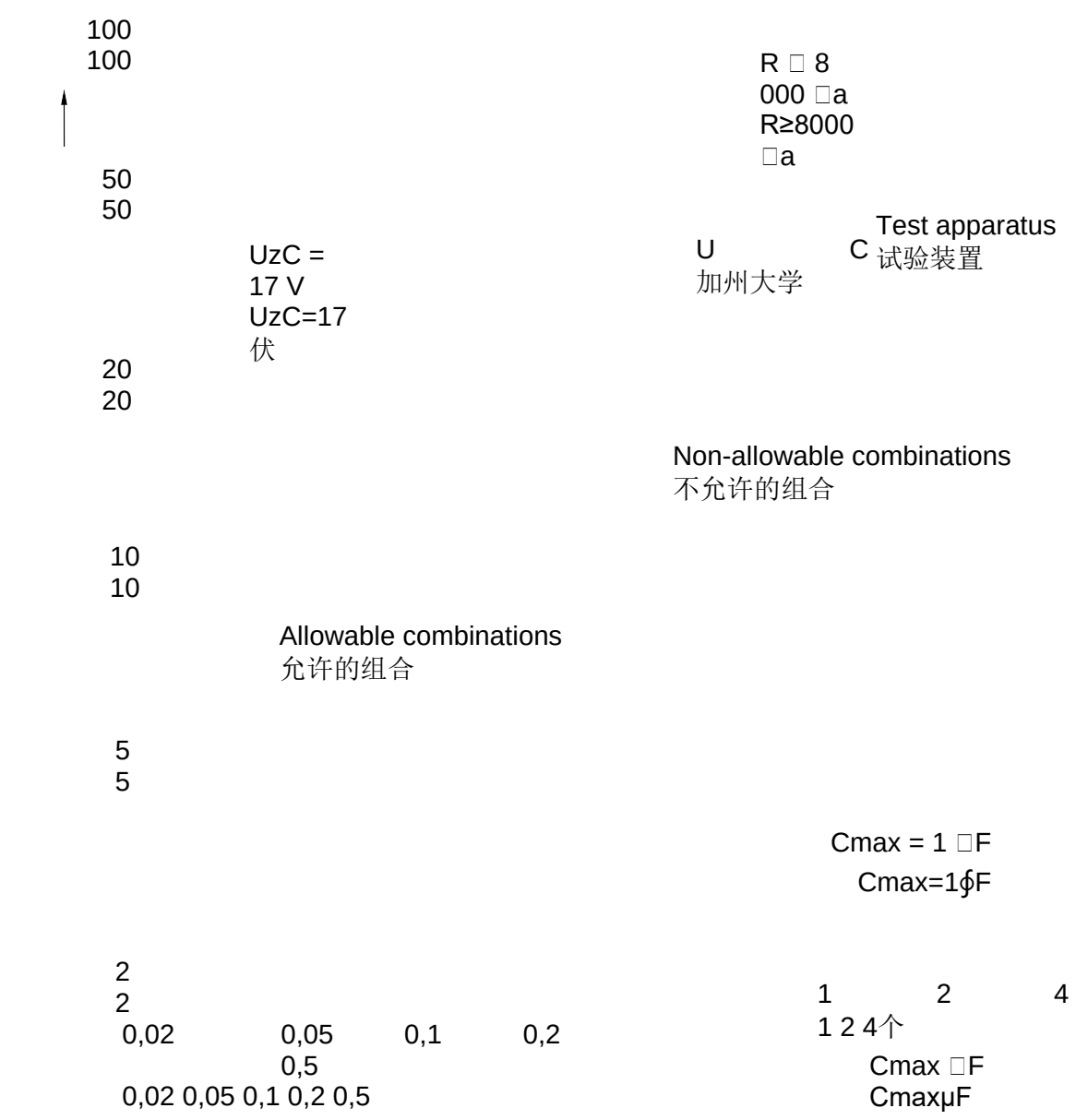
Compliance is checked by inspection, temperature measurements, comparison with design data or by measurement of U_{max} , I_{max} , R , L_{max} and C_{max} and using Figure G.4, Figure G.5 and Figure G.6. 通过检查、温度测量、与设计数据比较或测量 U_{max} 、 I_{max} 、 R 、 L_{max} 和 C_{max} ，并使用图G.4、图G.5和图G.6检查合规性。

2
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Figure G.4 – Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen

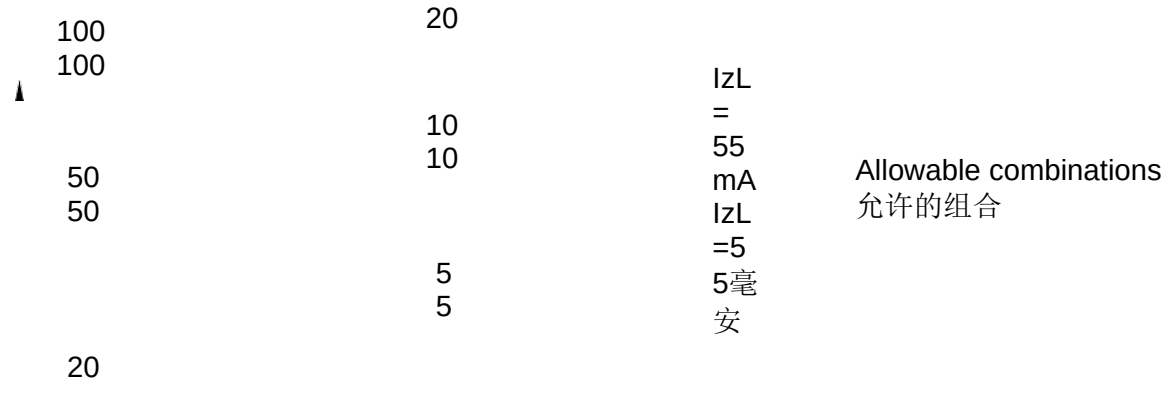
图G.4——在纯电阻电路中测量的最大允许电流IZR与最大允许电压UZR的函数，其中乙醚蒸汽与氧气的最易燃混合物



a 8 000 □ or the actual resistance, if R is less than 8 000 □ IEC 2456/05
8000□或实际电阻，如果R小于8000□ IEC 2456/05标准

Figure G.5 – Maximum allowable voltage Uzc as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen

图G.5-最大允许电压Uzc与电容Cmax的函数关系，在具有最易燃乙醚蒸汽与氧气混合物的电容电路中测量



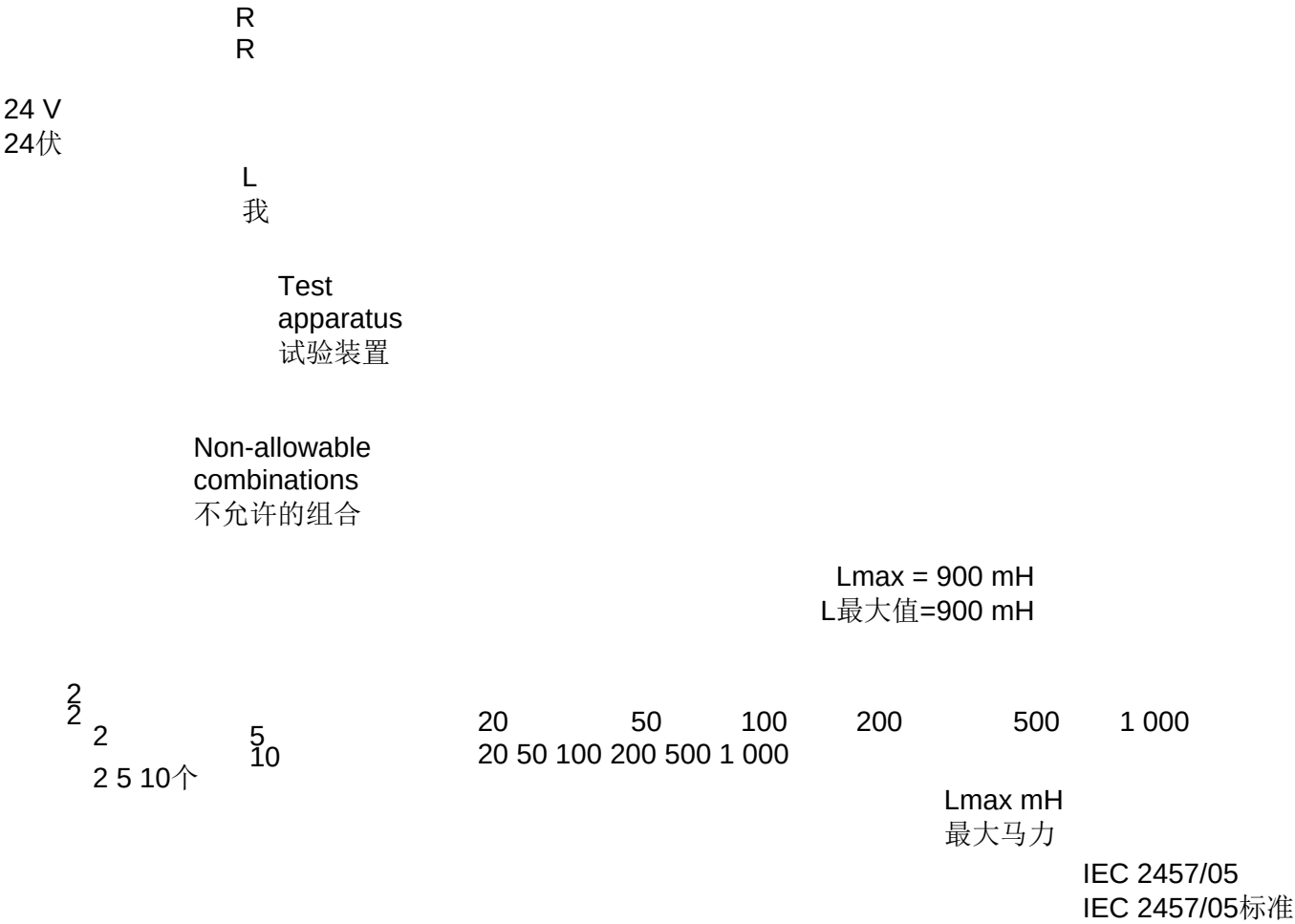


Figure G.6 – Maximum allowable current IZL as a function of the inductance Lmax
图G.6-最大允许电流IZL与电感Lmax的函数
measured in an inductive circuit with the most flammable mixture of
ether vapour with oxygen
在含有最易燃的乙醚蒸汽和氧气混合物的感应电路中测量

G.6.4 Heating elements

G、6.4加热元件

ME EQUIPMENT, its parts and components that heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-RESETTING THERMAL CUT-OUT, as an additional protection against overheating. 医用电气设备及其用氧气或一氧化二氮加热易燃麻醉混合物的部件和部件应配备一个非自动复位热断路器，作为防止过热的附加保护。

Compliance is checked by the corresponding test of 15.4.2.1. 通过15.4.2.1中的相应试验检查合规性。

The current-carrying part of the heating element shall not be in direct contact with the 加热元件的载流部分不得与 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE. 与氧气或一氧化二氮混合的易燃麻醉剂。

Compliance is checked by inspection. 通过检查检查合规性。

G.7 Test apparatus for flammable mixtures 可燃混合物试验装置

NOTE Formally Appendix F of the second edition. 正式注意第二版附录F。

The test apparatus comprises an ignition space with a volume of at least 250 cm³, which contains the prescribed atmosphere or mixture and a contact arrangement (see Figure G.7) providing sparks by opening and closing. 试验装置包括体积至少为250 cm³的点火空间，其中包含规定的大气或混合物，以及通过打开和关闭提供火花的接触装置（见图G.7）。

The contact arrangement consists of a cadmium disk with two grooves and a second disk with four tungsten wires having a diameter of 0,2 mm that slides over the first disk. The free length of the tungsten wires is 11 mm. The shaft to which the tungsten wires are connected rotates with a speed of 80 r/min. The shaft connected to the cadmium disk turns in opposite direction to the shaft connected to the disk with wires. 接触装置包括一个带有两个凹槽的镉盘和一个带有四根直径为0.2 mm的钨丝的第二个圆盘，在第一个圆盘上滑动。钨丝的自由长度为11 mm。连接钨丝的轴以80r/min的速度旋转，与镉盘相连的轴与用线连接的轴的转动方向相反。

The ratio of the rotation speed of the shaft connected to the wires and the other shaft is 50:12.

Both shafts are isolated from each other and from the frame.

与导线相连的轴与另一轴的转速之比为50:12。两个轴相互隔离，并与框架隔离。

The ignition space must be able to support an internal overpressure of 1,5 MPa. 点火空间必须能够承受1.5 MPa的内部过压。

With the contact arrangement, the circuit to be tested is closed or opened and it is checked if the sparks will ignite the atmosphere or mixture under test. 使用接触装置，待测电路闭合或断开，并检查火花是否会点燃被测大气或混合物。

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Dimensions in millimetres
尺寸单位为毫米

Legend

图例

- 1 Ignition space
点火空间
- 2 Cadmium disk
镉盘
- 3 Tungsten wire
钨丝
- 4 Shaft of wire disk
钢丝盘轴
- 5 Shaft of disk with grooves
带槽圆盘轴

Figure G.7 – Test apparatus
图G.7—试验装置

Annex H

附件H

(informative)

（资料性）

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

PEMS结构、PEMS开发生命周期和文档

H.1 Examples for PEMS/PESS structures

PEMS/PES结构示例

A PEMS can be a very simple piece of ME EQUIPMENT or a complex ME SYSTEM or anything in between.

PEMS可以是一个非常简单的医用电气设备，也可以是一个复杂的医用电气系统或介于两者之间的任何东西。

Figure H.1 shows some possible examples of a PEMS.
图H.1显示了PEMS的一些可能示例。

Figure H.1 a) shows a complex system. The PEMS breaks down into a number of major subsystems, which in turn are made up of subsystems, which include a PESS.

图H.1 a) 显示了一个复杂的系统。PEMS分为若干主要子系统，这些子系统又由子系统组成，其中包括PES。

Figure H.1 b) shows a simpler implementation. In this case the intermediate major subsystem level is missing and the PESS is a subsystem of the PEMS itself.

图H.1b) 显示了一个更简单的实现。在这种情况下，中间主要子系统级缺失，PESS是PEMS本身的子系统。

Figure H.1 c) illustrates the simplest implementation of a PEMS. In this case the PEMS and the

图H.1 c) 说明了PEMS的最简单实现。在这种情况下，PEMS和PESS are the same.
PES是一样的。

The structure of the PEMS is extremely important for implementing safety requirements. An architecture should be documented for the PEMS that describes the structure of the PEMS and the relationship between each PESS and the PEMS as a whole. The architecture should indicate: PEMS的结构对于实施安全要求极为重要。应记录PEMS的体系结构，该体系结构描述PEMS的结构以及每个PES和PEMS之间的关系。体系结构应表明：

- the division of the PEMS into components, especially those implemented in each PESS and including software components;
将PEMS划分为组件，尤其是在每个PES中实现的组件，包括软件组件；
- the functions to be performed by each PESS and its components (including where appropriate safety-related functions);
每个PES及其组件将执行的功能（包括适当的安全相关功能）；
- the interfaces between software components;
软件组件之间的接口；
- the interfaces between software components and components external to the software.
软件组件和软件外部组件之间的接口。

H.2 PEMS DEVELOPMENT LIFE-CYCLE model

PEMS开发生命周期模型

Compliance with the PEMS clause of this standard (Clause 14) requires that a PEMS

DEVELOPMENT LIFE-CYCLE be specified and then followed; it does not require that any particular PEMS DEVELOPMENT LIFE-CYCLE is used, but it does require that the PEMS DEVELOPMENT LIFE- CYCLE has certain attributes. These requirements can be found in 14.4.

符合本标准PEMS条款（第14条）要求规定并遵循PEMS开发生命周期；不要求使用任何特定的PEMS开发生命周期，但要求PEMS开发生命周期具有某些属性。这些要求见14.4。

The PEMS DEVELOPMENT LIFE-CYCLE is a part of the overall product life-cycle.
PEMS开发生命周期是整个产品生命周期的一部分。

Figure H.2 is a view of the PEMS DEVELOPMENT LIFE-CYCLE which shows activities grouped into two main PROCESSES. On the left is decomposition PROCESS and on the right is the integration PROCESS.
图H.2是PEMS开发生命周期的视图，显示了分为两个主要过程的活动。左边是分解过程，右边是集成过程。

Figure H.2 illustrates:
图H.2说明：

- layered design activities;
分层设计活动；
- for each layer of design, a corresponding layer of integration and VERIFICATION;
对于每一层的设计，对应一层的集成和验证；
- verified parts are integrated to assemble the next higher layer;
将验证过的部件集成在一起，组装下一个更高的层；
- problem resolution PROCESS interactions.
问题解决过程交互。

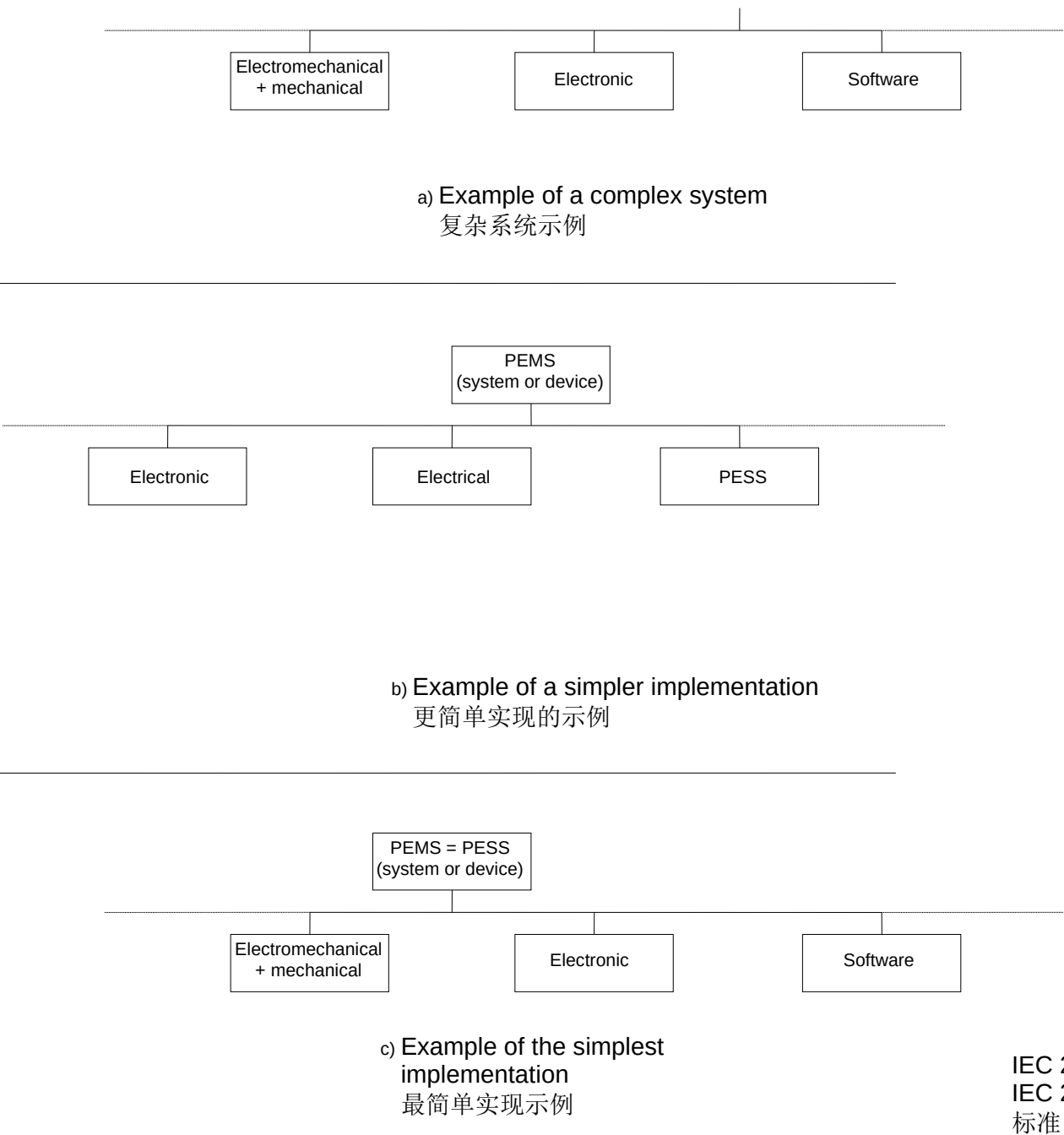


Figure H.1 – Examples of PEMS/ PESS structures
图H.1–PEMS/PESS结构示例

PEMS VALIDATION plan
PEMS验证计划

PEM
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PEMS
验证



Key:

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B

boxes represent typical PEMS
DEVELOPMENT LIFE-CYCLE
activities Solid arrows indicate typical
deliverables into/out of activities
代表典型PEMS开发生命周期活动的方
框实心箭头表示进入/退出活动的典型可
交付成果
Dashed arrows indicate deliverables just to
the RISK MANAGEMENT FILE
虚线箭头表示风险管理文件的可交付成果

IEC 2460/05
国际电工委员会2460/05

Output to the problem resolution PROCESS
输出到问题解决过程

Input from the problem resolution PROCESS
问题解决过程的输入

As the design is decomposed from the requirements, the functional building blocks, architecture and technology are decided. The decomposition PROCESS concludes when the design information enables the components of the PEMS to be built (examples of such design information are circuit diagrams and software code). The decomposition components are integrated together. VERIFICATION is performed as the components are integrated to determine whether or not the implementation satisfies the requirements. At the conclusion of the integration PROCESS, a PEMS VALIDATION is performed to determine whether or not the PEMS works as intended. 随着设计从需求中分解，确定了功能构建块、体系结构和技术。当设计信息使PEMS的组件得以构建时，分解过程结束（此类设计信息的示例为电路图和软件代码）。分解组件被集成在一起。在集成组件时执行验证，以确定实现是否满足需求。在集成过程结束时，将执行PEMS验证，以确定PEMS是否按预期工作。

H.3 Software PROCESSES

软件过程

H.3.1 PEMS DEVELOPMENT LIFE-CYCLE

PEMS开发生命周期

A PEMS DEVELOPMENT LIFE-CYCLE, such as the one illustrated in Figure H.2, consists of a number of PROCESSES that are composed of activities. Each activity is performed to accomplish specific goals. To apply RISK MANAGEMENT, confidence in the engineering activities on which the RISK MANAGEMENT is based is needed. In particular, this is a requirement for the software life-cycle. PEMS开发生命周期，如图H.2所示，由许多由活动组成的过程组成。每一项活动都是为了完成特定的目标。为了应用风险管理，需要对风险管理所基于的工程活动有信心。特别是，这是软件生命周期的要求。

IEC 62304 [26] (under development) describes the processes to be included in the software development life-cycle for the development of safe medical device software. IEC 62304[26]（正在开发中）描述了安全医疗设备软件开发的软件开发生命周期中要包含的过程。

H.3.2 Requirements specification

需求规范

To determine which functions create or control RISKS, it is necessary to fully identify the requirements of the PEMS/PESS. It is not possible to do an adequate RISK ASSESSMENT without a complete requirement specification and an architectural design that meets that specification. The requirements should include, as appropriate to the PEMS software: 为了确定哪些职能部门产生或控制风险，有必要充分确定PEMS/PES的要求。如果没有完整的需求规范和满足该规范的架构设计，就不可能进行充分的风险评估。如适用于PEMS软件，要求应包括：

- functional and capability requirements, including ESSENTIAL PERFORMANCE, physical characteristics, and environmental conditions under which the software is to perform;
功能和能力要求，包括软件的基本性能、物理特性和环境条件；
- interfaces external to the software;
软件外部接口；
- safety requirements including RISK CONTROL measures for hardware failures and potential software defects and specifications related to methods of operation and maintenance, environmental influences, and RISK CONTROL;
安全要求，包括硬件故障和潜在软件缺陷的风险控制措施，以及与操作和维护方法、环境影响和风险控制有关的规范；
- software driven alarm signals, warnings and OPERATOR messages;
软件驱动的报警信号、警告和操作信息；
- security requirements, where lack of security would compromise safety;
安全要求，缺乏安全性会损害安全性；
- human-factors engineering requirements related to the use of the PEMS, including those related to support for manual operations, human-equipment interactions, constraints on personnel, and areas needing concentrated human attention that are sensitive to human errors and training;

与使用PEMS相关的人为因素工程要求，包括与支持人工操作、人-设备交互、对人员的限制以及对人为错误和培训敏感的需要集中人力关注的领域：

- data definition and database requirements;
数据定义和数据库要求；
- installation and acceptance requirements for the PEMS software;
PEMS软件的安装和验收要求；
- documentation to be developed;
待编制的文件；
- operation and execution requirements;
运行和执行要求；
- maintenance requirements.
维护要求。

RISK ASSESSMENT should be used to determine the extent to which the architecture design can be used to mitigate the RISKS.

风险评估应用于确定架构（architecture）设计可用于减轻风险的程度。

H.3.3 Third-party and off-the-shelf (OTS) software **第三方和现成（OTS）软件**

To have the ability to identify known or foreseeable HAZARDS, it is also necessary to characterise any third-party or OTS software used in the PEMS. The developer should establish software requirements for third-party or OTS software. These requirements should include the following: 为了能够识别已知或可预见的危险，还需要描述PEMS中使用的任何第三方或OTS软件。开发者应建立第三方或OTS软件的软件需求。这些要求应包括以下内容：

- title and manufacturer, version level, release date, patch number and upgrade designation;
标题和制造商、版本级别、发布日期、补丁号和升级名称；
- the system hardware and software necessary to support proper operation (e.g. processor type and speed, memory type and size, and system, communication and display software requirements);
支持正确操作所需的系统硬件和软件（如处理器类型和速度、存储器类型和大小、系统、通信和显示软件要求）；
- interfaces to the software component;
与软件组件的接口；
- safety critical and RISK CONTROL measure functions dependent on the software component.
安全关键和风险控制措施功能依赖于软件组件。

H.3.4 Integration **集成**

The developer should establish an integration plan to integrate the components of each PESS and of the PEMS. The plan should include the approach, responsibilities and sequence, and include all software components. If the PESS software is built using incremental integration methods, sufficient regression testing should be performed to ensure that previous VERIFICATION is still sufficient. Integration tests should include test cases which expose software behaviour not only in response to the normal case, but also in response to exceptional, stress or worst case conditions. 开发人员应制定集成计划，以集成每个PES和PEMS的组件。计划应包括方法、责任和顺序，并包括所有软件组件。如果PESS软件是使用增量集成方法构建的，则应进行充分的回归测试，以确保先前的验证仍然充分。集成测试应该包括暴露软件行为的测试用例，这些测试用例不仅是对正常情况的响应，而且是对异常、压力或最坏情况的响应。

H.3.5 Configuration management **配置管理**

Because the RISK ANALYSIS relies on the requirements of the software, configuration management and change control are necessary to ensure that additional software functionality is not added during development without being considered by the RISK MANAGEMENT PROCESS. A configuration management plan should be established that describes: 由于风险分析依赖于软件的需求，配置管理和变更控制是必要的，以确保在开发过程中不添加额外的软件功能，而不考虑风险管理过程。应制定配置管理计划，该计划应说明：

- the items to be controlled;
控制项目；
- the configuration management activities;
配置管理活动；
- PROCEDURES and schedule for performing these activities;
执行这些活动的程序和时间表；
- responsibilities for performing these activities;
执行这些活动的责任；
- PROCEDURES to control the receipt, installation, and acceptance of each software component.
控制每个软件组件的接收、安装和验收的程序。

A scheme should be established for the unique identification of software configuration items and version control. This scheme should include any third-party and OTS software components.
应制定软件配置项的唯一标识和版本控制方案。该方案应包括任何第三方和OTS软件组件。

H.3.6	Modification/change 修改/变更控制	control

For modification/change control, the following should be performed:
对于修改/变更控制，应执行以下操作：

- identification and recording of change requests;
变更请求的识别和记录;
- analysis and evaluation of the changes;
变化的分析和评价;
- approval or disapproval of the request;
批准或不批准请求;
- implementation, VERIFICATION and release of the modified software.
修改后软件的实施、验证和发布。

An audit trail should be maintained, whereby each modification, the reason for the modification, and authorization of the modification can be traced. RECORDS of the history of controlled items should be retrievable.

应保持审计跟踪，以便追踪每次修改、修改原因和修改授权。受控项目的历史记录应可检索。

IEC 62304 describes the processes to be included in the software development life-cycle for the development of safe medical device software.

IEC 62304描述了安全医疗设备软件开发的软件开发生命周期中包含的过程。

H.4 Design and implementation 设计与实施

During application of the PEMS DEVELOPMENT LIFE-CYCLE model, design and implementation will include the selection of:

在应用PEMS开发生命周期模型的过程中，设计和实施将包括选择：

a) the	design	environment,	for	example:
	设计环境，例如：			
	– software development methods;			
	软件开发方法；			
	– computer aided software engineering (CASE) tools;			
	计算机辅助软件工程（CASE）工具；			
	– programming language;			
	程序设计语言；			
	– hardware and software development platforms;			
	硬件和软件开发平台；			
	– simulation tools;			
	模拟工具；			
	– design and coding standards;			
	设计和编码标准；			
b) electronic				components;
	电子元器件；			
c) redundant				hardware;
	冗余硬件；			
d) human-PEMS				interface;
	人PEMS接口；			
e) energy				sources;
	能源；			
f) environmental				conditions;
	环境条件；			
g) third-party				software;
	第三方软件；			
h) networking				options.
	网络选项。			

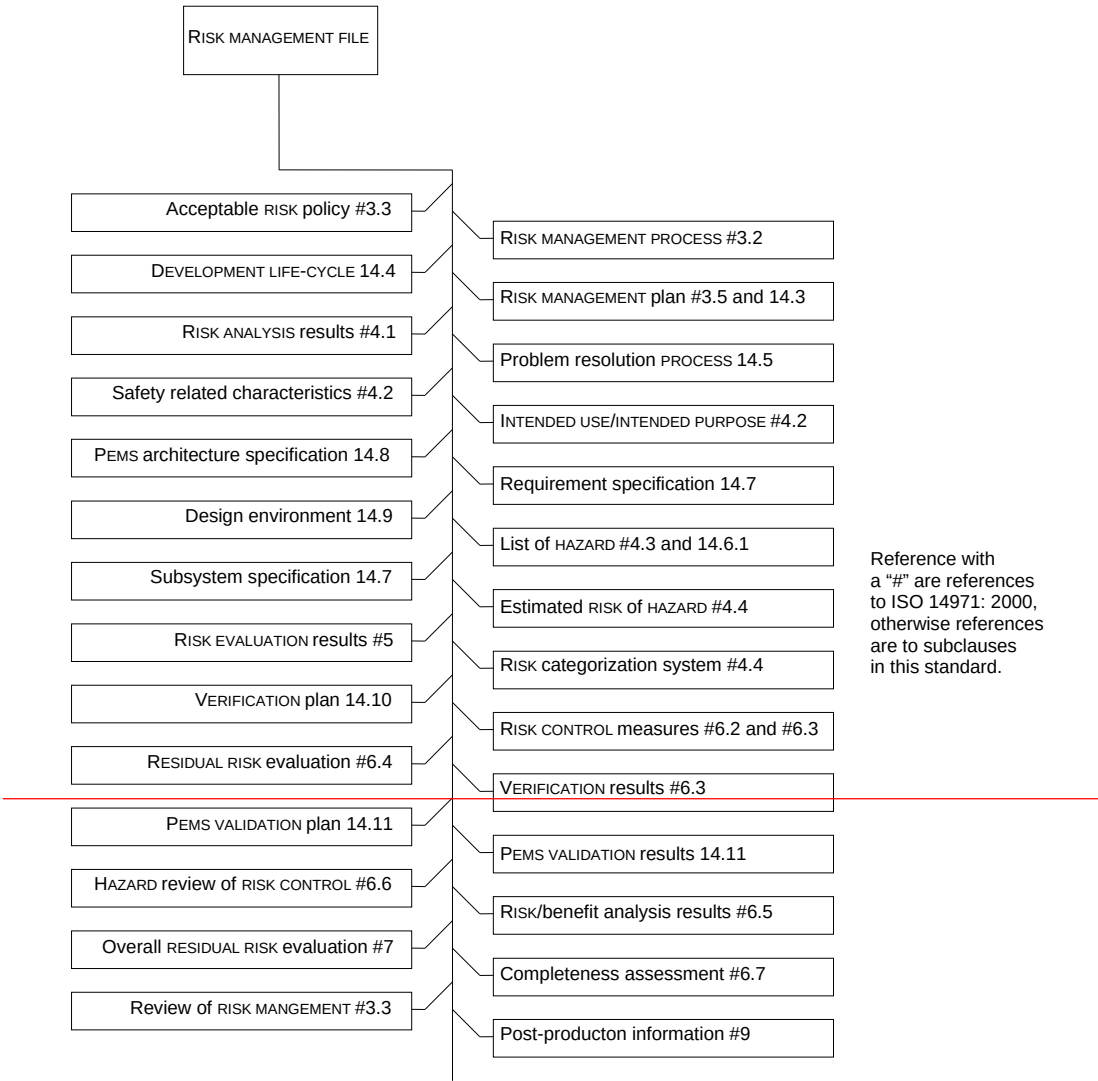
These elements of the design environment can be characterized in general and in the specific manner of their use in the design and implementation PROCESS.

设计环境中的这些元素可以在设计和实现过程中以一般和特定的方式进行描述。

H.5 Documentation 文档

Figure H.3 includes all of the documentation required by Clause 14 and ISO 14971:2000. It is intended to show an example structure only. Particular documentary references can be consolidated or distributed among several documents. The clause numbers preceded by a “#” are references to the clause numbers in ISO 14971:2000. Other numbers refer to the subclauses of this standard. Not used.

图H.3包括第14条和ISO 14971:2000要求的所有文件。它仅用于显示示例结构。特定的参考文献可以合并或分发到多个文件中。以“#”开头的条款编号是对ISO 14971:2000中条款编号的引用。其他数字参考本标准的子条款。未使用。



RESIDUAL RISK
剩余风险

VERIFICATION
验证
results
结果

RESIDU
AL RISK
剩余风险
evaluatio
n
评价
#6.4
#6.4条

VERIFICATION
验证
#6.3
#6.3条

Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000 Not used

图H.3—未使用第14条和ISO 14971:2000中的PEMS文件要求

H.6 NETWORK/DATA COUPLING

网络/数据耦合

PEMS intended to be incorporated into an IT-NETWORK

PEMS计划并入IT网络

H.6.1 General

总则

In the context of this standard, the information transmitted as a part of NETWORK/DATA COUPLING over an IT-NETWORK is that intended by the MANUFACTURER to be transmittable (i.e. not through illegal or illicit actions of unauthorized persons). 在本标准的上下文中，作为网络/数据耦合的一部分在IT网络上传输的信息是制造商希望能够传输的信息（即，不是通过未授权人员的非法或非法行为）。

NETWORK/DATA COUPLING as used in this standard does not include information transferred across user interfaces. The MANUFACTURER stipulates the possible information types and their transmission protocols in the technical description (see 14.13). 本标准中使用的网络/数据耦合不包括跨用户界面传输的信息。制造商在技术说明中规定了可能的信息类型及其传输协议（见14.13）。

H.6.2 System

系统集成责任

integration

responsibilities

ME EQUIPMENT and ME SYSTEMS will sometimes be used together to create a system on an IT-NETWORK. This is likely to become more frequent with the increasing use of computers to analyze clinical data and control treatment. 有时会把我和一个系统连在一起创建一个系统。随着计算机越来越多地用于分析临床数据和控制治疗，这种情况可能会变得更加频繁。

Sometimes ME EQUIPMENT will have been designed by the MANUFACTURER to work on an IT-NETWORK with other ME EQUIPMENT, however, it will often be the case that the separate ME EQUIPMENT will not have been designed to work with each other all other ME EQUIPMENT on an IT-NETWORK. Someone has to be responsible for ensuring that all the separate ME EQUIPMENT on an IT-network work together satisfactorily in the integrated system; in other words, someone has to be responsible for designing the integrated system IT-NETWORK. 有时，制造商会将医用电气设备设计为与其他医用电气设备一起在信息技术网络上工作，但是，通常情况下，单独的医用电气设备不会被设计为与信息技术网络上的所有其他医用电气设备一起工作。必须有人负责确保IT网络上的所有独立ME设备在集成系统中令人满意地协同工作；换句话说，必须有人负责设计集成系统IT网络。

It is recognized that the system IT-NETWORK integrator often has to comply with particular regulatory requirements.

众所周知，系统IT网络集成商通常必须遵守特定的监管要求。

In order to perform its function, the system IT-NETWORK integrator needs to know: 为了执行其功能，系统IT网络集成商需要知道：

- how the integrated system IT-NETWORK is intended to be used; 如何使用集成系统IT网络；
- the required performance of the integrated system IT-NETWORK; 集成系统IT网络所需的性能；
- the intended configuration of the system IT-NETWORK; 系统IT网络的预期配置；
- the constraints on the extendibility of the system IT-NETWORK; 系统IT网络可扩展性的约束条件；
- the specifications of all ME EQUIPMENT and other equipment to be integrated; 所有医用电气设备和其他待集成设备的规格；
- the performance of each ME EQUIPMENT and other equipment; and

各医用电气设备和其他设备的性能；以及

- the information flow in and around the system IT-NETWORK.
系统内部和周围的信息流。

This information will not be available to the individual MANUFACTURERS, and for this reason each individual MANUFACTURER cannot carry out the role of system IT-NETWORK integrator. In any case the system IT-NETWORK integrator has to be a single person or organisation that has overall responsibility, this overall responsibility can not be shared between several different MANUFACTURERS. The responsibility of a MANUFACTURER is limited to providing the required information on their equipment (see 14.13).
这些信息不会提供给各个制造商，因此每个单独的制造商不能履行系统IT网络集成商的角色。在任何情况下，系统IT网络集成商必须是一个具有全面责任的个人或组织，这种总体责任不能在几个不同的制造商之间分担。制造商的责任仅限于提供其设备所需的信息（见14.13）。

Obviously a RESPONSIBLE ORGANIZATION can employ a MANUFACTURER to integrate their system IT-NETWORK. In this case the whole system IT-NETWORK can become an ME SYSTEM and it will be the MANUFACTURER'S responsibility to provide a correctly integrated system. In this case the system could be separately regulated.
显然，一个负责任的组织可以雇佣制造商来整合他们的系统IT网络。在这种情况下，整个系统IT网络可以成为一个ME系统，制造商有责任提供一个正确的集成系统。在这种情况下，可以单独对系统进行监管。

The system IT-NETWORK integrator should be competent to assess and address the HAZARDS that are likely to arise from integrating a system IT-NETWORK and to ensure that the RESIDUAL RISKS of the individual PEMS are maintained.
系统IT网络集成商应能够评估和解决集成系统IT网络可能产生的危害，并确保维持单个PEM的残余风险。

Typically a system IT-NETWORK integrator would:
通常，系统IT网络集成商将：

- plan the integration of any ME EQUIPMENT or ME SYSTEM and non-medical equipment in accordance with the instructions provided by the various MANUFACTURERS;
根据各制造商提供的说明，计划任何医用电气设备或医用电气系统与非医疗设备的集成；

- perform RISK MANAGEMENT on the integrated system IT-NETWORK; and
对集成系统IT网络进行风险管理；以及
- pass on any MANUFACTURER'S instructions to the RESPONSIBLE ORGANIZATION where these are required for the safe operation of the integrated system IT-NETWORK. These instructions should include warnings about the HAZARDS of any change of configuration.
将制造商的任何说明传达给负责组织，以便集成系统IT网络的安全运行。这些说明应包括任何配置变更的危险警告。

H.7 Design considerations for NETWORK/DATA COUPLING IT-NETWORKS 网络/数据耦合IT网络的设计考虑

H.7.1 Introduction Overview 简介概述

From the viewpoint of a PEMS MANUFACTURER, any type of a NETWORK/DATA COUPLING an IT- NETWORK is a source of additional causes for HAZARDS HAZARDOUS SITUATIONS. In principle any NETWORK/DATA COUPLING IT-NETWORK that is outside the control of the PEMS MANUFACTURER should never be presumed to be 100 % reliable.
从PEMS制造商的角度来看，任何类型的网络/数据耦合IT网络都是导致危险情况的额外原因。原则上，不在PEMS制造商控制范围内的任何网络/数据耦合IT网络都不应假定为100%可靠。

H.7.2 Causes of HAZARDS HAZARDOUS SITUATIONS associated with NETWORK/DATA COUPLING IT-NETWORKS 危害原因与网络/数据耦合IT网络相关的危险情况

In NETWORK/DATA COUPLED systems IT-NETWORKS, likely causes for HAZARDS HAZARDOUS SITUATIONS are:

在网络/数据耦合系统IT网络中，危险情况的可能原因是：

- loss of data;
数据丢失；
- inappropriate data interchange;
数据交换不当；
- corrupted data;
数据损坏；
- inappropriate timing of data;
数据时机不当；
- unexpected receipt of data;
意外接收数据；
- unauthorized access to data.
未经授权访问数据。

Supplementing Annex A of ISO 14971:2000 when identifying the causes of HAZARDS
确定危害原因时补充ISO 14971:2000附录A
associated with NETWORK/DATA COUPLING, at least the following should be considered:
与网络/数据耦合相关，至少应考虑以下因素：

Supplementing Annex E of ISO 14971:2007, at least the following initiating events or circumstances that can lead to HAZARDOUS SITUATIONS associated with IT-NETWORKS should be considered:
作为ISO 14971:2007附录E的补充，至少应考虑以下可能导致与IT网络相关的危险情况的始发事件或情况：

- remote servicing (external access to the network);
远程服务（网络外部接入）；

- operating system (compatibility of operating systems);
操作系统（操作系统的兼容性）；
- modification/upgrades of software (operating systems, applications, etc.);
软件（操作系统、应用程序等）的修改/升级；
- interface compatibility (data collisions, data formats):
接口兼容性（数据冲突、数据格式）：
 - connections (modification of hardware, network connectors);
连接（修改硬件、网络连接器）；
 - network interface boards (compatibility);
网络接口板（兼容性）；
 - network protocols (DICOM, HL7, etc.);
网络协议（DICOM、HL7等）；
- packet address structure/timing;
分组地址结构/定时；
- normal network loads/bandwidth;
正常网络负载/带宽；
- peak network load;
峰值网络负载；
- data media (longevity and retrievability);
数据媒体（寿命和可检索性）；
- security (viruses, worms, unauthorized software updates or upgrades);
安全性（病毒、蠕虫、未经授权的软件更新或升级）；
- maximum acceptable response time;
最大可接受响应时间；
- acceptable failure rate of the network;
网络可接受的故障率；
- availability of the network (planned and unplanned maintenance);
网络可用性（计划内和计划外维护）；
- inconsistency in interfaces/formats resulting in loss of fidelity during information transfer;
接口/格式不一致，导致信息传输过程中保真度下降；

- heterogeneous network topologies.
异构网络拓扑。

Supplementing Annex D of ISO 14971:2000 when considering the potential causes for
考虑潜在原因时，补充ISO 14971:2000附录D

HAZARDS listed above, the following questions should be taken into account:
以上列出的危害，应考虑以下问题：

Supplementing Annex C of ISO 14971:2007, the following questions should be taken into account
when identifying the characteristics that could impact on safety:

作为ISO 14971:2007附录C的补充，在确定可能影响安全的特性时，应考虑以下问题：

- a) Reasonably foreseeable misuses
可合理预见的滥用

Is connection to the network inconsistent with the INTENDED USE of each constituent PEMS?
网络连接是否与各组成PEM的预期用途不一致？

- b) Incorrect data flow to or from each constituent PEMS
每个组成PEM的数据流不正确

What are the data transferred by the network used for, and to which tasks are they related?
What are the consequences of a breakdown of the NETWORK/DATA COUPLING IT- NETWORK ?
网络传输的数据用于什么？它们与哪些任务相关？网络/数据耦合IT网络故障的后果是什么？

- c) Deviation from the specified operational characteristics of any constituent PEMS
偏离任何组成PEM的规定运行特性

What are the operational characteristics of the PEMS and to what degree are they
affected by the NETWORK/DATA COUPLING IT-NETWORK?
PEMS的运行特性是什么？它们在多大程度上受网络/数据耦合IT网络的影响？

- d) Incomplete characterization of NETWORK/DATA COUPLING IT-NETWORK parameters
网络/数据耦合IT网络参数的不完全表征

Is the network topology, configuration, parameters (e.g. open or closed, bandwidth,
transmission protocol) completely characterized? Are there any breakdown
网络拓扑结构、配置、参数（如开放或封闭、带宽、传输协议）是否完整？有什么故障吗
characteristics/concepts and what are these?
特征/概念以及这些是什么？

- e) Excessive use/load of the NETWORK/DATA COUPLING IT-NETWORK by the network nodes
网络节点过度使用/负载耦合IT网络的网络/数据

What is the planned number of network nodes and their assumed degree of use? Are the
resources sufficient to meet the needs of both the NETWORK/DATA COUPLING IT-NETWORK
itself and the devices connected to it?
网络节点的计划数量及其假定的使用程度是多少？资源是否足以满足网络/数据耦合IT网络本身和与
之相连的设备的需求？

- f) Use errors
使用错误

What skills are required by the OPERATOR for the effective operation of the system?
操作员需要哪些技能才能有效地操作系统？

- g) Inadequate configuration management
配置管理不充分

Do periodic service tasks alter the network's IT-NETWORK'S characteristics (e.g. after remote
access, updates or upgrades)? Does the RESPONSIBLE ORGANIZATION ensure that
modifications to each constituent PEMS are reviewed and approved?
定期服务任务是否会改变网络的IT网络特征（例如，在远程访问、更新或升级之后）？责任组织是
否确保对每个组成PEM的修改都得到审查和批准？

- h) Information in wrong place
信息放错地方了

Does data arrive at a convenient and predictable location? Is it accompanied by irrelevant data that could confuse the OPERATOR or obscure the wanted data? When it arrives, is its source adequately indicated?
数据是否到达方便且可预测的位置？它是否伴随着不相关的数据，可能会混淆操作员或模糊需要的数据？当它到达时，它的来源是否得到充分的指示？

H.7.3 Network classification based on the consequence to the PATIENT Not used

H.7.3.1 Consequence to the PATIENT

基于对患者未使用的后果的网络分类H.7.3.1对患者的后果

In order to relate the causes in H.7.2 to the consequences for the PATIENT, it may be useful to classify NETWORK/DATA COUPLINGS both by the consequences and the reaction time, where reaction time is the time delay between a NETWORK/DATA COUPLING failure and the onset of HARM to the PATIENT. 为了将H.7.2中的原因与对患者造成的后果联系起来，根据后果和反应时间对网络/数据耦合进行分类可能是有用的，其中反应时间是网络/数据耦合故障与对患者造成伤害之间的时间延迟。

Table H.1 contains an example of a NETWORK/DATA COUPLING classification based on these considerations.
表H.1包含基于这些考虑因素的网络/数据耦合分类示例。

**H.7.3.2 Class C NETWORK/DATA COUPLING (PATIENT vital data, time critical)
C类网络/数据耦合（患者重要数据，时间紧迫）**

This is the NETWORK/DATA COUPLING for all time critical application/PROCESSES. It is not linked to any other network, because a link could result in uncontrollable RISKS. All resources are available only for the nodes of this network. The availability needs to be close to 100 %. Disruptions need to be avoided and last for only a few minutes per year. Responsibility is
这是所有时间关键型应用程序/进程的网络/数据耦合。它不与任何其他网络相连，因为一个链接可能导致无法控制的风险。所有资源仅可用于此网络的节点。可用性需要接近100%。需要避免干扰，并且每年仅持续几分钟。责任是

assigned to a single PEMS MANUFACTURER/system contractor only. Network nodes comply with the requirements established by this MANUFACTURER/contractor. An example of this class is a PATIENT monitoring network.
仅分配给单一PEMS制造商/系统承包商。网络节点符合制造商/承包商制定的要求。这个类的一个例子是病人监护网络。

Table H.1 – NETWORK/DATA COUPLING classification Not used
表H.1-未使用的网络/数据耦合分类

Consequence 后果	Reaction time 反应时间	Class 等级	Example (s) 示例
Death/serious injury 死亡/重伤	Second(s) 秒	C C	Infusion (closed loop); false control of a surgical robot 输液（闭环）；外科机器人的错误控制
	Minute(s) 分钟	C C	Suppressed alarm transmission 抑制报警传输
	Hour(s) 小时	C/B 断路器	False therapy data to ventilator 呼吸机假治疗数据
Medium injury 中度伤害	Second(s) 秒	C C	Wrong alarm transmission, false control of a surgical robot 错误的警报传输，外科机器人的错误控制
	Minute(s) 分钟	C/B 断路器	Wrong alarm transmission, false control of a surgical robot 错误的警报传输，外科机器人的错误控制
	Hour(s) 小时	C/B 断路器	Falsified image; loss of a therapy report 伪造的图像；丢失治疗报告
Minor injury 轻伤	Second(s) 秒	B B	
	Minute(s) 分钟	B B	Loss of a radiograph 射线照片丢失
	Hour(s) 小时	B/A B/A公司	
Negligible 可以忽略不计的	Second(s) 秒	A A	
	Minute(s) 分钟	A A	
	Hour(s) 小时	A A	

H.7.3.3 Class B NETWORK/DATA COUPLING (PATIENT vital data, non-time critical) B类网络/数据耦合（患者重要数据，非时间关键型）

This is the NETWORK/DATA COUPLING for non-time critical application/PROCESSES that handle therapeutic or diagnostic PATIENT data. This NETWORK/DATA COUPLING can be linked to another one by a defined and controllable/secured interface. The availability needs to be very high, and because of a lack of alternatives, disruptions should last only for short periods.
这是用于处理治疗或诊断患者数据的非时间关键型应用程序/进程的网络/数据耦合。这种网络/数据耦合

可以通过一个定义的、可控制的/安全的接口连接到另一个。可用性需要非常高，而且由于缺乏替代方案，中断应该只持续很短的时间。

- The responsibility is assigned to the RESPONSIBLE ORGANIZATION or system integrator. In the case of multiple PEMS, the contention of data priority needs to be defined.
责任分配给责任组织或系统集成商。在多个pem的情况下，需要定义数据优先级的争用。
- The network nodes should follow selected criteria/minimum set of parameters. A radiology network can serve as an example.
网络节点应遵循选定的标准/最小参数集。放射科网络可以作为一个例子。

H.7.3.4 Class A NETWORK/DATA COUPLING A类网络/数据耦合

This is the NETWORK/DATA COUPLING for any applications (including PATIENT administrative/demographic data) that operate on validated PATIENT data only and are not assigned to class “C” or “B” networks. Also, it can be accepted that these applications are unavailable for a longer period because there are alternatives. An example is a general hospital administration network where:
这是任何应用程序（包括患者管理/人口统计数据）的网络/数据耦合，这些应用程序仅对经验证的患者数据进行操作，而不分配给“C”或“B”类网络。此外，可以接受的是，这些应用程序在较长时间内不可用，因为还有其他选择。一个例子是综合医院管理网络，其中：

- the responsibility is assigned to the RESPONSIBLE ORGANIZATION;
责任分配给责任组织；
- there are many types of network nodes.
网络节点有多种类型。

H.7.4 NETWORK/DATA COUPLING IT-NETWORK parameters
H、7.4网络/数据耦合IT网络参数

The use of a NETWORK/DATA COUPLING an IT-NETWORK for exchange of data either between PEMS or between PEMS and other information technology equipment requires the knowledge about both the structure of the NETWORK/DATA COUPLING IT-NETWORK and the PROCESSES/functions running inside them. This is important because MANUFACTURERS of PEMS or NETWORK/DATA COUPLINGS IT-NETWORKS should select the configuration of their products such that: 使用网络/数据耦合IT网络在PEMS之间或PEMS与其他信息技术设备之间交换数据，需要了解网络/数据耦合IT网络的结构及其内部运行的过程/功能。这一点很重要，因为PEMS或网络/数据耦合IT网络的制造商应选择其产品的配置，以便：

- they comply with internationally recognized network standards (Ethernet, Fast Ethernet, GigaBitEthernet, FDDI, etc.) and use the available bandwidth appropriately according to the INTENDED USE; 它们符合国际公认的网络标准（以太网、快速以太网、千兆以太网、FDDI等），并根据预期用途适当使用可用带宽；
- they achieve the optimal performance for their application 它们实现了应用程序的最佳性能

A mixture of different NETWORK/DATA COUPLINGS IT-NETWORK configurations/parameter settings can emerge which are not always compatible for the different NETWORK/DATA COUPLINGS IT- NETWORK nodes in spite of the fact that they comply to valid international standards. 可能会出现不同网络/数据耦合IT网络配置/参数设置的混合，尽管这些网络/数据耦合IT网络节点符合有效的国际标准，但并不总是兼容的。

To avoid or at least to minimize the resulting potential of disruption, a match of a minimum set of NETWORK/DATA COUPLINGS IT-NETWORK parameters derived from the relevant standards is required.

为避免或至少最小化由此产生的中断可能性，需要匹配从相关标准导出的网络/数据耦合IT网络参数。

To ensure a reliable installation of NETWORK/DATA COUPLED PEMS and minimize the RISK to PATIENTS, the PEMS MANUFACTURER, the RESPONSIBLE ORGANIZATION, and the system integrator need to communicate all relevant technical parameters to each other. This level of detail is necessary to avoid inappropriate assumptions that result in unacceptable RISK.

为了确保网络/数据耦合PEMS的可靠安装，并将对患者的风险降至最低，PEMS制造商、责任机构和系统集成商需要相互交流所有相关的技术参数。为了避免导致不可接受的风险的不恰当假设，这种详细程度是必要的。

Figure H.4 contains a list of parameters potentially required to be specified. Due to the rapid evolution of NETWORK/DATA COUPLING IT-NETWORK technology, this table should be seen as a starting point. It should be clear if the table should be maintained and who should be responsible for maintaining it.

图H.4包含可能需要指定的参数列表。由于网络/数据耦合IT网络技术的快速发展，本表应被视为一个起点。应该明确是否应该维护该表以及由谁负责维护它。

Obje cts 物体	Descript ion 说明	Value/Comment 值/注释
Application and Operating System: 应用程序和操作系统：		
Operating System / Version: 操作系统/版本：		
Network protocols: 网络协议：		
Detailed data for specific application / transport protocol (if used) 特定应用/传输协议的详细数据（如果使用）		
HL7 HL7型	HL 7 version HL 7版本	
	Formats of message types used 使用的消息类型格式	
	Free fields (which are used) 可用字段（已使用）	
	Ports 端口	
	HL7 Protocol (TCP/IP Lower Layer) HL7协议（TCP/IP下层）	
DICOM Service classes DICOM服务类	A) Test: A) 测试：	Verification 验证
	B) Transfer: B) 转账：	Storage 保管部
		Query/Retrieve 查询/检索
	C) Documentation: C) 文件：	Print management 打印管理
	D) Organization: D) 组织机构：	Modality work list management 模态工作列表管理
		Performed procedure step 执行的程序步骤
	E) Information: E) 信息：	Study contents notification 研究内容通知
		Patient management 病人管理
		Storage commitment 储存承诺
		Study component management 研究组件管理
		Results management 成果管理
	F) External Storage: F) 外部存储：	Media storage 媒体存储

DICOM Objects DICOM对象	e.g. COMPUTER RADIOGRAPHY IMAGE e、g.计算机射线照相图像	
	Other Modality Objects 其他形态对象	
DICOM host name DICOM主机名		
DICOM AET called DICOM AET呼叫		
DICOM AET calling DICOM AET呼叫		
DICOM Port called 已调用DICOM端口		
DICOM Port calling DICOM端口调用		
Detailed Parameters with respect to the lower protocol layers 关于较低协议层的详细参数		
Network data 网络数据	Physical connection 物理连接	
	Network interface card parameters 网络接口卡参数	
Network-Administration 网络管理		
Port number of connected Switch / HUB / Router 连接的交换机/集线器/路由器的端口号		
IP-Address IP地址		
Subnet mask 子网掩码		
Host-Name 主机名		
IT-Domain IT领域		
Active-Directory / LDAP Server Active Directory/LDAP服务器		
Default Gateway 默认网关 (Access via Router) 通过路由器访问		
Remote Control 远程控制		
Remote Monitoring 远程监控		
Modem Connection 调制解调器连接		
Remote Service IP- Address 远程服务IP地址		

Other Parameters 其他参数	

Figure H.4 – Example of potential parameters required to be specified for
图H.4–需要指定的潜在参数示例
NETWORK/DATA COUPLING an IT-NETWORK
网络/数据耦合IT网络

Annex I
附件一
(informative)
（资料性）

ME SYSTEMS aspects
ME系统方面

I.1 Combinations of ME EQUIPMENT and non-ME EQUIPMENT
医用电气设备和非医用电气设备的组合

I.1.1 Introduction
介绍

This annex provides a summary of situations that could occur when different combinations of equipment are used in various medical environments. To keep this summary short, no more than two items of equipment (A and B) are used per situation. 本附件概述了在各种医疗环境中使用不同设备组合时可能出现的情况。为使本摘要简短，每个情况下使用的设备（A和B）不得超过两个。

I.1.2 Localities in a medical environment
医疗环境中的地点

The following localities are foreseen (see also Table I.1):
预计以下地点（另见表I.1）：

- the PATIENT ENVIRONMENT as part of a medically used room;
作为医疗用房一部分的病人环境；
- a medically used room, excluding the PATIENT ENVIRONMENT;
医疗用房，不包括患者环境；
- the non-medically used room (a room not designed for medical treatment, for example, an office or a storage room).
非医疗用房（非医疗用房，如办公室或储藏室）。

A protective earth can be dedicated to each of the three localities listed above.
保护性接地可用于上述三个位置中的每一个。

NOTE A potential difference (V) can exist between the protective earths in different localities. In case of an interruption of protective earthing (fault condition) for equipment in the PATIENT ENVIRONMENT, this potential difference can appear on the ENCLOSURE of the equipment causing a HAZARD resulting in a HAZARDOUS SITUATION for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the ME EQUIPMENT APPLIED PART is of TYPE B.

注：不同位置的保护接地之间可能存在电位差（V）。如果患者环境中的设备的保护接地（故障条件）中断，则该电位差可能出现在设备外壳上，对操作员或患者造成危险，如果操作员同时接触设备和如果医用电气设备应用部分为B型，则为患者提供。

I.1.3 Basic principles
基本原则

- PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards.
患者只能连接到符合本标准的医用电气设备的应用部件。其他设备应符合相关的IEC或ISO标准。
- In fault condition the allowable TOUCH CURRENT is 500 □A.

在故障条件下，允许的接触电流为500 μ A。

- All equipment complying with the safety standard applicable to the originally intended, non-medical use, herein called IEC XXXXX, and placed in the PATIENT ENVIRONMENT needs measures to limit the TOUCH CURRENT, if this exceeds the values specified in 16.6.1.

如果接触电流超过16.6.1中规定的值，则所有符合适用于最初预期、非医疗用途的安全标准（本文称为IEC XXXXX）并放置在患者环境中的设备需要采取措施限制接触电流。

I.1.4 Examples of ME SYSTEMS

ME系统示例

Two items of equipment are placed within the PATIENT ENVIRONMENT (see situation No. 1 in Table I.1).

两项设备放置在患者环境中（见表I.1中的情况1）。

There are several possibilities designated 1a through 1f:

有几种可能性被指定为1a到1f:

1a: Items A and B both comply with IEC 60601: Subclause 16.6 is satisfied.

1a: A项和B项均符合IEC 60601：满足第16.6款。

1b: Items A and B both comply with IEC 60601 and are powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high when the earth conductor in the MULTIPLE SOCKET-OUTLET is broken.

1b: 项目A和B均符合IEC 60601，并通过多个插座供电：当多个插座中的接地导体断开时，泄漏电流可能过高。

1c: Item A complies with IEC 60601 and item B complies with IEC XXXXX: only the TOUCH CURRENT of item B has to be limited when any single PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of the equipment, is interrupted, if necessary, by applying an additional protective earth or a separating transformer to item B.

1c: A项符合IEC 60601，B项符合IEC XXXXX：只有当设备的任何单个保护接地导体或等效导体中断时，才需要限制项目B的接触电流，如有必要，通过在项目B上施加额外的保护接地或隔离变压器。

1d: Same as 1c, with both items powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high for causes as listed under 1b and 1c.

1d: 与1c相同，两个部件都通过多个插座供电：对于1b和1c中列出的原因，泄漏电流可能过高。

1e: Item A is powered from item B with item A complying to IEC 60601 and being an insert to item B, complying to IEC XXXXX. Item B needs the measures for a power supply as described by the MANUFACTURER and needs to fulfil the requirement of 16.3. If necessary, apply an additional protective earth or a separating transformer to item B.
1e:A项由B项供电，A项符合IEC 60601，是B项的插件，符合IEC XXXXX。B项需要制造商所述的电源措施，并且需要满足16.3的要求。如有必要，在B项上附加保护接地或隔离变压器。

1f: Same as 1e, with item A not being an insert to item B: see 1e.

Situations 2 and 3 can be derived from situation 1 of Table I.1.

1f: 与1e相同，A项不是B项的插入项：见1e。情况2和3可从表1.1的情况1中得出。

NOTE The practical means of compliance indicated in Table I.1 are not intended to be an exhaustive list.

注：表I.1中所示的实际合规方法并非详尽列表。

Table I.1 – Some examples of ME SYSTEMS for illustration
表I.1–医用电气系统示例

Situation No. 情况编号。		Medically used room 医疗用房		Non- medically used room 非医疗用 房	Examples of possible 可能的例 子 causes for exceedin g 超标原因 LEAKAG E 泄漏 CURREN T limits 电流限制	Practical means of complianc e 实际遵守方 法 Apply 16.5 in all situations 在所有情况 下适用16.5
		Inside the 在 PATIENT ENVIRONMENT 患者环境	Outside the 外面 PATIEN T 病人 ENVIRO NMENT 环境			
1 1	1a Items A and B are 1a项目A 和B是 ME EQUIPME NT 医用电气 设备	Mains ns Plug 插头 Mai Plu			Multiplied 倍增 APPLIED PARTS 应用部件 of the same type can cause the total 同一类型 的 PATIENT LEAKAGE CURRENT to 病人漏电流 exceed limits See Note 1. 超出限值 见注1。	– Verify total –核实总数 PATIENT LEAKAG E CURRE NT 病人漏电 流
	1b Items A and B are 1b项目 A和B是 ME EQUIPME NT 医用电气 设备 powered via a MULTIPL	A B 甲B IEC 60601 IEC 60601 IEC 60601国际电工 委员会60601 MULTIPLE SOCKET-OUTLET 多插座			Earth conductor of the MULTIPLE SOCKET- OUTLET is 多个插座 的接地导 体为 broken 破碎的 See also 1a.	– Additional –附加 PROTEC TIVE EARTH 保护接地 CONNECTI ON 连接 (for A or B) or, (A或B)

E SOCKET - OUTLET 通过多个 插座供电				另见1a。	或， - Separati ng transform er -分离变 压器
1c Item A is 项目为A1c ME EQUIPME NT 医用电气 设备 and B is Non- 而B不是- ME EQUIPME NT 医用电气 设备	Mains ns 主电源 Plug g 插头 Mai Plu			Due to high 由于高 TOUCH CURRENT 接触电流 of B B的	- Additional -附加 PROTEC TIVE EARTH 保护接地 CONNECTI ON 连接 (for B) or, (B) 或， - Separat ing transform er (for B) -分离变 压 器 (用于 B)
1d Item A is 1d项目A是 ME EQUIPME NT 医用电气 设备 and B is non- 而B不是- ME EQUIPME NT 医用电气 设备 powered via a MULTIPL E SOCKET - OUTLET 通过多个 插座供电	A B 甲B IEC 60601 IEC xxxxx IEC 60601 IEC xxxxx MULTIPLE SOCKET-OUTLET 多插座			The earth conductor of the 的接地导 体 MULTIPLE SOCKET- 多个插座- OUTLET is broken or, 插座坏了 或， Due to high 由于高 TOUCH CURRENT 接触电流 of B B的	- Additional -附加 PROTEC TIVE EARTH 保护接地 CONNECTI ON 连接 (for A or B) or, (A或B) 或， - Separati ng transform er -分离变 压器

	1e Item A is 1e项目A是 ME EQUIPME NT 医用电气 设备 powered from specified 由指定电 源供电 power supply in item B B项电源	Mains 干线 Plug A 插头 IEC 60601 IEC 60601标准 B IEC xxxxx 国际电工委 员会 xxxxx			Due to high 由于高 TOUCH CURRENT 接触电流 of B B的	– Additional –附加 PROTEC TIVE EARTH 保护接地 CONNECTI ON 连接 (for B) or, (B) 或, – Separat ing transfor mer (for B) –分离变 压 器 (用 于 B)
	1f Item A is 1f项目 A是 ME EQUIPME NT 医用电气 设备 powered from 电源来自 NON- 非- ME EQUIPME NT 医用电气 设备 power supply in B B电源	M a i n s P l u g 电 源 插 头				

Table I.1 (continued)
表I.1（续）

Situation No. 情况编号。	Medically used room 医疗用房		Non- used room 非医疗用房		Practical means of compliance 实际遵守方法	
	PATIENT ENVIRONMENT 患者环境 Outside the 外面 PATIENT	Patient ENVIRONMENT 环境 medically 医学上	used room 二手房 causes 原因 exceeding	超过 LEAKAGE E 泄漏 CURRENT T limits	电流限制 Apply 16.5 in all situations 在所有情况下 适用16.5	
2a Items A and B are 2a项目A 和B是 ME EQUIPMENT 医用电气设备	M ai ns P l u g 电 源 插 头 A IEC 6060 1 IEC 6060 1标 准	M ai n s P l u g 电 源 插 头 B IEC 6060 1 IEC 6060 1标 准		No causes of exceedin g 无超标原因 LEAKAGE CURRENT 漏电流	– No further measures are necessary –无需采取 进一步措施	
2b Items A and item B are 2b项目A 和项目B 是 ME EQUIPMENT 医用电气设备 powered via a MULTIPLE	2 2 2c Item A is 项目2c ME EQUIPMENT 医用电气设备 and item B is non- B项为非-	E SOCKET- OUTLET 通过多个插座 供电 ME EQUIPMENT 医用电气设备	ME EQUIPMENT 医用电气设备	A A I E C 6 0 6 0 1 I E C	60 60 1 标准 MULTIPLE SOCKET- OUTLET 多插座 M a i	

n
s

P
l
u
g

电
源
插
头

B
B
IEC 60601
IEC 60601标准

Main
s
干线
→

E
a
r
t
h

c
o
n
d
u
c
t
o
r

o
f

t
h
e

M
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broken
破碎的

Due to
high
由于高

- Additional
附加
PROTECT
IVE
EARTH
保护接地
CONNECTION
连接
(for A or B) or,
(A或B) 或,
- Separat
ing
transform
mer
隔离变
压器
- Do not
use
metal
不要使
用金属
connector
housing or,
连接器外
壳或,
- SEPAR
ATION
DEVIC
E
分离装
置

2d Item A is 二维项目A是	A A IEC 6060 1 IEC 6060 1标准	B B IEC xxx x 国际电工委员会 xxx x	The earth conductor of the 的接地导体 MULTIPLE SOCKET- 多个插座- OUTLET is broken 插座坏了	- Additional 附加 PROTECT IVE EARTH 保护接地 CONNECTION 连接 (for A or B) or, (A或B) 或, - Separat ing transfor mer 隔离变 压器
ME EQUIPM ENT 医用电气 设备 and item B is non- B项为非- ME EQUIPM ENT 医用电气 设备 powered via a MULTIPL E SOCKET - OUTLET 通过多个 插座供电		MULTIPLE SOCKET- OUTLET 多插座		
3a Items A and B are 3a项目A 和B是 ME EQUIPM ENT 医用电气 设备	Mains 干线 Plug A 插头A IEC 606 01 IEC 606 01标准	Common protective earth 公共保护接 地	M als 线 B PI ug IEC 60601 B插头 IEC 60601	No causes of exceedin g 无超标原 因 LEAKAG E CURRE NT 漏电流
3b Item A is 3b A项为 ME EQUIPM ENT 医用电气 设备 and item B is non- B项为非- ME EQUIPM ENT 医用电气 设备	3 三	Mains 干线 Plug A 插头A IEC 60601 IEC 60601标准	Comm on protecti ve earth 公共保 护接地	Main s Plu g 电 源 插 头 B IEC xxxxx 国际电 工委 员会 xxxxx
				Due to high 由于高 TOUCH CURRENT 接触电流 of B B的 See rationale for 16.5. 见16.5的基本原理。

- Do not use metal 不要使用金属 connect	or housing	for 连接器外壳 SIGNAL 信号 INP	UT / OUTPUT	PART or, 输入 / 输出	出部分或， - SEPARATION DEVICE 分离装置
3c Item A is 3c项目A是 ME EQUIPMENT 医用电气设备 and item B in is 中的B项是 ME EQUIPMENT 医用电气设备 or non- 或者没有 - ME EQUIPMENT 医用电气设备	Main Plug 电源插头 A IEC 60601 1 IEC 60601 1标准 Common protective earth 公共保护接地		Mains 线 B Plug IEC 60601 B插头 IEC 60601 or IEC xxxxx 或 IEC xxxxx x	of A and B A和B的 b) Due to high 由于高 TOUCH CURRENT 接触电流 of B B的 See rationale for 16.5. 见16.5的 基本原理。	- Do not use metal 不要使用金属 connector 连接器 housing in the 住房 PATIENT 病人 ENVIRONMENT 环境
			Protective earth with potential difference 电位差 保护地 a) Potential difference between 电位差 PROTECTIVE EARTH 保护接地 CONNECTIONS 连接	- Additional 附加 PROTECTIVE EARTH 保护 接地 CONNECTION for (A), or (A) , 或 - SEPARATION DEVICE, or 分离装置 , 或	

Table I.1 (continued)
表I.1（续）

NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.
NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards. NOTE 4 Separating transformer: see 16.9.2.1.
NOTE 5 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment "B" then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or SEPARATION DEVICE.

I.2 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)
一、多插座（MSO）应用实例

Figure I.1 shows an example of the construction of a MULTIPLE SOCKET-OUTLET.
Figure I.2 shows some examples of application of MUPTILE SOCKET-OUTLETS.
图I.1显示了多个插座的构造示例。图I.2显示了多个插座的应用示例。

Male plug for ME EQUIPMENT
医用电气设备插头

Cover
封面

Spacers
垫片

Plate fixed on MSO
MSO固定板

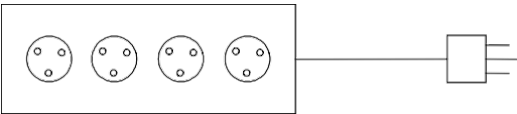
MSO
MSO公司

View from A-A (male plug connected)
A-A视图（插头连接）

A
A A A

A

Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO)
(accessible only with the use of a TOOL)
图I.1—多插座（MSO）的构造示例（仅使用工具才能访问）



MULTIPLE
SOCKET-
OUTLET
多插座

Transformer
assembly with
special socket-
outlet
带专用插座的变
压器组件

Transformer
assembly with
permanently
connected
MULTIPLE
SOCKET-OUTLET
带永久连接多个插
座的变压器组件

1:1
1: 1 Outlets
经销店

Transformer assembly
incorporating
变压器总成
MULTIPLE SOCKET-
OUTLET
多插座

Circuit diagram of an
integral MSO
整体MSO电路图
and transformer assembly
变压器总成
IEC 2464/05
IEC 2464/05标准

Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)
图I.2—多个插座（MSO）的应用示例

Annex J

附件J

(informative)

（资料性）

Survey of insulation paths

绝缘路径测量

(see 8.5.1)

（见8.5.1）

1 MOOP

1个MOOP

SECON

DARY

CIRCUI

T

二次回

路

1 MOOP

1个MOOP

LY EARTHED

ENCLOSURE

保护接地外壳

IEC

2465/0

5

IEC

2465/0

5标准

P

R

O

T

E

C

T

I

V

E

Figure J.1 – Insulation example 1

图J.1–绝缘示例1

2 MOOP

2个月

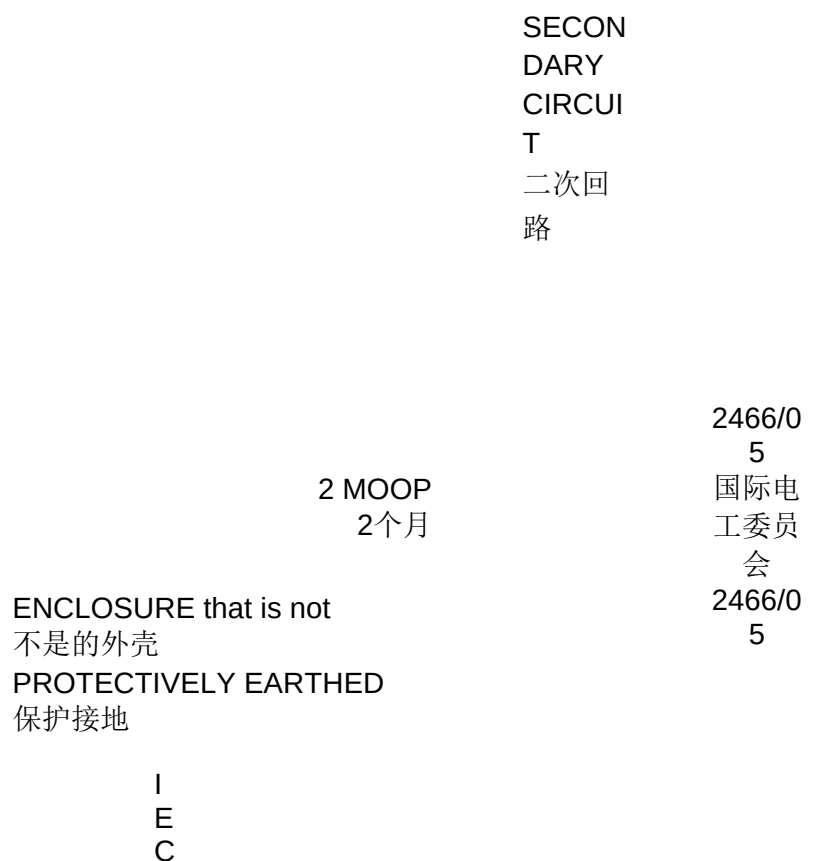


Figure J.2 – Insulation example 2
图J.2–绝缘示例2

SUPPLEMENTARY INSULATION
附加绝缘
ONE MEANS OF PROTECTION
一种保护手段

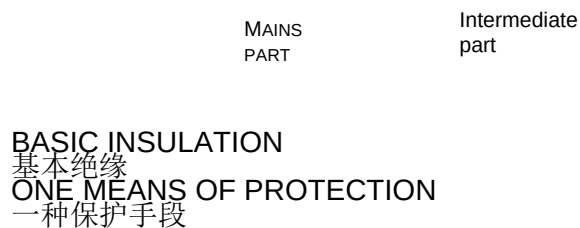


Figure J.3 – Insulation example 3
图J.3–绝缘示例3

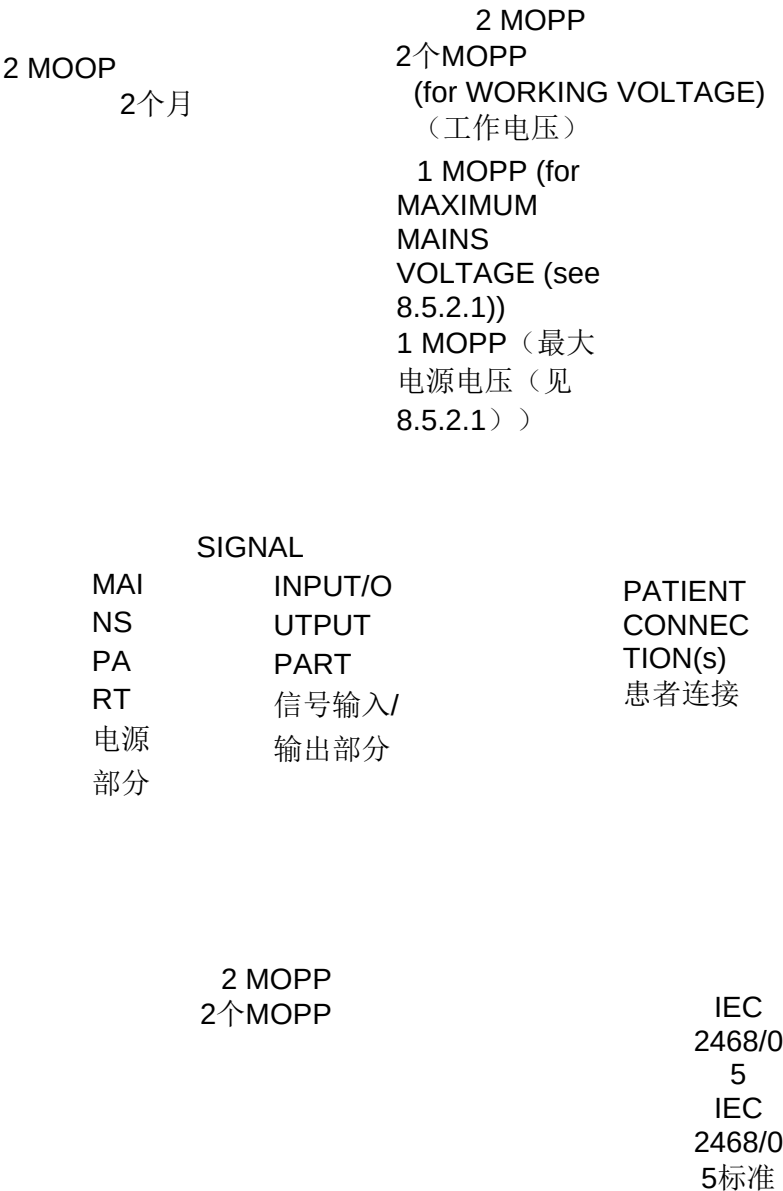
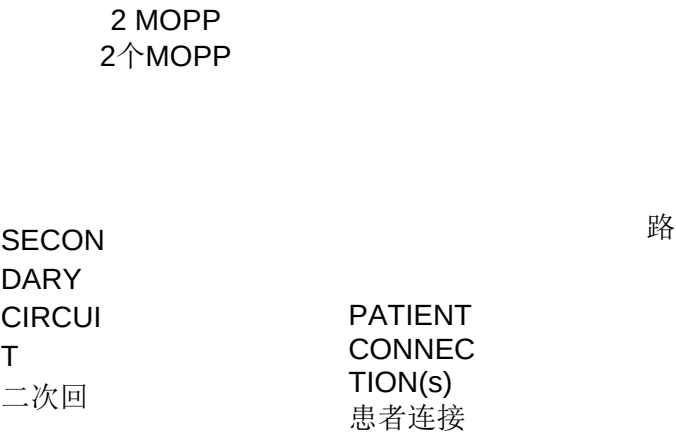


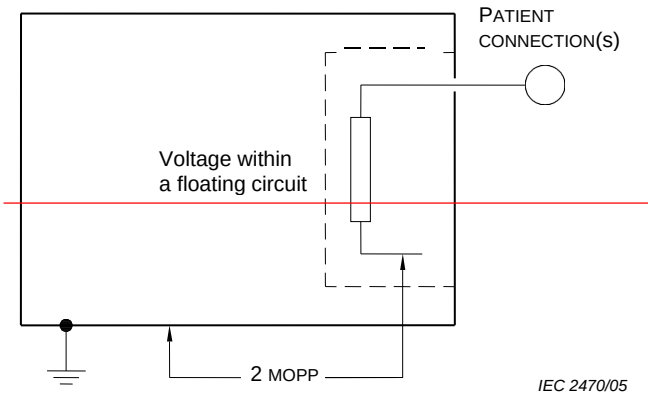
Figure J.4 – Insulation example 4
图J.4–绝缘示例4



2 MOPP
2个MOPP

IEC
2469/0
5
国际电
工委员
会
2469/0
5

Figure J.5 – Insulation example 5
图J.5-绝缘示例5



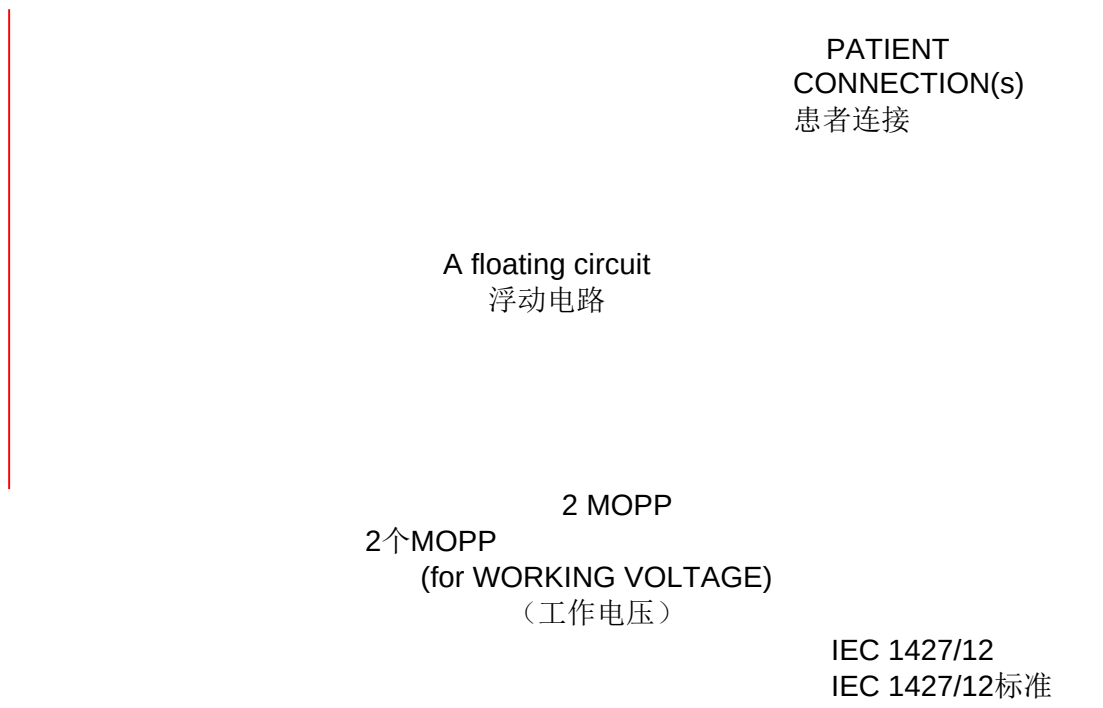
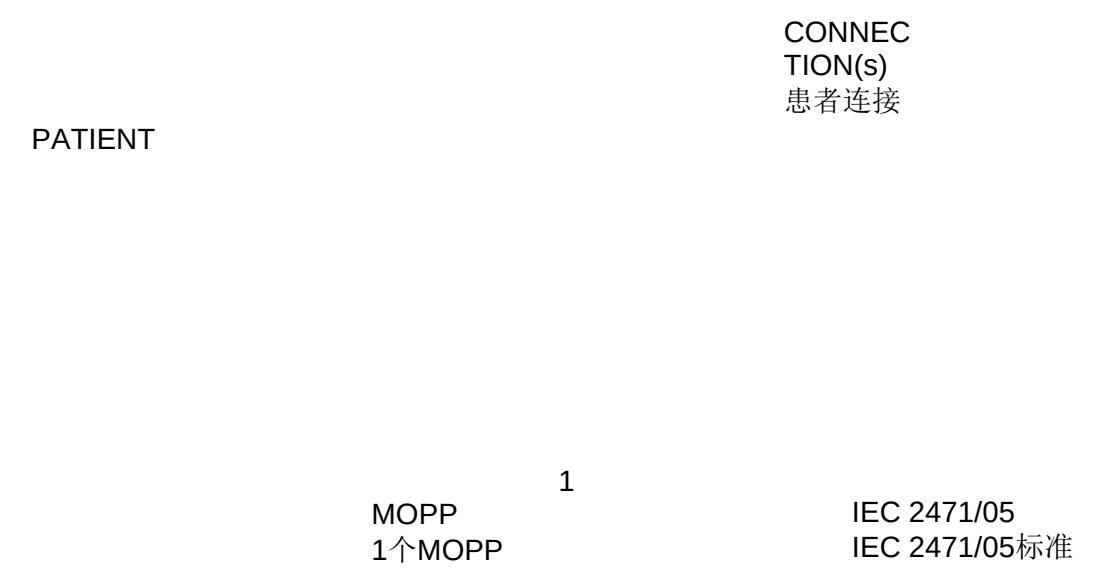


Figure J.6 – Insulation example 6
图J.6–绝缘示例6



NOTE WORKING VOLTAGE is the MAXIMUM MAINS VOLTAGE.
注：工作电压为最大电源电压。

Figure J.7 – Insulation example 7
图J.7–绝缘示例7

Annex K
附件K
(informative)
（资料性）

Simplified PATIENT LEAKAGE CURRENT diagrams
简化病人漏电流图

Figure K.2, Figure K.4 and Figure K.5 illustrate a special test condition in Table 4, which is neither a NORMAL CONDITION nor a SINGLE FAULT CONDITION.

图K.2、图K.4和图K.5说明了表4中的一种特殊试验条件，它既不是正常工况，也不是单一故障工况。

Current in □A
电流（单位：A）

IEC 2472/05
IEC 2472/05标准

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material
图K.1–带绝缘材料外壳的医用电气设备
(simplified Figure 15)
(see 8.7.4.7 a))
(简图15)（见
8.7.4.7a））

Current in □A
电流（单位：A）

IEC 2473/05
IEC 2473/05标准

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART
图K.2–带有F-TYPE应用部件的医用电气设备
(simplified Figure 16)
(see 8.7.4.7 b))
(简图16)（见
8.7.4.7b））

Current in □A
电流（单位：A）

IEC 2474/05
IEC 2474/05标准

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART

图K.3—带应用部分和信号输入/输出部分的医用电气设备
(simplified Figure 17)
(see 8.7.4.7 c))
（简图17）（见
8.7.4.7 c））

Current in □A
电流（单位：A）

IEC 2475/05
IEC 2475/05标准

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not

图K.4—医用电气设备，带有B型应用部件的患者连接

PROTECTIVELY EARTHED
保护接地

(simplified Figure 18)
(see 8.7.4.7 d))
（简图18）（见
8.7.4.7 d））

Current in □A
电流（单位：A）

IEC 2476/05
IEC 2476/05标准

Example with the measuring supply circuit of Figure F.1.
图F.1测量电源电路示例。

Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF
APPLIED PART that is not
图K.5–带有BF型应用部件的患者连接的医用电气设备
PROTECTIVELY EARTHED
保护接地
(simplified Figure 18)
(see 8.7.4.7 d))
(简图18) (见
8.7.4.7 d))

Annex L
附录L
(normative)
（规范性）

Insulated winding wires for use without interleaved insulation
无交错绝缘用绝缘绕组线
(see 8.8.2)
（见8.8.2）

L.1 Introduction
介绍

This annex specifies winding wire whose insulation may be used to provide BASIC INSULATION, SUPPLEMENTARY INSULATION, DOUBLE INSULATION or REINFORCED INSULATION in wound

本附录规定了绕组线，其绝缘可用于提供基本绝缘、辅助绝缘、双重绝缘或加强绝缘 components without interleaved insulation.
无交错绝缘的部件。

This annex covers round winding wires having diameters between 0,05 mm and 5,00 mm.
本附录包括直径在0.05 mm和5.00 mm之间的圆形绕组线。

L.2 Wire construction
导线施工

If the wire is insulated with two or more spirally wrapped layers of tape, the overlap of layers shall be adequate to ensure continued overlap during manufacture of the wound component. The layers of spirally wrapped wire insulation shall be sufficiently secured to maintain the amount of overlap.
如果导线用两层或两层以上缠绕的胶带绝缘，则各层的重叠应足以确保在制造缠绕部件时继续重叠。螺旋缠绕电线绝缘层应足够牢固，以保持重叠量。

L.3 TYPE TEST
型式试验

The wire shall pass the tests of L.3.1 to L.3.4, carried out at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless specified otherwise.
除非另有规定，钢丝应通过L.3.1至L.3.4的试验，试验温度在15°C至35°C之间，相对湿度在45%至75%之间。

L.3.1 Dielectric strength
介电强度

The test sample is prepared according to IEC 60851-5:19962008, Subclause 4.4.1 (for a twisted pair). The sample is then subjected to the test of 8.8.3 for the appropriate type and number of MOP(s). The test voltage is at least twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3), with a minimum of:
根据IEC 60851-5:19962008第4.4.1款（双绞线）制备试样。然后对样品进行8.8.3中所述的适当类型和数量的拖把试验。试验电压至少为表6和表7中适当电压的两倍（见8.8.3），最小值为：

- 3 000 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or
基本绝缘或辅助绝缘为3000 V；或

- 6 000 V for REINFORCED INSULATION.
6 000 V用于加强绝缘。

L.3.2 Flexibility and adherence **灵活性和坚持性**

The sample is subjected to test 8 of IEC 60851-3:19962009, Subclause 5.1.1, using the mandrel diameters of Table L.1. The test sample is then examined in accordance with IEC 60851-3:19972009, Subclause 5.1.1.4, followed by the test of 8.8.3, for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The test voltage is at least the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of:
使用表L.1中的心轴直径，对样品进行IEC 60851-3:19962009第5.1.1款中的试验8。然后根据IEC 60851-3:19972009第5.1.1.4款对试样进行检查，然后进行8.8.3中的试验，以确定合适的MOP类型和数量，但在导线和心轴之间施加试验电压。试验电压至少为表6和表7中的适当电压（见8.8.3），最小值为：

- 1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or
基本绝缘或辅助绝缘为1500V；或
- 3 000 V for REINFORCED INSULATION.
3 000 V用于加强绝缘。

Table L.1– Mandrel diameter
表L.1——心轴直径

NOMINAL conductor diameter 标称导体直径 mm 毫米	Mandrel diameter 心轴直径 mm ± 0,2 mm 毫米±0.2毫米
0,05 – 0,34 0,05–0,34	4,0 4,0个
0,35 – 0,49 0,35–0,49	6,0 6,0分
0,50 – 0,74 0,50–0,74	8,0 8,0分
0,75 – 2,49 0,75–2,49	10,0 10,0分
2,50 – 5,00 2,50–5,00	four times the conductor diameter a 导线直径a的四倍
a I accordance with 60317- [9]. n IEC 43 [9] – 在符合IEC 60317- 一 43号 。	

The tension to be applied to the wire during winding on the mandrel is calculated from the wire diameter to be equivalent to 118 MPa ± 11,8 MPa (118 N/mm² ± 11,8 N/mm²). 在卷筒上缠绕时施加在钢丝上的张力根据钢丝直径计算得出，相当于118 MPa±11.8 MPa（118 N/mm²±11.8 N/mm²）。

L.3.3 Heat shock 热冲击

The sample is subjected to test 9 of IEC 60851-6:1996, followed by the dielectric strength test of 8.8.3 for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The voltage is not less than the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of: 样品应进行IEC 60851-6:1996中的试验9，然后对适当类型和数量的MOP进行8.8.3中的介电强度试验，但试验电压施加在电线和心轴之间。电压不低于表6和表7中的适当电压（见8.8.3），最小值为：

- 1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or
基本绝缘或辅助绝缘为1500V；或
- 3 000 V for REINFORCED INSULATION.
3 000 V用于加强绝缘。

The oven temperature is the relevant temperature for the thermal class of insulation in Table L.2.

烘箱温度是表L.2中绝缘热等级的相关温度。

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

卷筒直径和在卷筒上缠绕时施加在钢丝上的张力如L.3.2所示。

The electric strength test is conducted at room temperature after removal from the oven.

从烘箱中取出后，在室温下进行电强度试验。

Table L.2 – Oven temperature
表L.2——烘箱温度

Thermal class 热等级	A A (10 5) (1 05)	E E (120) (1 20 个)	B B (13 0) (1 30 个)	F F (155) (1 55 个)	H H (18 0) (1 80)
Oven temperature 烘箱温度 °C ± 5 °C 摄氏度±5摄氏度	200 200	215 215	225 225	240 240	260 260

L.3.4 Retention of electric strength after bending 弯曲后保持电强度

Five samples are prepared as in L.3.2 above and tested as follows. Each sample is removed from the mandrel, placed in a container and positioned so that it can be surrounded by at least 5 mm of metal shot. The ends of the conductor in the sample are to be sufficiently long to avoid flash over. The shot is to be not more than 2 mm in diameter and consists of balls of stainless steel, nickel or nickel plated iron. The shot is gently poured into the container until the sample under test is covered by at least 5 mm of shot. The shot is cleaned periodically with a suitable solvent (for example, 1,1,1-trichloroethane). 按照上述L.3.2的规定制备五个样品，并按以下步骤进行试验。将每个样品从芯轴上取下，放在容器中，并将其放置在至少5 mm的金属丸周围。样品中导体的端部应足够长，以避免闪络。弹丸直径不超过2 mm，由不锈钢、镍或镀镍铁球组成。将钢丸轻轻倒入容器中，直到被测样品被至少5 mm的钢丸覆盖。用合适的溶剂（例如1,1,1-三氯乙烷）定期清洁钢丸。

NOTE The above test PROCEDURE is reproduced from 4.6.1.c) of IEC 60851-5:1988 (second edition including amendment 1), now withdrawn. It is not included in the third fourth edition of that standard.

注：上述试验程序复制自IEC 60851-5:1988（第二版包括修改件1）的4.6.1.c），现已撤销。该标准的第三四版中不包括该标准。

The test voltage is at least the appropriate test voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

试验电压至少为表6和表7（见8.8.3）中适用于适当类型和数量的MOP的适当试验电压，最小值为：

- 1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or
基本绝缘或辅助绝缘为1500V；或
- 3 000 V for REINFORCED INSULATION.
3 000 V用于加强绝缘。

The test voltage is applied between the shot and the conductor.

试验电压施加在铅球和导体之间。

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

卷筒直径和在卷筒上缠绕时施加在钢丝上的张力如L.3.2所示。

L.4 Tests during manufacture **制造过程中的试验**

L.4.1 General **总则**

The wire is subjected by the wire manufacturer to electric strength tests during manufacture as specified in L.4.2 and L.4.3.

电线制造商应按照L.4.2和L.4.3的规定，在制造过程中对电线进行电气强度试验。

L.4.2 Routine testing **常规试验**

The test voltage for routine testing is to be the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

常规试验的试验电压应为表6和表7（见8.8.3）中适用于适当类型和数量的MOP的适当电压，最小值为：

- 1 500 V r.m.s. or 2 100 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION;
or
基本绝缘或辅助绝缘为1500 V r.m.s.或2 100 V峰值；或
- 3 000 V r.m.s. or 4 200 V peak for REINFORCED INSULATION.
3 000 V r.m.s.或4200 V峰值，用于加强绝缘。

L.4.3 Sampling tests **抽样试验**

Twisted pair samples are tested in accordance with IEC 60851-5:19962008, Subclause 4.4.1. The minimum breakdown voltage is twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of: 根据IEC 60851-5:19962008第4.4.1款测试双绞线样品。最小击穿电压是表6和表7（见8.8.3）中适当类型和数量MOP的适当电压的两倍，最小值为：

- 3 000 V r.m.s. or 4 200 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION;
or
基本绝缘或辅助绝缘为3000 V r.m.s.或4200 V峰值；或
- 6 000 V r.m.s. or 8 400 V peak for REINFORCED INSULATION.
6 000 V r.m.s.或8 400 V峰值，用于加强绝缘。

Annex M
附件M
(normative)
（规范性）

Reduction of pollution degrees
降低污染程度
(see 8.9.1.8)
（见8.9.1.8）

Table M.1 shows additional protective measures that may be used to reduce the pollution degree.
表M.1显示了可用于降低污染程度的其他保护措施。

Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection
表M.1——通过使用附加保护降低内部环境的污染程度

Additional protection 附加保护	From pollution degree 2 of external environment to: 从外部环境污染等级2 到:	From pollution degree 3 of external environment to: 从外部环境污染等级3 到:
ENCLOSURE IPX4 of IEC 60529 IEC 60529外壳IPX4	2 2	2 2
ENCLOSURE IPX5 or IPX6 of IEC 60529 IEC 60529外壳IPX5或IPX6	2 2	2 2
ENCLOSURE IPX7 or IPX8 of IEC 60529 IPX5或IEC 605外壳	2 (see note) 2（见注 释）	2 (see note) 2（见注 释）
Hermetically sealed ENCLOSURE 密封外壳	1 1	1 1
Constantly heated 持续加热	1 1	1 1
Encapsulated 封装的	1 1	1 1
Coated 涂层	1 1	2 2
NOTE Reduction can be to pollution degree 1, if the equipment is manufactured with a low internal humidity and the manufacturer's instructions specify that, after opening the ENCLOSURE, the ENCLOSURE is reassembled in a controlled humidity environment or a desiccant is used. 注：如果设备是在低内部湿度下制造的，并且制造商的说明书规定，打开外壳后，在受控湿度环境中重新组装外壳或使用干燥剂，则可将其降低至1级污染程度。		

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- [67] IEC 62471:2006, Photobiological safety of lamps and lamp systems
IEC 62471:2006, 灯和灯系统的光生物安全
- [68] ISO 7396-1, Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum
ISO 7396-1, 医用气体管道系统-第1部分：压缩医用气体和真空管道系统
- [69] ISO 14708 (all parts), Implants for surgery – Active implantable medical devices
ISO 14708（所有部分），外科植入物-有源植入式医疗器械
- [70] ISO 15001, Anaesthetic and respiratory equipment – Compatibility with oxygen
ISO 15001, 麻醉和呼吸设备-与氧气的相容性
- [71] ANSI/AAMI HE-75:2009, Human Factors Engineering – Design of Medical Devices
ANSI/AAMI HE-75:2009, 人为因素工程-医疗器械设计

[72] UL 2556:2007, UL Standard for Safety Wire and Cable Test Methods
UL 2556:2007, UL安全电线电缆试验方法标准

INDEX OF ABBREVIATIONS AND ACRONYMS 缩略语索引

Abbreviation 缩写	Term 期限
a.c. a、c。	Alternating current 交流电
AEL AEL公司	Accessible emission limit 可及排放限值
AMSO 阿姆索	Auxiliary mains socket-outlet 辅助电源插座
AP 美联社	Anaesthetic-proof 麻醉证明
APG APG公司	Anaesthetic-proof category G (gas) G类麻醉证明（气体）
CASE 案件	Computer aided software engineering 计算机辅助软件工程
CAT 猫	Computer assisted tomography 计算机辅助断层摄影术
CRT 阴极射线管	Cathode ray tube 阴极射线管
CTI CTI公司	Comparative tracking index 比较跟踪指数
d.c. d、c。	Direct current 直流电
DICOM DICOM	Digital imaging and communication in medicine 医学数字成像与通信
ELV 弱电	Extra-low voltage 超低电压
EUT 受验设备	Equipment under test 试验设备
FDDI FDDI公司	Fibre distributed data interface 光纤分布式数据接口
FMEA FMEA	Failure modes and effects analysis 失效模式及影响分析
FV FV公司	Flammability classification according to IEC 60695-11-10 根据IEC 60695-11-10的可燃性分类
HL7 HL7型	Health Level 7 健康水平7
IBP IBP公司	Invasive blood pressure catheter 有创血压导管
ICRP 红十字委员会	International commission for radiation protection 国际辐射防护委员会
IEV IEV公司	International Electrotechnical Vocabulary 国际电工词汇

IP IP地址	International protection in relation to the protection requirements of IEC 60529 or Internet protocol in relation to NETWORK/DATA COUPLING 与IEC 60529或与网络/数据耦合相关的互联网协议的保护要求相关的国际保护
IPS IPS公司	Isolated power supply 隔离电源
IT 它	Information technology 信息技术
LDAP LDAP	Light weight directory access protocol 轻型目录访问协议
LED 发光二极管	Light emitting diode 发光二极管
MAR 宗教硕士	Minimum angle resolvable 最小角度可分辨
MD 医学博士	Measuring device, see 8.7.4.4 测量装置, 见8.7.4.4
ME 我	MEDICAL ELECTRICAL, see 3.63 and 3.64 医用电气, 见3.63和3.64
MOOP 穆普	MEANS OF OPERATOR PROTECTION, see 3.58 操作员保护方法, 见3.58
MOP 拖把	MEANS OF PROTECTION, see 3.60 保护方法, 见3.60
MOPP MOPP公司	MEANS OF PATIENT PROTECTION, see 3.59 患者保护方法, 见3.59
MPSO MPSO公司	Multiple portable socket-outlet 多个便携式插座
MSO MSO公司	MULTIPLE SOCKET-OUTLET, see 3.67 多插座, 见3.67
OTS OTS公司	Off the shelf 现成的
PEMS PEMS公司	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, see 3.90 可编程电气医疗系统, 见3.90
PESS 佩斯	PROGRAMMABLE ELECTRONIC SUBSYSTEM, see 3.91 可编程电子子系统, 见3.91
PTC PTC公司	Positive temperature coefficient device 正温度系数装置
PTFE 聚四氟乙烯	Polytetrafluoroethylene 聚四氟乙烯
PVC 聚氯乙烯	Polyvinyl chloride 聚氯乙烯

Abbreviation 缩写	Term 期限
RFID 射频识别	Radio-frequency identification 射频识别
r.m.s. r、硕士。	Root mean square 均方根
SAR 特别行政区	Specific absorption rate 比吸收率
SELV 塞尔夫	Safety extra-low voltage 安全特低电压
SI 硅	System international
SIP/SOP	SIGNAL INPUT/OUTPUT PART, see 3.115.
TCP	Transport connection protocol
TENS	Transcutaneous electronic nerve stimulator
TFE	Tetrafluoroethylene
UPS	Uninterruptible power supply
VDU	Video display unit

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