UL 60601-1

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Medical Electrical Equipment, Part 1: General Requirements for Safety

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UL Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 60601-1

First Edition, Dated April 25, 2003

Revisions: This Standard contains revisions through and including June 30, 2003.

Summary of Topics

Revisions are being issued to add a note after those requirements that have rationales located in Appendix A and Annex DVC. These requirements and rationales are now more identifiable. Previously, IEC requirements that contained rationales were only marked with an asterisk. These revisions also contain several editorial corrections.

Announcement Bulletin(s): This Standard contains the announcement bulletin(s) dated July 16, 1997, May 10, 1999 and June 16, 2000. The announcement bulletin is located at the end of the Standard (after the adoption bulletin(s)).

The following table lists the future effective date with the corresponding item.

Future Effective Date	Reference
February 6, 2004	6.3 g)

The master for this Standard at UL's Northbrook Office is the official document insofar as it relates to a UL service and the compliance of a product with respect to the requirements for that product and service, or if there are questions regarding the accuracy of this Standard.

Revisions of UL Standards for Safety are issued from time to time. A UL Standard for Safety is current only if it incorporates the most recently adopted revisions.

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The requirements in this Standard are now in effect, except for those paragraphs, sections, tables, figures, and/or other elements of the Standard having future effective dates as indicated in the preface. The prior text for requirements that have been revised and that have a future effective date are located after the Standard, and are preceded by a ″SUPERSEDED REQUIREMENTS″ notice.

New product submittals made prior to a specified future effective date will be judged under all of the requirements in this Standard including those requirements with a specified future effective date, unless the applicant specifically requests that the product be judged under the current requirements. However, if the applicant elects this option, it should be noted that compliance with all the requirements in this Standard will be required as a condition of continued Listing, Recognition, Classification and Follow-Up Services after the effective date, and understanding of this should be signified in writing.

This Standard consists of pages dated as shown in the following checklist:

UL 60601-1

Medical Electrical Equipment, Part 1: General Requirements for Safety

Prior to the first edition of UL 60601-1, the requirements for the products covered by this Standard were included in UL 2601-1. This Standard replaces UL 2601-1.

First Edition

April 25, 2003

An effective date included as a note immediately following certain requirements is one established by Underwriters Laboratories Inc.

Revisions of this Standard will be made by issuing revised or additional pages bearing their date of issue. A UL Standard is current only if it incorporates the most recently adopted revisions, all of which are itemized on the transmittal notice that accompanies the latest set of revised requirements.

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UL INTRODUCTION

This is an explanation of the intended implementation of Particular and Collateral Requirements associated with product evaluation using this standard. For continuity some of the introductory information from IEC 60601-1 is repeated here.

PARTICULAR STANDARDS:

UL 60601-1 contains requirements for safety which are generally applicable to all medical electrical equipment. For certain types of equipment, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Requirements exist, the General Standard should not be used alone. Special care is required in applying the General Standard to equipment for which no Particular Standard exists.

COLLATERAL STANDARDS:

When the equipment falls within the scope of one or more Collateral Standards, such standard(s) may, optionally, also be used.

Note – Where any of these (Collateral and Particular) standards are not yet published by UL, then the corresponding IEC Publications are used.

Preface (UL)

This UL Standard is based on IEC Publication 60601-1: Second Edition – Medical Electrical Equipment, Part 1: General Requirements for Safety, as revised by Amendments 1 and 2. IEC publication 60601-1 is copyrighted by the IEC.

The text, figures and tables of IEC Publication Medical Electrical Equipment, Part 1: General Requirements for Safety, IEC 60601-1 copyright 1988 as amended in 1991 and 1995, are used in this Standard with the consent of the IEC and the American National Standards Institute (ANSI). The IEC copyrighted material has been reproduced with permission from ANSI. ANSI should be contacted regarding the reproduction of any portion of the IEC material. The IEC Foreword and Introduction are not a part of the requirements of this Standard but are included for information purposes only. Copies of IEC Publication 60601-1 may be purchased from ANSI, 11 West 42nd Street, New York, New York, 10036, (212) 642-4900.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

UL Effective Date

As of June 30, 2003, all products Listed by UL must comply with the requirements in this Standard except for Clause 6.3 (g), which is effective February 6, 2004.

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Foreword (UL)

A. This Standard contains basic requirements for products covered by Underwriters Laboratories Inc. (UL) under its Follow-Up Service for this category within the limitations given below and in the Scope section of this Standard. These requirements are based upon sound engineering principles, research, records of tests and field experience, and an appreciation of the problems of manufacture, installation, and use derived from consultation with and information obtained from manufacturers, users, inspection authorities, and others having specialized experience. They are subject to revision as further experience and investigation may show is necessary or desirable.

B. The observance of the requirements of this Standard by a manufacturer is one of the conditions of the continued coverage of the manufacturer's product.

C. A product which complies with the text of this Standard will not necessarily be judged to comply with the Standard if, when examined and tested, it is found to have other features which impair the level of safety contemplated by these requirements.

D. A product employing materials or having forms of construction which conflict with specific requirements of the Standard cannot be judged to comply with the Standard. A product employing materials or having forms of construction not addressed by this Standard may be examined and tested according to the intent of the requirements and, if found to meet the intent of this Standard, may be judged to comply with the Standard.

E. UL, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of UL represent its professional judgment given with due consideration to the necessary limitations of practical operation and state of the art at the time the Standard is processed. UL shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. UL shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard.

F. Many tests required by the Standards of UL are inherently hazardous and adequate safeguards for personnel and property shall be employed in conducting such tests.

NATIONAL DIFFERENCES

GENERAL

National Differences from the text of International Electrotechnical Commission (IEC) Publication 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, copyright 1988 as amended in 1991 and 1995 are indicated by notations (differences) and are presented in bold text.

There are five types of National Differences as noted below. The difference type is noted on the first line of the National Difference in the standard. The standard may not include all types of these National Differences.

DR – These are National Differences based on the **National Electrical Code (NEC)** and **other U.S. Regulatory Requirements**.

D1 – These are National Differences which are based on **basic safety principles and requirements**, elimination of which would compromise safety for U.S. consumers and users of products.

D2 – These are National Differences based on **safety practices**. These are differences for IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the manufacturer's part.

DC – These are National Differences based on the **component standards** and will not be deleted until a particular component standard is harmonized with the IEC component standard.

DE – These are National Differences based on **editorial comments or corrections**.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1 (1977), entitled “Safety of medical electrical equipment, Part 1: General requirements”.

The text of this Standard is based on the following documents:

Six Months’ Rule	Report on Voting	Two Months’ Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

Amendment 1 has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Six Months’ Rule	Report on Voting
62A(CO)36	62A(CO)39

Full information on the voting for the approval of this amendment can be found in the Voting Report indicated in the above table.

Amendment 2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

DIS	Report on voting
62A(CO)45	62A/181/RVD

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

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller roman type.

Test specifications and headings of sub-clauses: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS

* Rationale (Appendix A).

DV.1 DE *Addition:*

The numbering system in the standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

DV.2 DE *Addition:*

Due to pagination differences, references to page numbers in the IEC text have been modified to reference the correct information.

DV.3 DE *Modification of the print types:*

Notes have been added to requirements that have corresponding rationales located in Appendix A and Annex DVC.

INTRODUCTION

Amendment 1 contains a first series of revisions to IEC Publication 601-1 (second edition, 1988): Medical electrical equipment, Part 1: General requirements for safety.

Aware of the need and the urgency for a General Standard covering electromedical EQUIPMENT, the majority of National Committees voted in 1977 in favour of the first edition of IEC 601-1, based on a draft which 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, had required years of effort in order to prepare that first Standard, which served as a universal reference since its publication.

However, its frequent application revealed room for improvement, and careful work of revision subsequently undertaken and continued over a number of years resulted in the second edition (1988). The present publication contains further modifications.

The General Standard contains requirements of safety which are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of EQUIPMENT, these requirements are supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, the General Standard should not be used alone. Special care is required in applying the General Standard to EQUIPMENT for which no Particular Standard exists.

In some countries EQUIPMENT may only be certified as complying with the Standard if either a Particular Standard or an authorized document based on the General Standard is available, stating which clauses are applicable for the EQUIPMENT concerned.

Amendment 2 contains a second series of revisions to IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*.

It is intended to facilitate interpretation and application of the General Standard. It also identifies additional aspects of safety which were not previously covered. Significant changes include the following:

– APPLIED PARTS are now identified by requirements covering the possibility of physical contact with the PATIENT during NORMAL USE, without electrical considerations; individual PATIENT CONNECTIONS are then defined by requirements concerning electrical contact with the PATIENT during NORMAL USE;

– classification of the degree of protection against electric shock (TYPES CF/BF/B) is not related any more to the word EQUIPMENT but now clearly relates to individual APPLIED PARTS; it is more logical because the degree of protection is determined in fact by that of the APPLIED PART; this means no extra requirements and tests but more differentiation and clarification of the required actions;

– general requirements are included for EQUIPMENT in which the APPLIED PART is marked as providing protection against the discharge voltage from a defibrillator and for which there is no Particular Standard;

– limits for the d.c. component of PATIENT LEAKAGE CURRENT are included to align with the requirement for PATIENT AUXILIARY CURRENT;

– clarification concerning the degree of protection against ingress of liquids by using IP Code, as detailed in the basic safety publication IEC 529 is an improvement;

– the term ″not used″, which was introduced in the second edition of IEC 601-1, is replaced, where applicable, by the wording ″no general requirement″ in order to avoid misunderstanding; this means that a Particular Standard may specify requirements if it is deemed necessary;

– references to existing IEC Collateral Standards 601-1-1, 601-1-2, 601-1-3 and future IEC 601-1-4 (see Appendix L), are included;

– additional requirements are included regarding the information which must be supplied by the manufacturer in order to improve the international acceptance of symbols and units and to provide more information about the intended use of the EQUIPMENT; the latter is becoming necessary due to the relation with performance safety aspects;

– some requirements and test methods have been aligned with other existing IEC standards;

– a number of accidents having being reported due to USER error during the use of biopotential connectors (as electrodes having attached leads terminating in 2 mm exposed metal pin connectors), some additional requirements have been introduced to prevent the recurrence of such accidents whatever the type of EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety

SECTION ONE – GENERAL

1 *Scope and object

*See rationale for 1

1.1 *Scope*

This Standard applies to the safety of MEDICAL ELECTRICAL EQUIPMENT (as defined in Sub-clause 2.2.15).

Although this Standard is primarily concerned with safety, it contains some requirements regarding reliable operation where this is connected with safety.

SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

Appendices in this Standard are not mandatory unless made so by an explicit statement in the main text.

1.1DV D2 ***Replacement of the third paragraph of 1.1 with the following:***

SAFETY HAZARDS resulting from intended physiological function of EQUIPMENT covered by this Standard are not considered. These requirements do not contemplate the investigation of protection against ionizing radiation or radioactive isotopes. Such EQUIPMENT is subject to Federal radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.

*See rationale for 1.1DV

1.2 *Object*

The object of this Standard is to specify general requirements for the safety of MEDICAL ELECTRICAL EQUIPMENT and to serve as the basis for the safety requirements of Particular Standards.

1.3 **Particular Standards*

A Particular Standard takes priority over this General Standard.

*See rationale for 1.3

1.4 *Environmental conditions*

See Section Two.

1.5 *Collateral Standards*

In the IEC 601 series, Collateral Standards specify general requirements for safety applicable to:

– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. electromagnetic compatibility).

If a Collateral Standard applies to a Particular Standard, then the Particular Standard takes priority over the Collateral Standard.

2 Terminology and definitions+

For the purpose of this Standard, the following shall apply:

– Where the terms ″voltage″ and ″current″ are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

– The auxiliary verb:

• “shall” means that compliance with a requirement or a test is mandatory for compliance with this Standard;

• “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this Standard;

• “may” is used to describe a permissible way to achieve compliance with a requirement or test.

+The defined terms are alphabetically listed in the Index.

2.1 *EQUIPMENT parts, auxiliaries and ACCESSORIES*

2.1.1 ACCESS COVER: Part of an ENCLOSURE or guard providing the possibility of access to EQUIPMENT parts for the purpose of adjustment, inspection, replacement or repair.

2.1.2 ACCESSIBLE METAL PART: Metal part of EQUIPMENT which can be touched without the use of a TOOL. See also Sub-clause 2.1.22.

2.1.3 ACCESSORY: Optional component necessary and/or suitable to be used with EQUIPMENT in order to enable, facilitate or improve the intended use of EQUIPMENT or to integrate additional functions.

2.1.4 ACCOMPANYING DOCUMENTS: Documents accompanying EQUIPMENT or an ACCESSORY and containing all important information for the USER, OPERATOR, installer or assembler of EQUIPMENT, particularly regarding safety.

2.1.5 *APPLIED PART: A part of the EQUIPMENT which in NORMAL USE:

– necessarily comes into physical contact with the PATIENT for the EQUIPMENT to perform its function; or

– can be brought into contact with the PATIENT; or

– needs to be touched by the PATIENT.

*See rationale for 2.1.5

2.1.6 ENCLOSURE: Exterior surface of EQUIPMENT including:

– all ACCESSIBLE METAL PARTS, knobs, grips and the like;

– accessible shafts;

– for the purpose of tests, 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.

2.1.7 F-TYPE ISOLATED (FLOATING) APPLIED PART (hereinafter referred to as F-TYPE APPLIED PART): APPLIED PART isolated from other parts of the EQUIPMENT to such a degree that no current higher than the PATIENT LEAKAGE CURRENT allowable in SINGLE FAULT CONDITION flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the APPLIED PART and earth.

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

2.1.8 Not used.

2.1.9 INTERNAL ELECTRICAL POWER SOURCE: Power source intended to provide the electrical power necessary to operate EQUIPMENT and which is incorporated in that EQUIPMENT.

2.1.10 LIVE: 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.

2.1.11 Not used.

2.1.12 MAINS PART: Entirety of all parts of EQUIPMENT intended to have a CONDUCTIVE CONNECTION with the SUPPLY MAINS. For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 1).

2.1.13 Not used.

2.1.14 Not used.

2.1.15 *PATIENT CIRCUIT: Any electrical circuit which contains one or more PATIENT CONNECTIONS.

PATIENT CIRCUITS include all conductive parts which are not insulated from the PATIENT CONNECTIONS to the extent necessary to comply with the dielectric strength requirements (see clause 20) or which are not separated from the PATIENT CONNECTIONS to the extent necessary to comply with the CREEPAGE DISTANCE and AIR CLEARANCE requirements (see 57.10).

*See rationale for 2.1.15

2.1.16 Not used.

2.1.17 PROTECTIVE COVER: Part of an ENCLOSURE or guard provided to prevent accidental access to parts which might be hazardous if contacted.

2.1.18 SIGNAL INPUT PART: Part of EQUIPMENT, not being an APPLIED PART, intended to receive input signal voltages or currents from other EQUIPMENT, for example, for display, recording or data processing (see Figure 1).

2.1.19 SIGNAL OUTPUT PART: Part of EQUIPMENT, not being an APPLIED PART, intended to deliver output signal voltages or currents to other EQUIPMENT, for example, for display, recording or data processing (see Figure 1).

2.1.20 Not used.

2.1.21 SUPPLY EQUIPMENT: EQUIPMENT which supplies electrical power to one or more items of EQUIPMENT.

2.1.22 ACCESSIBLE PART: Part of EQUIPMENT which can be touched without the use of a TOOL.

2.1.23 *PATIENT CONNECTION: Every individual part of the APPLIED PART through which current can flow between the PATIENT and the EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

*See rationale for 2.1.23

2.1.24 *TYPE B APPLIED PART: APPLIED PART complying with the specified requirements of this Standard to provide protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and marked with symbol 1, table DII, of Appendix D.

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

*See rationale for 2.1.24

2.1.25 *TYPE BF APPLIED PART: 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 and marked with symbol 2, table DII, of Appendix D.

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

*See rationale for 2.1.25

2.1.26 *TYPE CF APPLIED PART: 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 and marked with symbol 3, table DII, of Appendix D.

*See rationale for 2.1.26

2.1.27 *DEFIBRILLATION-PROOF APPLIED PART: APPLIED PART having protection against the effects of a discharge of a cardiac defibrillator to the PATIENT.

*See rationale for 2.1.27

2.2 *EQUIPMENT types (classification)*

2.2.1 Not used.

2.2.2 CATEGORY AP EQUIPMENT: EQUIPMENT or 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.

2.2.3 CATEGORY APG EQUIPMENT: EQUIPMENT or 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.

2.2.4 CLASS I EQUIPMENT: 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 the connection of the EQUIPMENT to the PROTECTIVE EARTH CONDUCTOR in the fixed wiring of the installation in such a way that ACCESSIBLE METAL PARTS cannot become LIVE in the event of a failure of the BASIC INSULATION (see Figure 2).

2.2.5 CLASS II EQUIPMENT: 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 (see Figure 3).

2.2.6 Not used.

2.2.7 DIRECT CARDIAC APPLICATION: Use of APPLIED PART which may come in direct CONDUCTIVE CONNECTION to the PATIENT'S heart.

2.2.8 Not used.

2.2.9 Not used.

2.2.10 Not used.

2.2.11 EQUIPMENT (see Sub-clause 2.2.15)

2.2.12 FIXED EQUIPMENT: EQUIPMENT which is fastened or otherwise secured at a specific location in a building or a vehicle and can only be detached by means of a TOOL.

2.2.13 HAND-HELD EQUIPMENT: EQUIPMENT intended to be supported by the hand during NORMAL USE.

2.2.14 Not used.

2.2.15 MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT): Electrical EQUIPMENT, provided with not more than one connection to a particular SUPPLY MAINS and intended to diagnose, treat, or monitor the PATIENT under medical supervision and which makes physical or electrical contact with the PATIENT and/or transfers energy to or from the PATIENT and/or detects such energy transfer to or from the PATIENT.

The EQUIPMENT includes those ACCESSORIES as defined by the manufacturer which are necessary to enable the NORMAL USE of the EQUIPMENT.

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2.2.16 MOBILE EQUIPMENT: TRANSPORTABLE EQUIPMENT intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

2.2.17 PERMANENTLY INSTALLED EQUIPMENT: EQUIPMENT that is electrically connected to the SUPPLY MAINS by means of a permanent connection which can only be detached by the use of a TOOL.

2.2.18 PORTABLE EQUIPMENT: TRANSPORTABLE EQUIPMENT intended to be moved from one location to another while used or between periods of use while being carried by one or more persons.

2.2.19 Not used.

2.2.20 Not used.

2.2.21 STATIONARY EQUIPMENT: Either FIXED EQUIPMENT or EQUIPMENT which is not intended to be moved from one place to another.

2.2.22 Not used.

2.2.23 TRANSPORTABLE EQUIPMENT: EQUIPMENT which is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range.

Examples: MOBILE EQUIPMENT and PORTABLE EQUIPMENT.

2.2.24 Not used.

2.2.25 Not used.

2.2.26 Not used.

2.2.27 Not used.

2.2.28 Not used.

2.2.29 INTERNALLY POWERED EQUIPMENT: EQUIPMENT able to operate from an INTERNAL ELECTRICAL POWER SOURCE.

2.3 *Insulation*

2.3.1 AIR CLEARANCE: Shortest path in air between two conductive parts.

2.3.2 *BASIC INSULATION: Insulation applied to LIVE parts to provide basic protection against electric shock.

*See rationale for 2.3.2

2.3.3 CREEPAGE DISTANCE: Shortest path along the surface of insulating material between two conductive parts.

2.3.4 *DOUBLE INSULATION: Insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION.

*See rationale for 2.3.4

2.3.5 Not used.

2.3.6 Not used.

2.3.7 *REINFORCED INSULATION: Single insulation system applied to LIVE parts which provides a degree of protection against electric shock equivalent to DOUBLE INSULATION under the conditions specified in this Standard.

*See rationale for 2.3.7

2.3.8 SUPPLEMENTARY INSULATION: 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.

2.4 *Voltages*

2.4.1 HIGH VOLTAGE: Any voltage over 1 000 V a.c. or over 1 500 V d.c. or 1 500 V peak value.

2.4.2 MAINS VOLTAGE: 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.

2.4.3 *SAFETY EXTRA-LOW VOLTAGE (SELV): Voltage which does not exceed a NOMINAL value of 25 V a.c. or 60 V d.c. at RATED supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the SUPPLY MAINS by a SAFETY EXTRA-LOW VOLTAGE TRANSFORMER or by a device with an equivalent separation.

*See rationale for 2.4.3

2.5 *Currents*

2.5.1 EARTH LEAKAGE CURRENT: Current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR.

2.5.2 ENCLOSURE LEAKAGE CURRENT: Current flowing from the ENCLOSURE or from parts thereof, excluding APPLIED PARTS, accessible to the OPERATOR or PATIENT in NORMAL USE, through an external CONDUCTIVE CONNECTION other than the PROTECTIVE EARTH CONDUCTOR to earth or to another part of the ENCLOSURE.

2.5.3 LEAKAGE CURRENT: Current that is not functional. The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, ENCLOSURE LEAKAGE CURRENT and PATIENT LEAKAGE CURRENT.

2.5.4 *PATIENT AUXILIARY CURRENT: Current flowing in the PATIENT in NORMAL USE between parts of the APPLIED PART and not intended to produce a physiological effect, for example, bias current of an amplifier, current used in impedance plethysmography.

*See rationale for 2.5.4

2.5.5 Not used.

2.5.6 PATIENT LEAKAGE CURRENT: Current flowing from the APPLIED PART via the PATIENT to earth or flowing from the PATIENT via an F-TYPE APPLIED PART to earth originating from the unintended appearance of a voltage from an external source on the PATIENT.

2.6 *Earth terminals and conductors*

2.6.1 Not used.

2.6.2 Not used.

2.6.3 FUNCTIONAL EARTH CONDUCTOR: Conductor to be connected to a FUNCTIONAL EARTH TERMINAL (see Figure 1).

2.6.4 *FUNCTIONAL EARTH TERMINAL: Terminal directly connected to a point of a measuring supply or control circuit or to a screening part which is intended to be earthed for functional purposes (see Figure 1).

*See rationale for 2.6.4

2.6.5 Not used.

2.6.6 POTENTIAL EQUALIZATION CONDUCTOR: Conductor providing a connection between EQUIPMENT and the potential equalization busbar of the electrical installation.

2.6.7 PROTECTIVE EARTH CONDUCTOR: Conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system (see Figure 1).

2.6.8 PROTECTIVE EARTH TERMINAL: 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 (see Figure 1).

2.6.9 PROTECTIVELY EARTHED: Connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this Standard.

2.7 *Electrical connection (devices)*

2.7.1 APPLIANCE COUPLER: Means enabling the connection of a flexible cord to EQUIPMENT without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET (see Figure 5).

2.7.2 APPLIANCE INLET: Part of an APPLIANCE COUPLER incorporated in or fixed to EQUIPMENT (see Figures 1 and 5).

2.7.3 Not used.

2.7.4 AUXILIARY MAINS SOCKET-OUTLET: Socket-outlet with MAINS VOLTAGE on EQUIPMENT, accessible without the use of a TOOL and intended for provision of mains supply to other EQUIPMENT or to other separate parts of the EQUIPMENT.

2.7.5 CONDUCTIVE CONNECTION: Connection through which a current can flow exceeding the allowable LEAKAGE CURRENT.

2.7.6 *DETACHABLE POWER SUPPLY CORD: Flexible cord intended to be connected to EQUIPMENT by means of a suitable APPLIANCE COUPLER (see Figures 1, 2 and 5 and Sub-clause 57.3).

*See rationale for 2.7.6

2.7.7 EXTERNAL TERMINAL DEVICE: TERMINAL DEVICE by which electrical connection to other EQUIPMENT is made.

2.7.8 FIXED MAINS SOCKET-OUTLET: Mains socket-outlet installed in a fixed wiring system in a building or a vehicle (see Figure 5).

2.7.9 INTERCONNECTION TERMINAL DEVICE: TERMINAL DEVICE by which internal connections within EQUIPMENT or between EQUIPMENT parts are made.

2.7.10 MAINS CONNECTOR: Part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord which is intended to be connected to the SUPPLY MAINS. A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of EQUIPMENT (see Figures 1 and 5 and Sub-clause 57.2).

2.7.11 MAINS PLUG: Part integral with or intended to be attached to a POWER SUPPLY CORD of EQUIPMENT, to be inserted into a FIXED MAINS SOCKET OUTLET (see Figure 5).

2.7.12 MAINS TERMINAL DEVICE: TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made (see Figure 1).

2.7.13 Not used.

2.7.14 Not used.

2.7.15 Not used.

2.7.16 TERMINAL DEVICE: Part of EQUIPMENT by which electrical connection is made; it may contain several individual contacts.

2.7.17 POWER SUPPLY CORD: Flexible cord, fixed to or assembled with EQUIPMENT for mains supply purposes.

2.8 *Transformers*

2.8.1 Not used.

2.8.2 Not used.

2.8.3 SAFETY EXTRA-LOW VOLTAGE TRANSFORMER: Transformer with an output-winding which is electrically separated from earth and the body of the transformer by at least BASIC INSULATION and which is electrically separated from the input-winding by an insulation at least equivalent to DOUBLE INSULATION or REINFORCED INSULATION and which is designed to supply SAFETY EXTRA-LOW VOLTAGE circuits.

2.8.4 Not used.

2.8.5 Not used.

2.8.6 Not used.

2.9 *Controls and limiting devices*

2.9.1 ADJUSTABLE SETTING (of a control or limiting device): Setting which can be altered by the OPERATOR without the use of a TOOL.

2.9.2 Not used.

2.9.3 Not used.

2.9.4 FIXED SETTING (of a control or limiting device): Setting not intended to be altered by the OPERATOR and which can only be altered by means of a TOOL.

2.9.5 Not used.

2.9.6 Not used.

2.9.7 OVER-CURRENT RELEASE: Protective device which causes a circuit to open with or without delay, when the current in the device exceeds a predetermined value.

2.9.8 Not used.

2.9.9 Not used.

2.9.10 SELF-RESETTING THERMAL CUT-OUT: THERMAL CUT-OUT which automatically restores the current after the relevant part of EQUIPMENT has cooled.

2.9.11 Not used.

2.9.12 THERMAL CUT-OUT: Device which, during abnormal operation, limits the temperature of EQUIPMENT or of parts of it, by automatically opening the circuit or by reducing the current, and which is so constructed that its setting cannot be altered by the OPERATOR.

2.9.13 THERMOSTAT: A temperature sensing control, which is intended to keep a temperature between two particular values under normal operating conditions and which may have provision for setting by the OPERATOR.

2.10 *Operation of* EQUIPMENT

2.10.1 COLD CONDITION: The condition obtained if EQUIPMENT is de-energized for a sufficiently long time to attain the ambient temperature.

2.10.2 CONTINUOUS OPERATION: Operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.

2.10.3 CONTINUOUS OPERATION WITH INTERMITTENT LOADING: Operation in which EQUIPMENT is connected continuously to the SUPPLY MAINS. The stated permissible loading time is so short that the long term on-load operating temperature is not attained. The ensuing interval in loading is, however, not sufficiently long for cooling down to the long term no-load operating temperature.

2.10.4 CONTINUOUS OPERATION WITH SHORT-TIME LOADING: Operation in which EQUIPMENT is connected continuously to the SUPPLY MAINS. The stated permissible loading time is so short that the long term on-load operating temperature is not attained. The ensuing interval is, however, sufficiently long for cooling down to the long term no-load operating temperature.

2.10.5 DUTY CYCLE: Ratio of the operating time to the sum of the operating time and the ensuing interval. In the case of operating times and intervals of varying duration, it is calculated as a mean value over a sufficiently long time.

2.10.6 INTERMITTENT OPERATION: Operation in a series of specified identical cycles, each cycle being composed of a period of operation under normal load, without the specified limits of temperature being exceeded, followed by a rest period with the EQUIPMENT running idle or switched off.

2.10.7 NORMAL CONDITION: Condition in which all means provided for protection against SAFETY HAZARDS are intact.

2.10.8 NORMAL USE: Operation, including routine inspection and adjustments by the OPERATOR, and stand-by, according to the instructions for use.

2.10.9 PROPERLY INSTALLED: Condition in which at least the relevant instructions concerning installation given by the manufacturer in the ACCOMPANYING DOCUMENTS are observed.

2.10.10 SHORT-TIME OPERATION: Operation under normal load for a specified period, starting from COLD CONDITION without the specified limits of temperature being exceeded, the intervals between each period of operation being sufficient to allow the EQUIPMENT to cool down to COLD CONDITION.

2.10.11 SINGLE FAULT CONDITION: Condition in which a single means for protection against a SAFETY HAZARD in EQUIPMENT is defective or a single external abnormal condition is present (see Sub-clause 3.6).

2.10.12DV DR *Addition:*

X-RAY INSTALLATIONS (LONG-TIME RATING): A rating based on an operating interval of 5 minutes or longer.

*See rationale for 2.10.12DV

2.10.13DV DR *Addition:*

X-RAY INSTALLATIONS (MOMENTARY RATING): A rating based on an operating interval that does not exceed 5 seconds.

*See rationale for 2.10.13DV

2.11 *Mechanical safety*

2.11.1 HYDRAULIC TEST PRESSURE: PRESSURE applied to test a vessel or part of it for compliance with Clause 45.

2.11.2 *MAXIMUM PERMISSIBLE WORKING PRESSURE: PRESSURE specified by the manufacturer or by the inspection authority or competent person(s) in the report of the most recent examination.

*See rationale for 2.11.2

2.11.3 MINIMUM BREAKING LOAD: Maximum load where Hooke's Law is applicable.

2.11.4 PRESSURE (overpressure): Pressure above atmospheric (gauge pressure).

2.11.5 SAFE WORKING LOAD: Maximum load on an EQUIPMENT or EQUIPMENT part that can be permitted according to a declaration of the supplier of such an EQUIPMENT or EQUIPMENT part if his instructions for installation and use are followed.

2.11.6 SAFETY DEVICE: Means which protect the PATIENT and/or OPERATOR from a hazardous force due to excessive travel or from the fall of a suspended mass in the event of failure of a means of suspension.

2.11.7 STATIC LOAD: Maximum loading of a part excluding any loading caused by acceleration or deceleration of masses. Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility shall be considered.

2.11.8 SAFETY FACTOR: The ratio between the MINIMUM BREAKING LOAD and SAFE WORKING LOAD.

2.11.9 TOTAL LOAD: Sum of the STATIC LOAD and the forces caused by acceleration and deceleration occurring in NORMAL CONDITION.

2.12 *Miscellaneous*

2.12.1 Not used.

2.12.2 *MODEL OR TYPE REFERENCE (type number): Combination of figures, letters or both used to identify a particular model of EQUIPMENT.

*See rationale for 2.12.2

2.12.3 NOMINAL (value): Value quoted for reference purposes which is subject to agreed tolerances, for example, NOMINAL MAINS VOLTAGE, NOMINAL diameter of a screw.

2.12.4 PATIENT: Living being (person or animal) undergoing medical or dental investigation or treatment.

2.12.5 Not used.

2.12.6 Not used.

2.12.7 Not used.

2.12.8 RATED (value): Value assigned by the manufacturer to a quantity characteristic of the EQUIPMENT.

2.12.9 SERIAL NUMBER: Number and/or other designation used to identify an individual unit of a certain model of EQUIPMENT.

2.12.10 SUPPLY MAINS: Permanently installed power source which may also be used to supply electrical apparatus that is outside the scope of this Standard.

This also includes permanently installed battery systems in ambulances and the like.

2.12.11 Not used.

2.12.12 TOOL: Extra-corporeal object which may be used to secure or release fasteners or to make adjustments.

2.12.13 USER: Authority responsible for the use and maintenance of EQUIPMENT.

2.12.14 EMERGENCY TROLLEY: Wheeled trolley intended to support and convey life-supporting and resuscitation EQUIPMENT for cardio-respiratory emergencies.

2.12.15 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR: Mixture of a flammable anaesthetic vapour with air in such a concentration that ignition may occur under specified conditions. A mixture of the vapour of a flammable disinfection or cleaning agent with air may be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

2.12.16 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE: Mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition may occur under specified conditions.

2.12.17 OPERATOR: Person handling EQUIPMENT.

2.12.18 SAFETY HAZARD: Potentially detrimental effect on the PATIENT, other persons, animals, or the surroundings, arising directly from EQUIPMENT.

2.12.19DV D2 *Addition:*

PATIENT CARE EQUIPMENT: EQUIPMENT **intended for use in or likely to be used in the** PATIENT VICINITY.

2.12.20DV D2 *Addition:*

PATIENT VICINITY: **In areas in which** PATIENTS **are normally cared for, the** PATIENT VICINITY **is the space with surfaces likely to be contacted by the** PATIENT **or an attendant who can touch the** PATIENT. **This encloses a space within the room 1,83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2,29 m (7-1/2 feet) above the floor.**

*See rationale for 2.12.20DV

2.12.21DV D2 *Addition:*

INTERNATIONALLY HARMONIZED COMPONENT STANDARD: **A standard satisfying U.S. national and international safety concerns and may include national differences (exceptions) which modify the requirements of the relevant internationally recognized safety standard, (such as an IEC/ISO standard). When necessary, due to national safety concerns, the national differences may include the unique U.S. national safety, regulatory, and legal requirements taken from the relevant nationally recognized safety standard (such as an ANSI/UL standard).**

3 General requirements

3.1 EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFETY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION.

3.2 Not used.

3.3 Not used.

3.4 EQUIPMENT or parts thereof, using materials or having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained. See also Clause 54.

3.5 Not used.

3.6 *The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this Standard:

a) interruption of a PROTECTIVE EARTH CONDUCTOR (see Section Three);

b) interruption of one supply conductor (see Section Three);

*c) appearance of an external voltage on an F-TYPE APPLIED PART (see Section Three);

d) appearance of an external voltage on SIGNAL INPUT or on a SIGNAL OUTPUT PART (see Section Three);

e) leakage of the ENCLOSURE of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (see Section Six);

f) leakage of liquid (see subclause 44.4)

g) failure of an electrical component which might cause a SAFETY HAZARD (see Section Nine);

h) failure of mechanical parts which might cause a SAFETY HAZARD (see Section Four);

j) failure of temperature limiting devices (see Section Seven).

Where a SINGLE FAULT CONDITION results unavoidably in another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

*See rationale for 3.6

3.7 The following phenomena are considered by this Standard as unlikely to occur:

a) total electrical breakdown of a DOUBLE INSULATION;

b) electrical breakdown of a REINFORCED INSULATION;

c) interruption of a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR.

3.8 Earthing of a PATIENT is considered as a NORMAL CONDITION.

3.9 Unless otherwise specified in the instructions for use, EQUIPMENT shall not be required to withstand the effects of operation under separate dust covers or sterile covers (see Sub-clause 52.5.5).

Compliance with the requirements of this clause is considered to exist when the criteria of the relevant inspections and tests in this Standard are achieved.

3.10DV D2 *Addition of 3.10DV.1 – 3.10DV.3:*

*See rationale for 3.10DV

3.10DV.1 Components

3.10DV.1.1 In addition to compliance with this standard, the following components shall meet nationally recognized standards (such as ANSI/UL standards) or INTERNATIONALLY HARMONIZED COMPONENT STANDARDS:

a) Printed wiring boards

b) Lithium batteries

c) Optical isolators

d) Wiring and tubing

e) CRTs > 5 inches

Items a), c), and d) are exempt from this requirement if they are connected totally in an SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a SAFETY HAZARD.

3.10DV.2 Primary circuit components

3.10DV.2.1 In addition to compliance with this basic standard, components in the primary circuit up to the isolation transformer shall meet nationally recognized standards (such as ANSI/UL standards) or INTERNATIONALLY HARMONIZED COMPONENT STANDARDS.

3.10DV.3 Annex DVA tabulates UL component Standards covering components as specified in subclauses 3.10DV.1 and 3.10DV.2.

4 *General requirements for tests

*See rationale for 4

4.1 ***Tests***

Tests described in this Standard are type tests. Only insulation, components and constructional features the failure of which could produce in NORMAL CONDITION or SINGLE FAULT CONDITION a SAFETY HAZARD shall be tested.

*See rationale for 4.1

4.2 *Repetition of tests*

Unless otherwise specified in this Standard, tests shall not be repeated. This applies particularly to the dielectric strength tests, which are made only at the manufacturer's site or in test laboratories.

4.3 ***Number of samples***

Type tests are made on one representative sample of the item being tested.

Exceptionally, an additional sample may be required.

*See rationale for 4.3

4.4 *Components*

All components, the failure of which could cause a SAFETY HAZARD, shall be capable of withstanding the stresses encountered in the EQUIPMENT in NORMAL USE and shall satisfy the appropriate section of this Standard.

Compliance of the rating of such components with conditions of use is checked by inspection.

A component or EQUIPMENT part which has specified ratings exceeding that of its appropriate use in EQUIPMENT does not have to be tested for such a wider range (see also Sub-clause 56.1).

4.5 *Ambient temperature, humidity, atmospheric PRESSURE*

a) After the EQUIPMENT to be tested has been set up for NORMAL USE (according to 4.8) tests are carried out within the range of environmental conditions specified in 10.2.1, unless otherwise specified by the manufacturer.

For reference tests (if the results are dependent on the ambient condition) one set of atmospheric conditions specified in table I is recognized.

Table I
Specified atmospheric conditions

Temperature (°C)	*23 ± 2*
Relative humidity (%)	*60 ± 15*
Atmospheric PRESSURE	*860 hPa to 1 060 hPa* *(645 mm Hg to 795 mm Hg)*

b) EQUIPMENT shall be shielded from other influences (for example, draughts), which might affect the validity of the tests.

c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.

4.6 *Other conditions*

a) Unless otherwise specified in this Standard, EQUIPMENT is to be tested under the least favourable specified working conditions, but in accordance with the instructions for use.

b) EQUIPMENT having operating values which can be adjusted or controlled by the OPERATOR shall be adjusted during the tests to values least favourable for the relevant test, but in accordance with the instructions for use.

c) If the test results are influenced by the inlet PRESSURE and flow or chemical composition of the cooling liquid, the test shall be carried out within the limits for these conditions as prescribed in the technical description.

d) During any test under SINGLE FAULT CONDITION, one fault only at a time shall be applied (see Sub-clause 3.6).

e) Where cooling water is required, potable water shall be used.

4.7 *Supply and test voltages, type of current, nature of supply, frequency*

In the context of this Standard the MAINS VOLTAGE may be subject to fluctuations; these fluctuations are ignored for the purposes of the term "RATED".

a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations shall be taken into account.

The waveform of a supply voltage during tests shall be according to Sub-clause 10.2.2a).

Any test voltage below 1 000 V a.c. or 1 500 V d.c. or 1 500 V peak value shall not differ by more than 2% from the prescribed value. Any test voltage at and above 1 000 V a.c. or 1 500 V d.c. or 1 500 V peak value shall not differ by more than 3% from the prescribed value.

b) EQUIPMENT for a.c. only shall be tested with a.c. at RATED frequency (if marked) ±1 Hz between 0 and 100 Hz and ±1% above 100 Hz. EQUIPMENT marked with a RATED frequency range shall be tested at the least favourable frequency within that range.

c) EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., shall be tested in conditions (described in Sub-clause 4.6) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current.

d) EQUIPMENT for d.c. only shall be tested with d.c.; the possible influence of polarity on the operation of the EQUIPMENT shall be taken into consideration, according to the instructions for use.

e) Unless otherwise specified by this Standard or by a Particular Standard, EQUIPMENT shall be tested at the least favourable RATED voltage within the relevant range. It may be necessary to perform some of the tests more than once in order to establish the least favourable voltage.

f) EQUIPMENT for which alternative ACCESSORIES or components specified by the manufacturer are available shall be tested with those ACCESSORIES or components which give the least favourable conditions.

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g) EQUIPMENT intended for use with a specified power supply, for example regarding voltages, capacitances, insulation resistances respectively to earth, etc., shall be tested with such a specified power supply.

h) Measurement of voltages and currents shall be carried out with instruments which do not appreciably affect the magnitude of the values to be measured.

4.8 ***Preconditioning**

Before testing is started, EQUIPMENT shall be kept in the testing location unoperated for at least 24 h. Before the actual series of tests, it is operated as far as is necessary for the tests at RATED voltage, in accordance with the instructions for use.

*See rationale for 4.8

4.9 *Repairs and modifications*

In the event of the necessity for repairs or modifications after a failure or a likelihood of future failure during the sequence of tests, the testing laboratory and the supplier may agree either upon the presentation of a new sample on which all tests shall be carried out again or preferably, upon making all the necessary repairs or modifications after which only relevant tests shall be repeated.

4.10 ***Humidity preconditioning treatment**

Prior to the tests of 19.4 and 20.4, all EQUIPMENT not being IPX8, (see IEC 529, protected against the effects of continuous immersion in water) or EQUIPMENT parts shall be subjected to a humidity preconditioning treatment.

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

This test shall be applied only to those EQUIPMENT parts likely to create a SAFETY HAZARD when influenced by the climatic conditions that are simulated by the test.

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

Doors, drawers and ACCESS COVERS which can be opened or detached without the use of a TOOL shall be opened and detached.

The humidity preconditioning treatment shall be performed in a humidity cabinet containing air with a relative humidity of 93% ± 3%. The temperature of the air in the cabinet, at all places where EQUIPMENT can be located, shall be maintained within 2°C of any convenient value t in the range of +20°C to +32°C. Before being placed in the humidity cabinet, EQUIPMENT shall be brought to a temperature between t and t + 4°C, and kept at this temperature for at least 4 h before the humidity treatment.

EQUIPMENT and EQUIPMENT parts shall be kept in the humidity cabinet for:

– 2 days (48 h) for EQUIPMENT RATED IPX0 (non-protected);

– 7 days (168 h) for EQUIPMENT RATED IPX1 to IPX8.

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

*See rationale for 4.10

4.11 *Sequence*

It is recommended that all tests be performed in the sequence as given in Appendix C. The tests numbered C23 to C29 shall be performed in the specified sequence.

5 *Classification

*See rationale for 5

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in Clause 6. This includes:

5.1 *According to the type of protection against electric shock:

a) EQUIPMENT energized from an external electrical power source:

— CLASS I EQUIPMENT;

— CLASS II EQUIPMENT.

b) INTERNALLY POWERED EQUIPMENT.

*See rationale for 5.1

5.2 According to the degree of protection against electric shock:

— TYPE B APPLIED PART;

— TYPE BF APPLIED PART;

— TYPE CF APPLIED PART.

5.3 According to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1 *l)*).

5.4 According to the method(s) of sterilization or disinfection recommended by the manufacturer.

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

— EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE;

— CATEGORY AP EQUIPMENT;

— CATEGORY APG EQUIPMENT.

5.6 According to the mode of operation:

— CONTINUOUS OPERATION;

— SHORT-TIME OPERATION;

— INTERMITTENT OPERATION;

— CONTINUOUS OPERATION WITH SHORT-TIME LOADING;

— CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

5.7 Not used.

5.8 Not used.

6 Identification, marking and documents

For the purpose of this clause the following meanings shall apply to identification and marking:

– Permanently affixed:

Removable with a TOOL only or by appreciable force and capable of complying with the requirements of Sub-clause 6.1.

– Clearly legible:

• for warning statements, instructive statements or drawings: affixed in a prominent location and legible with normal vision from the OPERATOR'S position.

• for FIXED EQUIPMENT: discernible when the EQUIPMENT is mounted in its position of NORMAL USE.

• for TRANSPORTABLE EQUIPMENT and for STATIONARY EQUIPMENT which is not FIXED EQUIPMENT: discernible in NORMAL USE or after dislodging the EQUIPMENT from a wall against which it has been positioned or after turning the EQUIPMENT from its position of NORMAL USE and in the case of dismountable rack units, after their removal from the rack.

– Major part:

• for warning statements on outside or inside surfaces of the EQUIPMENT: on or near the control panel or on or near a relevant part.

• for MODEL OR TYPE REFERENCE and all markings referring to the SUPPLY MAINS (power input, voltage, current, frequency, classification, mode of operation, etc.): usually on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point.

6DV D2 ***Modification of 6 by adding 6DV.1 – 6DV.4:***

*See rationale for 6DV

6DV.1 The text of the marking prefaced with an upper case signal word "CAUTION", "WARNING", or "DANGER", shall consist of upper and lower case letters, in English, that comply with the following:

a) All words comprising the text of the marking, excluding the signal word, shall be in letters not less than 1,6 mm (1/16 inch) high, based upon upper case,

b) The signal word shall be in letters at least 2,8 mm (7/64 inch),

c) The letters shall be in contrast color to the background. Letters that are raised or indented and do not have a contrasting color to the background are not acceptable.

6DV.2 EQUIPMENT capable of emitting ionizing radiation shall bear a warning statement concerning the risk of injury to persons from X-radiation. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to PATIENT and OPERATOR unless safe exposure factors and operating instructions are observed."

6DV.3 When a manufacturer produces or assembles EQUIPMENT at more than one factory, the EQUIPMENT shall have a distinctive marking – which may be in code – by means of which it may be identified as the product of a particular factory.

6DV.4 Multiple-voltage EQUIPMENT intended for permanent connection to the branch circuit shall be marked to indicate the particular voltage for which it is connected when shipped from the factory. The marking may be in the form of a paper tag or any other nonpermanent material.

6.1 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

a) Mains operated EQUIPMENT

Mains operated EQUIPMENT, including separable components thereof which have a MAINS PART, shall be provided at least with "permanently affixed" and "clearly legible" markings on the "major part" of EQUIPMENT as described in Table II, Column 3.

b) INTERNALLY POWERED EQUIPMENT

INTERNALLY POWERED EQUIPMENT shall be provided at least with the following "permanently affixed" and "clearly legible" markings on the "major part" of EQUIPMENT as described in Table II, Column 4.

c) EQUIPMENT supplied from a specified power supply

EQUIPMENT intended to be supplied from a specified power supply (other than the SUPPLY MAINS and isolated from it), which is or is not part of the EQUIPMENT model or type shall be provided minimally with the following "permanently affixed" and "clearly legible" markings on the outside of the EQUIPMENT as described in Table II, Column 5.

If the specified power supply is not part of the EQUIPMENT model or type, the instructions for use of the EQUIPMENT shall additionally establish reference to the model or type of such a specified power supply. If safety aspects are involved, the model or type of such a specified power supply shall be permanently marked on the outside of the EQUIPMENT and included in the instructions for use.

Table II
Marking on the outside of EQUIPMENT

Requirements as specified in Sub-clauses	Subject	Mains operated EQUIPMENT (see Sub-clause 6.1*a)*)	INTERNALLY POWERED EQUIPMENT (see Sub-clauses 6.1*b)* and 14.5)	EQUIPMENT supplied from a specified power source (see Sub-clause 6.1*c)*)
6.1*e)*	Indication of origin	x	x	x
6.1*f)*	MODEL OR TYPE REFERENCE	x	x	x
6.1*g)*	Connection to the supply	x[2)]	–	–
6.1*h)*	Supply frequency (Hz)	x[2)]	–	–
6.1*j)*	Power input	x[2)]	–	–
6.1*k)*	Mains power output	x[1)]	–	–
6.1*l)*	Classification	x[1)]	x[1)]	x[1)]
6.1*m)*	Mode of operation	x[1)]	x[1)]	x[1)]
6.1*n)*	Fuses	x[1)]	x[1)]	x[1)]
6.1*p)*	Output	x[1)]	x[1)]	x[1)]
6.1*q)*	Physiological effects	x[1)]	x[1)]	x[1)]
6.1*r)*	CATEGORY AP/APG EQUIPMENT	x[1)]	x[1)]	x[1)]
6.1*s)*	HIGH VOLTAGE TERMINAL DEVICE	x[1)]	x[1)]	x[1)]
6.1*t)*	Cooling conditions	x[1)]	x[1)]	x[1)]
6.1*u)*	Mechanical stability	x[1)]	x[1)]	x[1)]
6.1*v)*	Protective packing	x[1)]	x[1)]	x[1)]
6.1*y)*	Earth terminals	x[1)]	x[1)]	x[1)]
6.1*z)*	Removable protective means	x[1)]	x[1)]	x[1)]

x Marking required.
[1)] If applicable.
[2)] Not for PERMANENTLY INSTALLED EQUIPMENT if marked on the inside. See also Sub-clause 6.2*a)*.

d) Minimum requirements for marking on EQUIPMENT and on interchangeable parts

If the size of the EQUIPMENT specified in Sub-clause 6.1 or the nature of its ENCLOSURE does not allow affixation of all specified markings, then at least the markings as indicated in Sub-clauses 6.1*e)*, 6.1*f)* and 6.1*g)* (not for PERMANENTLY INSTALLED EQUIPMENT), 6.1*l)* and 6.1*q)* (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS.

e) Indication of origin

The name and/or trade-mark of the manufacturer or supplier claiming that the EQUIPMENT complies with this Standard.

**f) MODEL OR TYPE REFERENCE*

g) Connection to the supply

– The RATED supply voltage(s) or voltage range(s) to which EQUIPMENT may be connected.

– Nature of supply, for example, number of phases (except for single-phase supply) and type of current.

h) Supply frequency

RATED frequency or RATED frequency range in hertz.

j) Power input (see Clause 7)

The RATED input shall be given in amperes or volt-amperes or in watts where the power factor exceeds 0,9.

In the case of 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 ±10% of the mean value of the given range.

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.

If the rating of 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 rating, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS.

The marked input of EQUIPMENT provided with means for the connection of supply conductors of other EQUIPMENT shall include the RATED (and marked) output of such means.

k) Mains power output

AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output.

l) Classification

– The symbol for CLASS II EQUIPMENT, if relevant (see Appendix D, Table DI, Symbol 10).

– A symbol, using the letters IP, followed by X and the relevant characteristic numeral (1 to 8) of IEC Publication 529, according to the degree of protection provided by the ENCLOSURE with respect to harmful ingress of water.

NOTE – EQUIPMENT of IPXO classification is not required to be marked as such.

– A symbol indicating the type of APPLIED PART according to the degree of protection against electric shock for TYPE B, TYPE BF and TYPE CF APPLIED PARTS (see Appendix D, table DII, symbols 1, 2 and 3).

For clear differentiation with symbol 2, symbol 1 shall not be applied in such a way as to give the impression of being inscribed within a square.

If the EQUIPMENT has more than one APPLIED PART with different degrees of protection, the relevant symbols shall be clearly marked on such APPLIED PARTS, or on or near relevant outlets (connection points).

DEFIBRILLATION-PROOF APPLIED PARTS shall be marked with the relevant symbols (see Appendix D, table DII, symbols 9, 10 and 11).

– If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, the symbol 14 in Appendix D, table DI, shall be marked near the relevant outlet.

No Text on This Page

m) Mode of operation

If no marking is provided, EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION.

**n) Fuses*

The type and rating of fuses accessible from the outside of EQUIPMENT shall be marked adjacent to the fuse-holder.

p) Output

– RATED output voltage and current or power (where applicable).

– Output frequency (where applicable).

q) Physiological effects (symbols and warning statements)

EQUIPMENT producing physiological effects which may cause danger to the PATIENT and/or OPERATOR shall bear a suitable symbol concerning the relevant hazard. The symbol shall appear in a prominent location so that it will be clearly visible after the EQUIPMENT has been installed.

If applicable, symbols for particular hazards, as adopted by ISO or IEC Publication 417, shall be used. For non-ionizing radiation (for example, high-power microwaves), Symbol 8 of Table DII of Appendix D shall be used.

For other hazards, where no specific symbol is available, Symbol 14 of Table DI of Appendix D shall be used.

r) CATEGORY AP/APG EQUIPMENT

For requirements on marking, see Clause 38.

s) HIGH VOLTAGE TERMINAL DEVICES

HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6).

t) Cooling conditions

Requirements for cooling provisions for EQUIPMENT (for example, supply of water or air) shall be marked.

u) Mechanical stability

For requirements on EQUIPMENT with a limited stability, see Clause 24.

v) Protective packing

If special measures have to be taken during transport or storage, the packing shall be marked accordingly (see Sub-clauses 6.8.3*d)* and 10.1 and ISO Publication R780).

Where premature unpacking of EQUIPMENT or EQUIPMENT parts may result in a SAFETY HAZARD, the packing shall be appropriately marked.

The packaging of EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile.

w) Not used.

x) Not used.

y) Earth terminals

– A terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR shall be marked with Symbol 9 of Table DI of Appendix D (see Sub-clause 18*e)*).

– A FUNCTIONAL EARTH TERMINAL shall be marked with Symbol 7 of Table DI of Appendix D.

**z) Removable protective means*

If EQUIPMENT has alternative applications which require the removal of a protective means to utilize 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 (see also Sub-clause 6.8).

Compliance with the requirements of Sub-clause 6.1 is checked as follows:

– Inspect the presence of required markings on the outside of EQUIPMENT.

– Test the durability of markings.

For determination of durability, 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 at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.

Markings shall be clearly legible after all the tests of this Standard have been performed (see Appendix C, Item C36). Adhesive labels shall not have worked loose or become curled at the edges.

When evaluating durability, the effect of NORMAL USE on markings is also to be taken into account.

*See rationale for 6.1

6.2 *Marking on the inside of* EQUIPMENT *or* EQUIPMENT *parts*

a) Marking on the inside of EQUIPMENT or EQUIPMENT parts shall be "clearly legible" as defined in Sub-clause 6.1. Concerning permanent affixation, it shall not be subjected to the rubbing test of Sub-clause 6.1.

The NOMINAL supply voltage or voltage range to which PERMANENTLY INSTALLED EQUIPMENT can be connected may be marked on the inside or the outside of EQUIPMENT, preferably adjacent to the supply connection terminals.

b) The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be clearly and indelibly marked near the heater or in the heater itself.

For heating elements or lampholders designed for use with heating lamps not intended to be changed by the OPERATOR and which can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

c) The presence of HIGH VOLTAGE parts shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6).

d) The type of battery and the mode of insertion (if applicable) shall be marked (see Sub-clause 56.7*b)*).

For batteries not intended to be changed by the OPERATOR and which can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

*e) Fuses accessible only with the aid of a TOOL shall be identified either by type and rating next to the fuse, or by at least a reference, for example, the diagram number which can be associated with the technical description in which the type and rating shall be stated.

f) PROTECTIVE EARTH TERMINALS shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC Publication 320.

g) FUNCTIONAL EARTH TERMINALS shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 7).

h) Terminals which are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED EQUIPMENT shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 8).

j) Markings required in Sub-clauses 6.2*f)*, *h)*, *k)* and *l)* on or near electrical connection points shall not be affixed to parts which have to be removed to make the connection. They shall remain visible after the connection has been made.

Markings on or near terminals shall comply with IEC Publication 445.

k) The correct method of connection of the supply conductors shall be marked clearly with terminal marking which should be affixed adjacent to the terminals, unless no SAFETY HAZARD can develop if connections are interchanged.

If EQUIPMENT is so small that the terminal marking cannot be affixed, it may be included in the ACCOMPANYING DOCUMENTS. If marking for connection to a three-phase supply is necessary, it shall be according to IEC Publication 445.

l) If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for permanently connected EQUIPMENT (including such conductors themselves), attains a temperature of more than 75°C during the normal temperature test, EQUIPMENT shall be marked with the following or any equivalent statement:

"For supply connections, use wiring materials suitable for at least ... °C".

This statement shall be located at or near the point where the supply connections are to be made and shall be clearly discernible after the connections have been made.

m) Not used.

n) Capacitors and/or the connected circuit parts shall be marked as required in Sub-clause 15*c)*.

Compliance with the requirements of Sub-clause 6.2 is checked by application of the tests and criteria as described in Sub-clause 6.1, except the rubbing test.

*See rationale for 6.2

6.2DV D2 *Modification of item l) in 6.2:*

Replace 75°C by 60°C.

*See rationale for 6.2DV

6.3 *Marking of controls and instruments*

a) A mains switch shall be clearly identified. "ON" and "OFF" positions shall be marked according to the relevant symbols of Appendix D (Symbols 15 and 16 of Table DI), or indicated by an adjacent indicator light or other unambiguous means.

b) Different positions of control devices and different positions of switches on EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by means of Symbols 17 and 18 of Table DI.

c) If in NORMAL USE the change of setting of a control could cause a SAFETY HAZARD to the PATIENT, such controls shall be provided with either:

– an associated indicating device, e.g. instruments or scale, or

– an indication of the direction in which the magnitude of the function changes. See also Sub-clause 56.10*c)*.

d) Not used.

e) Not used.

f) The functions of OPERATOR controls and indicators shall be identified.

g) Numeric indications of parameters shall be in SI units according to ISO 1000 with the following additions:

Units outside the International System, which can be used on EQUIPMENT:

– Plane angle units:

  • revolution,

  • grade,

  • degree,

  • minute of angle,

  • second of angle;

– Time units:

  • minute,

  • hour,

  • day;

– Energy unit:

  • electronvolt;

– PRESSURE of blood and other body fluids:

  • millimetre of mercury.

Compliance with the requirements of Sub-clause 6.3 is checked by inspection and application of the durability test of 6.1.

6.4 **Symbols*

a) Symbols used for marking according to Sub-clauses 6.1 to 6.3 shall conform to Appendix D, where applicable. See also Sub-clause 6.1*q)*.

b) Symbols used for controls and performance shall conform to IEC Publication 878, where applicable.

Compliance is checked by inspection and application of the durability test of 6.1.

*See rationale for 6.4

6.5 *Colours of the insulation of conductors*

a) A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

b) Any insulation on conductors inside EQUIPMENT which connect ACCESSIBLE METAL PARTS or other PROTECTIVELY EARTHED parts with a protective function to the PROTECTIVE EARTH TERMINAL shall be identified by the colours green and yellow at least at the termination of the conductors.

c) Identification by green and yellow insulation shall only be used for:

– PROTECTIVE EARTH CONDUCTORS (see Sub-clause 18*b)*);

– Conductors as specified in Sub-clause 6.5*b)*;

– POTENTIAL EQUALIZATION CONDUCTORS (see Sub-clause 18 *e)*);

– FUNCTIONAL EARTH CONDUCTORS as specified in Sub-clause 18 *l)*.

d) 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 Publication 227 (Amendment No. 1) or in IEC Publication 245.

e) Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC Publication 227 (Amendment No. 1) or with IEC Publication 245.

f) Where a multi-conductor cord is used between EQUIPMENT parts and the maximum allowed resistance of the protective earth connection would be exceeded if only the green and yellow coloured conductor were used, other conductors of the same cord may be connected in parallel with the green and yellow conductor, provided that the ends of such additional conductors are marked green and yellow.

Compliance with the requirements of Sub-clause 6.5 is checked by inspection.

6.6 *Identification of medical gas cylinders and connections*

a) Identification of the content of gas cylinders used in medical practice as a part of electrical EQUIPMENT shall be in accordance with ISO Recommendation ISO/R 32. See also Sub-clause 56.3*a)*.

b) The point of connection of gas cylinders shall be so identified on EQUIPMENT that errors are avoided when a replacement is made.

Compliance with the requirements of Sub-clause 6.6 is checked by inspection of the identification of the content, and the point of connection of gas cylinders.

6.6DV DR *Modification of 6.6 by replacing item (a) with the following:*

a) Identification of the content of gas cylinders used in medical practice as part of electrical EQUIPMENT, if accomplished through color coding, shall be in accordance with the color coding requirements of the Standard for Health Care Facilities, ANSI/NFPA 99. See also sub-clause 56.3(a).

*See rationale for 6.6DV

6.7 ***Indicator lights and push-buttons***

a) Colours of indicator lights

On EQUIPMENT the colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action.

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.

Table III
Recommended colours of indicator lights and their meaning for EQUIPMENT

Colour	Meaning
Yellow	Caution or attention required
Green	Ready for action
Any other colour	Meaning other than that of red or yellow

b) Colours of unilluminated push-buttons

The colour red shall be used only for the push-button by which a function is interrupted in case of emergency.

c) Not used.

d) Not used.

Compliance with the requirements of Sub-clause 6.7 is checked by inspection (see also Sub-clause 56.8).

*See rationale for 6.7

6.8 *ACCOMPANYING DOCUMENTS*

6.8DV D2 ***Modification of 6.8 by adding the following:***

Cord-connected EQUIPMENT shall be provided with instructions to indicate the type of attachment plug that should be used for connection to the alternate voltage.

6.8.1 **General*

EQUIPMENT shall be accompanied by documents containing at least instructions for use, a technical description and an address to which the USER can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a component part of EQUIPMENT.

All applicable classifications specified in Clause 5 shall be included in both the instructions for use and the technical description, if separable.

All markings specified in Sub-clause 6.1 shall be included in full in the ACCOMPANYING DOCUMENTS if they have not been permanently affixed to EQUIPMENT by the manufacturer. See also Sub-clause 6.1*d).*

Warning statements and the explanation of warning symbols (marked on the EQUIPMENT) shall be provided in the ACCOMPANYING DOCUMENTS.

*See rationale for 6.8.1

6.8.2 *Instructions for use*

**a) General information*

– Instructions for use shall state the function and intended application of the EQUIPMENT.

– Instructions for use shall contain all information necessary to operate the EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation.

– Instructions for use shall provide the USER or OPERATOR with information regarding potential electromagnetic or other interference between the EQUIPMENT and other devices together with advice regarding avoidance of such interference.

– Instructions for use shall include indications on recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.

– Instructions for use shall instruct the USER or OPERATOR in sufficient detail concerning cleaning, preventive inspection and maintenance to be performed by him, including the frequency of such maintenance.

Such instructions shall provide information for the safe performance of routine maintenance.

Additionally, instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by other persons, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.

– The meaning of figures, symbols, warning statements and abbreviations on EQUIPMENT shall be explained in the instructions for use.

*b) *Responsibility of the manufacturer*

Not used (see Appendix A).

c) SIGNAL OUTPUT and SIGNAL INPUT PARTS

If a SIGNAL OUTPUT or SIGNAL INPUT PART is intended only for connection to specified EQUIPMENT complying with the requirements of this Standard, this shall be stated in the instructions for use (see Sub-clauses 19.2*b)* and 19.2*c)*).

d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

For EQUIPMENT parts which come into contact with the PATIENT during NORMAL USE, instructions for use shall contain details about cleaning or disinfection or sterilization methods that may be used (see also Sub-clause 44.7) or, where necessary, identify suitable sterilization agents, and list the temperature, PRESSURE, humidity and time limits which such EQUIPMENT parts can tolerate.

e) Mains operated EQUIPMENT with additional power source

Instructions for use of mains operated EQUIPMENT containing an additional power source not automatically maintained in a fully usable condition shall contain a warning statement referring to the necessity for periodical checking or replacement of such an additional power source. If CLASS I EQUIPMENT is specified for operation connected to a SUPPLY MAINS and alternatively using an INTERNAL ELECTRICAL POWER SOURCE, instructions for use shall contain a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.

f) Removal of primary batteries

Instructions for use of EQUIPMENT containing primary batteries shall contain a warning to remove these batteries if EQUIPMENT is not likely to be used for some time, unless there is no risk of a SAFETY HAZARD arising.

g) Rechargeable batteries

Instructions for use of EQUIPMENT containing rechargeable batteries shall contain instructions to ensure safe use and adequate maintenance.

h) EQUIPMENT with a specified power supply or battery charger

Instructions for use shall identify power supplies or battery chargers necessary to ensure compliance with the requirements of this Standard.

j) Environmental protection

Instructions for use shall:

– identify any risks associated with the disposal of waste products, residues, etc. and of the EQUIPMENT and ACCESSORIES at the end of their useful lives;

– provide advice on minimizing these risks.

*See rationale for 6.8.2

6.8.3 *Technical description*

**a) General*

The technical description shall provide all data, which is essential for safe operation. This shall include:

– data mentioned in subclause 6.1;

– all characteristics of the EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found.

In addition to details required to be included in instructions for use, the technical description shall state whether particular measures or particular conditions are to be observed for installing EQUIPMENT and bringing EQUIPMENT into use.

b) Replacement of fuses and other parts

– If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of EQUIPMENT, the required type and rating of fuses shall be indicated in at least the technical description.

– The technical description shall contain instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during NORMAL USE.

c) Circuit diagrams, component part lists, etc.

The technical description shall contain a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the USER'S appropriately qualified technical personnel to repair those parts of EQUIPMENT which are designated by the manufacturer as repairable.

d) Environmental conditions for transport and storage

The technical description shall contain a specification of the permissible environmental conditions for transport and storage which shall be repeated on the outside of the packaging of the EQUIPMENT (see Sub-clause 6.1 *v)*).

*See rationale for 6.8.3

6.8.4 Not used.

6.8.5 Not used.

Compliance with the requirements of Sub-clause 6.8 is checked by inspection of the ACCOMPANYING DOCUMENTS.

7 Power input

7.1 The steady state current or power input of EQUIPMENT at RATED voltage, steady state operating temperature, and at operational settings specified by the manufacturer shall not exceed the marked rating as required by Sub-clause 6.1*j)* by more than:

a) for EQUIPMENT with a power input mainly caused by electric motor drive(s):

+25% for a RATED input power up to and including 100 W or 100 VA;

+15% for a RATED input power over 100 W or 100 VA;

b) for other EQUIPMENT:

+15% for a RATED input power up to and including 100 W or 100 VA;

+10% for a RATED input power over 100 W or 100 VA.

Compliance with the requirements of Sub-clause 7.1 is checked by inspection and by the following tests:

– EQUIPMENT shall be operated as specified in the instructions for use until the input has reached a stable value.

Current or power input shall be measured and compared with markings or the contents of the ACCOMPANYING DOCUMENTS.

Measured values shall not exceed the limits required in this clause.

– For EQUIPMENT marked with one or more RATED voltage ranges the test is made at both upper and lower limits of the ranges, unless the marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is made at a voltage equal to the mean value of that range.

– The steady state current shall be measured with a true r.m.s. reading instrument, for example, a thermal instrument.

Power input, if expressed in voltamperes, shall either be measured with a voltampere meter or be determined as the product of the steady state current (measured as described above) and the supply voltage.

7.2 Not used.

SECTION TWO – ENVIRONMENTAL CONDITIONS

Note – This Section replaces the former Section Two: "Safety requirements," of the first edition.

8 *Basic safety categories

The content of Clause 8 of the first edition has now been transferred to Appendix A1.1.

9 Removable protective means

Not used. Replaced by Sub-clause 6.1*z)*.

10 Environmental conditions

The former title of this clause "Special environmental conditions" and the corresponding text are not used.

10.1 *Transport and storage*

EQUIPMENT shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer (see 6.8.3 *d)*).

10.2 *Operation*

EQUIPMENT shall comply with all the requirements of this Standard when operated in NORMAL USE under the least favourable combination of the following conditions:

10.2.1 **Environment (see also 4.5)*

a) An ambient temperature range of +10°C to +40°C.

b) A relative humidity range of 30% to 75%.

c) An atmospheric PRESSURE range of 700 hPa to 1 060 hPa.

d) A temperature of the water at the inlet of water-cooled EQUIPMENT not higher than 25°C.

*See rationale for 10.2.1

10.2.2 **Power supply*

*a) EQUIPMENT shall be suitable for a power supply having:

– a RATED voltage not exceeding:

• 250 V for HAND-HELD EQUIPMENT;

• 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for EQUIPMENT with a RATED apparent power input of up to 4 kVA;

• 500 V for all other EQUIPMENT;

– a sufficiently low internal impedance (as may be required by a Particular Standard);

– voltage fluctuation not exceeding ±10% of the NOMINAL voltage except momentary fluctuations exceeding -10% and of a duration of less than 1 s, for example those occurring at irregular intervals caused by operation of X-ray generators or similar EQUIPMENT;

– no voltage in excess of the NOMINAL value +10% between any of the conductors of the system or between any of these conductors and earth;

– voltages which are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;

– a frequency of not more than 1 kHz;

– a frequency which deviates not more than 1 Hz from the NOMINAL value up to 100 Hz and not more than 1% from the NOMINAL value from 100 Hz to 1 kHz;

– the protective measures as described in IEC Publication 364.

b) An INTERNAL ELECTRICAL POWER SOURCE, if replaceable, shall be specified by the manufacturer.

Compliance with the conditions of 10.2 is checked by application of the tests of this Standard.

*See rationale for 10.2.2

10.2.2DV DR *Modification of item a) in 10.2.2:*

Replace ″500 V″ with ″600 V″ in both locations in the text associated with the first dash. In the text of the last dash of this sub-clause, add ″and the National Electrical Code, ANSI/NFPA 70″ after the reference to ″IEC Publication 364″.

*See rationale for 10.2.2DV

11 Not used.

12 Not used.

Transferred to Sub-clause 3.6.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13 General

EQUIPMENT shall be so designed that the risk of electric shock in NORMAL USE and in SINGLE FAULT CONDITION is obviated as far as practicable.

Compliance is considered to be fulfilled if EQUIPMENT meets the relevant requirements of this section.

14 Requirements related to classification

14DV DR *Modification of 14 by adding the following:*

All FIXED EQUIPMENT and PERMANENTLY INSTALLED EQUIPMENT shall be CLASS I EQUIPMENT.

*See rationale for 14DV

14.1 *CLASS I EQUIPMENT*

a) CLASS I EQUIPMENT may have parts with DOUBLE INSULATION or REINFORCED INSULATION or parts operating at SAFETY EXTRA-LOW VOLTAGE or ACCESSIBLE PARTS protected by protective impedance in cases where conductive parts of an electrical circuit have to be accessible to enable EQUIPMENT to function.

*b) If the isolation of the MAINS PART from ACCESSIBLE METAL PARTS of EQUIPMENT specified for an external d.c. power source is accomplished by BASIC INSULATION only, a separate PROTECTIVE EARTH CONDUCTOR shall be provided.

*See rationale for 14.1

14.2 *CLASS II EQUIPMENT*

a) CLASS II EQUIPMENT shall be one of the following types:

1) insulation-enclosed CLASS II EQUIPMENT:

EQUIPMENT having a durable and substantially continuous ENCLOSURE of insulating material which envelops all conductive parts with the exception of small parts, such as name-plates, screws and rivets, which are isolated from LIVE parts by insulation at least equivalent to REINFORCED INSULATION. The ENCLOSURE of insulation-enclosed CLASS II EQUIPMENT may form a part or the whole of the SUPPLEMENTARY INSULATION;

2) metal-enclosed CLASS II EQUIPMENT:

EQUIPMENT having a substantially continuous conductive ENCLOSURE in which DOUBLE INSULATION is used throughout the MAINS PARTS (except for those parts where REINFORCED INSULATION is used, because the application of DOUBLE INSULATION is manifestly impracticable);

3) EQUIPMENT which is a combination of types 1) and 2) above.

b) If EQUIPMENT is fitted with a device for changing over from Class I to Class II protection, all of the following requirements shall be fulfilled:

– the change-over device shall clearly indicate the selected Class;

– for change-over the use of a TOOL shall be necessary;

– the EQUIPMENT shall comply with the whole range of requirements for the Class selected at any given time;

– in the Class II position the device shall interrupt the connection of the PROTECTIVE EARTH CONDUCTOR to EQUIPMENT or change it into a FUNCTIONAL EARTH CONDUCTOR, complying with the requirements of Clause 18.

c) CLASS II EQUIPMENT may be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also Sub-clauses 18*k)* and *l)*.

14.3 Not used.

14.4 *CLASS I and CLASS II EQUIPMENT*

a) In addition to BASIC INSULATION, EQUIPMENT shall be provided with an additional protection according to the requirements of CLASS I or CLASS II EQUIPMENT (see Figures 2 and 3).

b) In EQUIPMENT specified for power supply from an external d.c. power source (for example, for use in ambulances), no SAFETY HAZARD shall develop when a connection with the wrong polarity is made.

14.5 *INTERNALLY POWERED EQUIPMENT*

a) Not used.

*b) INTERNALLY POWERED EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I or CLASS II EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED EQUIPMENT while not so connected.

*See rationale for 14.5

14.6 **TYPES B, BF and CF APPLIED PARTS*

a) Not used.

b) Not used.

c) APPLIED PARTS which are specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be TYPE CF.

d) Not used.

*See rationale for 14.6

14.7 Not used.

Compliance with the requirements of Clause 14 is checked by inspection and relevant tests.

15 Limitation of voltage and/or energy

a) Not used.

b) EQUIPMENT intended to be connected to the SUPPLY MAINS by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the supply pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V.

Compliance is checked by the following test:

EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range.

EQUIPMENT is disconnected from the SUPPLY MAINS by means of the plug with the EQUIPMENT mains switch in the "On" or "Off" position whichever is least favourable.

The voltage between the pins of the plug and between either pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test.

The measured voltages shall not exceed 60 V.

The test shall be performed ten times.

The test between lines and ENCLOSURE shall not be performed if interference suppression capacitors are used with a capacitance between each line and earth of less than 3 000 pF for RATED voltages up to and including 250 V or 5 000 pF for RATED voltages up to and including 125 V.

The test between lines shall not be performed if interference suppression capacitors less than or equal to 0,1 µF are connected between them.

c) LIVE parts of capacitors or circuit parts connected to them, which become accessible after 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 residual energy exceeding 2 mJ.

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device which is included and which permits manual discharging is acceptable. The capacitor(s) and/or the connected circuitry shall then be marked.

Compliance is checked by the following test:

EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS as at present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts shall be measured and the retained energy calculated. If a non-automatic discharging device is specified by the manufacturer, its inclusion and marking shall be ascertained by inspection.

16 *ENCLOSURES and PROTECTIVE COVERS

*See rationale for 16

a) EQUIPMENT shall be so constructed and enclosed that there is protection against contact with LIVE parts, and with parts which can become LIVE in SINGLE FAULT CONDITIONS.

This requirement applies for all positions of EQUIPMENT when it is operated as in NORMAL USE, even after opening of lids and doors and removal of parts without the use of a TOOL or according to the instructions for use.

During the insertion or removal of lamps, protection against contact with LIVE parts of the lamp shall be ensured if the replacement of the lamp is possible without the use of a TOOL.

This requirement shall be applied taking into account that:

1) It does not apply to LIVE parts of electrodes in general in the APPLIED PART of EQUIPMENT, in so far as they are necessarily connected directly or indirectly to the body of the PATIENT during NORMAL USE.

2) Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds which may replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as ENCLOSURES providing protection against contact with LIVE parts.

3) Not used.

4) Not used.

*5) Where the occurrence of a CONDUCTIVE CONNECTION, either directly or through the body of the OPERATOR, between a part accessible without the use of a TOOL and a PATIENT is impossible in NORMAL USE, such a part may assume, in case of a fault in its BASIC INSULATION, a voltage to earth not exceeding 25 V a.c. or 60 V d.c.

Instructions for use shall instruct the OPERATOR not to touch such a part and the PATIENT simultaneously.

Compliance with the requirements of Sub-clause 16a) is checked by inspection and by a test with the standard test finger shown in Figure 7, applied in a bent or straight position. In addition openings in EQUIPMENT, other than those giving access to LIVE parts in plugs, connectors and socket outlets, are tested with the test pin shown in Figure 8.

The standard test finger and the test pin are applied without appreciable force in every possible position, except that EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 40 kg shall not be tilted. EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, shall be tested in its final mounting position.

Openings preventing the entry of the standard test finger of Figure 7 shall be mechanically tested by means of a straight unjointed test finger of the same dimensions, which shall be applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 7 shall be repeated, the finger being pushed through the opening if necessary.

It shall not be possible to touch with the standard test finger or the test pin BASIC INSULATION, bare LIVE parts or LIVE parts protected only by lacquer, enamel, ordinary paper, cotton, oxide film, beads or sealing compound, or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

For signalling contact with LIVE parts, the use of a lamp and a test voltage of at least 40 V is recommended.

EQUIPMENT openings shall be mechanically tested by means of the test-hook (see Figure 9), if the hook can be inserted.

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. No LIVE parts shall become accessible and the CREEPAGE DISTANCE and AIR CLEARANCES of LIVE parts shall not be reduced below the values as specified in Sub-clause 57.10.

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Compliance is checked using the standard test finger and by inspection.

b) Any opening in a top cover of an ENCLOSURE shall be so positioned or dimensioned that accessibility of LIVE parts by means of a freely and vertically suspended test rod with a diameter of 4 mm and a length of 100 mm, penetrating up to its length, is prevented.

Compliance is checked in NORMAL USE by inserting through the holes a metal test rod with a diameter of 4 mm and a length of 100 mm. The test rod is suspended freely and vertically, the penetration being limited to its length. The test rod shall not become LIVE and shall not touch BASIC INSULATION or any parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

*c) Conductive parts of actuating mechanisms of electrical controls which are accessible after the removal of handles, knobs, levers and the like shall either:

– have a resistance of not more than 0,2 Ω to the PROTECTIVE EARTH TERMINAL of the EQUIPMENT when measured with a test voltage of not more than 50 V a.c. open circuit and a test current not less than 1 A, or

– shall be separated from LIVE parts by one of the means described in Sub-clause 17*g)*.

The requirements of this sub-clause do not apply to controls in secondary circuits which are isolated from the MAINS PART by at least BASIC INSULATION and having RATED circuit voltages not exceeding 25 V a.c. or up to and including 60 V d.c. or peak value. In these cases shafts and the like may be isolated from parts of the circuit by BASIC INSULATION only.

Compliance is checked by calculation of the resistance from current and voltage drop. It shall not exceed the required value. Alternatively, the presence of adequate separation shall be confirmed by inspection.

*d) Parts within the ENCLOSURE of EQUIPMENT with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by an external mains switch or a plug device that is accessible at all times (for example, in circuits for room lighting, remote control of the main switch etc.) shall be protected against contact even after opening of the ENCLOSURE (for example, for the purpose of maintenance) by additional coverings or, in the case of a spatially separated arrangement, shall be marked clearly as "LIVE".

Compliance is checked by inspection of the required covers or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 7.

*e) ENCLOSURES protecting against contact with LIVE parts shall be removable only with the aid of a TOOL or, alternatively, an automatic device shall make these parts not LIVE, when the ENCLOSURE is opened or removed.

Excluded are:

1) ENCLOSURES or EQUIPMENT parts removable without the use of a TOOL and allowing the OPERATOR in NORMAL USE to have access to LIVE parts operating at a voltage not exceeding 25 V a.c. or 60 V d.c. or peak value supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in Sub-clauses 17*g)* 1) to 5).

Examples which are applicable are:

– covers of illuminated push-buttons;

– covers of indicator lamps;

– covers over recorder pens;

– plug-in modules;

– covers of battery compartments.

2) Lampholders allowing access to LIVE parts after removal of the lamp.

In such a case instructions for use shall instruct the OPERATOR not to touch such a part and the PATIENT simultaneously.

Compliance is checked by inspection and:

– by measurement of the effectiveness of an automatic switching off or discharging device;

– by measurement of the voltage of LIVE parts accessible with the standard test finger of Figure 7.

f) Openings for the adjustment of pre-set controls which may be adjusted by the USER in NORMAL USE by using a TOOL shall be so designed that the TOOL used for adjustment is not able to touch inside the opening BASIC INSULATION or any LIVE parts or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

Compliance is checked by inspection and by insertion through the opening of a metal test rod with a diameter of 4 mm and a length of 100 mm, in every possible position, in case of doubt with a force of 10 N. The rod shall not contact BASIC INSULATION or any LIVE parts or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

g) Not used.

17 *Separation

*See rationale for 17

(Previous title: Insulation and protective impedances)

a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see Sub-clause 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded.

This requirement may be fulfilled by one of the following methods:

1) The APPLIED PART is separated from LIVE parts by BASIC INSULATION only, but PROTECTIVELY EARTHED and the APPLIED PART has such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.

2) The APPLIED PART is separated from LIVE parts by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing metal screen.

3) The APPLIED PART is not PROTECTIVELY EARTHED but is separated from LIVE parts by an intermediate PROTECTIVELY EARTHED circuit which, in the event of any insulation failure, cannot produce a LEAKAGE CURRENT to the APPLIED PART exceeding the allowable value.

4) The APPLIED PART is separated from LIVE parts by DOUBLE or REINFORCED INSULATION.

5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values.

Compliance with Sub-clause 17a) is checked by inspection and measurement.

If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART and LIVE parts does not comply with the requirements of Sub-clause 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.

The PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured as described in Sub-clause 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.

If inspection of the APPLIED PART in Item 1) and of the PROTECTIVELY EARTHED metal part in Item 2) and of the intermediate circuit in Item 3) gives rise to doubts concerning the effectiveness of the separation under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured after short-circuiting of the insulation between LIVE parts and the APPLIED PART (item 17 a) 1) above), between LIVE parts and the metal part (item 17 a) 2) above) or between LIVE parts and the intermediate circuit (item 17 a) 3) above).

Transient currents occurring during the first 50 ms following the short-circuit shall be disregarded. After 50 ms, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall not exceed the allowable value for SINGLE FAULT CONDITION.

Additionally EQUIPMENT and/or its circuits are examined to determine whether the limitation of LEAKAGE CURRENTS and/or PATIENT AUXILIARY CURRENT to the prescribed values is dependent on the insulating properties of junctions in semiconductor devices which are interposed between the APPLIED PART and the MAINS PART; the APPLIED PART and other LIVE parts and for F-TYPE APPLIED PARTS between the APPLIED PART and earthed parts.

In the event that such semiconductor devices are so identified, they shall be short-circuited to simulate a break-down of the critical junction, one at a time, to establish that the allowable LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT for SINGLE FAULT CONDITION are not exceeded.

b) Not used.

c) An APPLIED PART shall have no CONDUCTIVE CONNECTION to ACCESSIBLE METAL PARTS which are not PROTECTIVELY EARTHED.

Compliance is checked by inspection and the LEAKAGE CURRENT test of Sub-clause 19.4.

d) Hand-held flexible shafts of CLASS I EQUIPMENT shall be isolated from the motor shaft by SUPPLEMENTARY INSULATION.

ACCESSIBLE METAL PARTS driven by an electric motor of Class I protection and which during NORMAL USE are likely to come into direct contact with an OPERATOR or PATIENT, and which cannot be PROTECTIVELY EARTHED, shall be isolated from the motor shaft by at least SUPPLEMENTARY INSULATION capable of withstanding the dielectric strength test appropriate to the RATED voltage of the motor and having adequate mechanical strength.

Compliance is checked by inspection and test of the insulation between hand-held flexible shafts and/or driven ACCESSIBLE METAL PARTS of CLASS I EQUIPMENT and the motor shafts. The test specified for SUPPLEMENTARY INSULATION (see Sub-clause 20.4) shall be applied.

Compliance with the requirements for CREEPAGE DISTANCES and AIR CLEARANCES is checked additionally (see Sub-clause 57.10).

e) Not used.

f) Not used.

g) ACCESSIBLE PARTS not being an APPLIED PART shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see Sub-clause 3.6) in such a way that allowable LEAKAGE CURRENTS are not exceeded (see Clause 19).

This requirement may be fulfilled by one of the following methods:

1) The ACCESSIBLE PART is separated from LIVE parts by BASIC INSULATION only, but PROTECTIVELY EARTHED.

2) The ACCESSIBLE PART is separated from LIVE parts by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing conductive screen.

3) The ACCESSIBLE PART is not PROTECTIVELY EARTHED but is separated from LIVE parts by an intermediate PROTECTIVELY EARTHED circuit which in the event of any insulation failure cannot produce an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.

4) The ACCESSIBLE PART is separated from LIVE parts by DOUBLE or REINFORCED INSULATION.

5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.

Compliance is checked by inspection of the required separation in order to find out where an insulation failure might cause a SAFETY HAZARD.

If the CREEPAGE DISTANCE and/or AIR CLEARANCE between an ACCESSIBLE PART and LIVE parts does not comply with the requirements of Sub-clause 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.

The ENCLOSURE LEAKAGE CURRENT shall subsequently be measured as described in Sub-clause 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.

If inspection of the PROTECTIVELY EARTHED metal part in item 17 g) 2) or of the intermediate circuit in item 17 g) 3) gives rise to doubt concerning the effectiveness of the separation under SINGLE FAULT CONDITION the ENCLOSURE LEAKAGE CURRENT shall be measured by short-circuiting the insulation between LIVE parts and the metal part (item 17 g) 2) above) or between LIVE parts and the intermediate circuit (item 17 g) 3) above).

Transient currents occurring during the first 50 ms following the application of the short-circuit shall be disregarded.

After 50 ms, the ENCLOSURE LEAKAGE CURRENT shall not exceed the allowable value for SINGLE FAULT CONDITION.

Additionally EQUIPMENT and/or its circuits shall be examined to determine if the limitation of LEAKAGE CURRENTS and/or PATIENT AUXILIARY CURRENTS to the prescribed values is dependent on the insulating properties of junctions in semiconductor devices which are interposed between the ACCESSIBLE PART and LIVE parts.

In the event that such semiconductor devices are so identified, they shall be short-circuited to simulate a break-down of the critical junction, one at a time, to establish that the allowable LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS for SINGLE FAULT CONDITION are not exceeded.

*h) Arrangements used to isolate DEFIBRILLATION-PROOF APPLIED PARTS from other parts shall be so designed that:

– during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies do not appear on:

- the ENCLOSURE, including the outer surfaces of accessible leads and connectors,
- any SIGNAL INPUT PART,
- any SIGNAL OUTPUT PART,
- metal foil for test on which the EQUIPMENT is placed and which has an area at least equal to the base of the EQUIPMENT,

– after exposure to the defibrillation voltage, the EQUIPMENT, after any necessary time of recovery stated in the ACCOMPANYING DOCUMENTS, shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

Compliance is checked by the following impulse voltage tests:

– (Common-mode test) The EQUIPMENT is connected to the test circuit shown in figure 50. The test voltage is applied to all the PATIENT CONNECTIONS connected together and isolated from earth;

– (Differential-mode test) The EQUIPMENT is connected to the test circuit shown in figure 51. The test voltage is applied to each PATIENT CONNECTION in turn with all the remaining PATIENT CONNECTIONS being connected to earth.

NOTE – The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

During each test:

– the PROTECTIVE EARTH CONDUCTOR of CLASS I EQUIPMENT is connected to earth. CLASS I EQUIPMENT which is capable of operation without a SUPPLY MAINS, e.g. having an internal battery, is tested again without the protective earth connection;

– the EQUIPMENT shall not be energized;

– insulating surfaces of APPLIED PARTS are covered with metal foil or immersed in a saline solution as specified in 19.4 h) 9);

– any connection to a FUNCTIONAL EARTH TERMINAL is removed; where a part is internally connected to earth for functional purposes, either such a connection shall be considered a protective earth connection and shall comply with the requirements of clause 18, or it shall be removed for the purpose of the present text;

– parts specified in the first dash of this subclause that are not PROTECTIVELY EARTHED are connected to an oscilloscope.

After the operation of S, the peak voltage between the points Y1 and Y2 shall not exceed 1 V.

Each test is repeated with V_T reversed.

After any necessary time of recovery, stated in the ACCOMPANYING DOCUMENTS, the EQUIPMENT shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

18 Protective earthing, functional earthing and potential equalization

*See rationale for 18

*a) ACCESSIBLE PARTS of CLASS I EQUIPMENT separated from LIVE parts by BASIC INSULATION shall be connected by sufficiently low impedance to the PROTECTIVE EARTH TERMINAL. See also Sub-clause 17*g)*.

Compliance is checked by inspection and the tests of Sub-clauses 18f) and 18g).

b) The PROTECTIVE EARTH TERMINAL shall be suitable for connection to the protective conductor in the installation either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR. For constructional requirements for the earth connection see Clause 58.

Compliance is checked by inspection (see Sub-clause 18f)).

c) Not used.

d) Not used.

e) If EQUIPMENT is provided with a means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR this connection shall comply with the following requirements:

– be readily accessible;

– accidental disconnection is prevented in NORMAL USE;

– the conductor can be detached without the use of a TOOL;

– the POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR;

– the connection means shall be marked with Symbol 9, Table DI.

Compliance is checked by inspection.

f) For EQUIPMENT without a POWER SUPPLY CORD the impedance between the PROTECTIVE EARTH TERMINAL and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,1 Ω.

For EQUIPMENT with an APPLIANCE INLET the impedance between the protective earth contact in the APPLIANCE INLET and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,1 Ω.

For EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,2 Ω.

Compliance is checked by the following test:

A current of 25 A or 1,5 times the RATED current of the EQUIPMENT, whichever is greater (±10%), from current source with a frequency of 50 Hz or 60 Hz 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 ACCESSIBLE METAL PART which could become LIVE in case of failure in BASIC INSULATION.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed the values indicated in this sub-clause.

*g) The impedance of protective earth connections other than those described in Sub-clause 18*f)* is allowed to exceed 0,1 Ω if the continuous fault current to an ACCESSIBLE PART in case of failure in BASIC INSULATION of such a part or of a component connected to such a part is limited to such an extent that the allowable value of the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION is not exceeded.

Compliance is checked by inspection and measurement of the ENCLOSURE LEAKAGE CURRENT in a SINGLE FAULT CONDITION. See also Sub-clause 17g).

h) Not used.

j) Not used.

k) FUNCTIONAL EARTH TERMINALS shall not be used to provide protective earthing.

Compliance is checked by inspection.

l) If CLASS II 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 functional earth for these screens and shall be coloured green and yellow.

The insulation of such internal screens and all internal wiring connected to them shall be DOUBLE INSULATION or REINFORCED INSULATION.

In such case the FUNCTIONAL EARTH TERMINAL of such EQUIPMENT shall be marked so as to distinguish it from a PROTECTIVE EARTH TERMINAL and additionally there shall be an explanation in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and measurement. The insulation shall be tested as described in Clause 20.

18DV D2 ***Modification of 18 by adding the following items:***

m) All parts of X-ray EQUIPMENT operating at over 600 V ac, 850 V dc, or 850 V peak shall be enclosed within PROTECTIVELY EARTHED (grounded) ENCLOSURES. The connections from the high-voltage EQUIPMENT to X-ray tubes and other high-voltage components shall be made with high-voltage shielded cables intended for operation at over 600 V ac, 850 V dc, or 850 V peak.

n) All accessible non-current carrying conductive parts, likely to become energized, of X-ray and associated EQUIPMENT (controls, tables, transformer tanks, shields of shielded cables, tube heads and supports, etc.) shall be PROTECTIVELY EARTHED (grounded) in accordance with Clause 18.

*See rationale for 18DV

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

19.1 *General requirements*

a) The electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the specified values.

b) The specified values of the continuous EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:

– Both at operating temperature and following the humidity preconditioning treatment, as described in Sub-clauses 4.10 and 19.4.

– In NORMAL CONDITION and in the specified SINGLE FAULT CONDITIONS (see Sub-clause 19.2).

– With EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position.

– With the highest RATED supply frequency.

– With a supply equal to 110% of the highest RATED MAINS VOLTAGE.

The measured values shall not exceed the allowable values given in Sub-clause 19.3.

c) EQUIPMENT specified for connection to a SELV source can only comply with the requirements of this Standard if such a source complies with this Standard and if the EQUIPMENT, tested in combination with such a source, complies with the requirements for allowable LEAKAGE CURRENTS.

Such EQUIPMENT and INTERNALLY POWERED EQUIPMENT shall be investigated for ENCLOSURE LEAKAGE CURRENT but only as far as described in Sub-clause 19.4*g)* 3).

*d) The measurement of the ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT shall only be performed:

– to earth from each part, if present, of the ENCLOSURE not PROTECTIVELY EARTHED;

– between parts, if present, of the ENCLOSURE not PROTECTIVELY EARTHED.

e) The PATIENT LEAKAGE CURRENT shall be measured (see Appendix K):

– in TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;

– in TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function of the APPLIED PART connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;

– in TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.

If the manufacturer specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT cord and electrodes), the PATIENT LEAKAGE CURRENT measurements shall be made with the least favourable specified detachable part.

f) The PATIENT AUXILIARY CURRENT shall be measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS connected together.

g) EQUIPMENT with multiple PATIENT CONNECTIONS shall be investigated to ensure that, under NORMAL CONDITIONS, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values while one or more PATIENT CONNECTIONS are:

– disconnected from the PATIENT; and

– disconnected from the PATIENT and earthed.

Testing shall be carried out if an examination of the EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT may increase to excessive levels under the above conditions, and actual measurements should be limited to a representative number of combinations.

*See rationale for 19.1

19.2 *SINGLE FAULT CONDITIONS*

*a) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured under the following SINGLE FAULT CONDITIONS:

– the interruption of each supply conductor one at a time;

– the interruption of a PROTECTIVE EARTH CONDUCTOR (not applicable in the case of EARTH LEAKAGE CURRENT). Not to be investigated if a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR is specified;

– see also Sub-clauses 17*a)* and 17*g)*.

b) Additionally the PATIENT LEAKAGE CURRENT shall be measured under the following SINGLE FAULT CONDITIONS:

– a voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART.

This requirement shall not apply in the following cases:

• The SIGNAL INPUT PART(S) or SIGNAL OUTPUT PART(S) are designated by the manufacturer for connection to EQUIPMENT in situations where a risk of external voltage does not exist (see IEC 601-1-1).

• for TYPE B APPLIED PARTS, unless inspection of the circuits and physical arrangement shows that a SAFETY HAZARD exists;

• for F-TYPE APPLIED PARTS.

– A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between any F-TYPE APPLIED PART and earth.

– A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and any ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED.

This requirement does not apply:

• for TYPE B APPLIED PARTS, unless inspection of the circuits and physical arrangements shows that a SAFETY HAZARD exists;

• for F-TYPE APPLIED PARTS.

c) Additionally, the ENCLOSURE LEAKAGE CURRENT shall be measured with a voltage equal to 110% of the highest RATED MAINS VOLTAGE, applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART.

This requirement is only applied where the SIGNAL INPUT PART(S) or SIGNAL OUTPUT PART(S) are designated by the manufacturer for connection to EQUIPMENT in situations where a risk of external voltage exists (see IEC 601-1-1).

*See rationale for 19.2

19.3 *****_Allowable values_

a) The allowable values of the continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table IV for d.c. and a.c. and composite waveforms. Unless stated otherwise values may be d.c. or r.m.s.

b) The allowable values stated in table IV apply to currents flowing through the network of figure 15 and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in figure 15).

Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION.

c) Not used.

d) Not used.

e) Not used, but see Notes 3) and 4) of Table IV.

Table IV
*Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS, in milliamperes

Current		Type B		Type BF		Type CF	
		N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.
EARTH LEAKAGE CURRENT general		0,5	1[1)]	0,5	1[1)]	0,5	1[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes [2)] and [4)]		2,5	5[1)]	2,5	5[1)]	2,5	5[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to note [3)]		5	10[1)]	5	10[1)]	5	10[1)]
ENCLOSURE LEAKAGE CURRENT		0,1	0,5	0,1	0,5	0,1	0,5
PATIENT LEAKAGE CURRENT	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
according to note 5)	a.c.	0,1	0,5	0,1	0,5	0,01	0,05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the SIGNAL INPUT PART or SIGNAL OUTPUT PART)		–	5	–	–	–	–
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)		–	–	–	5	–	0,05
PATIENT AUXILIARY CURRENT	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
according to note 5)	a.c.	0,1	0,5	0,1	0,5	0,01	0,05

N.C.: NORMAL CONDITION

S.F.C.: SINGLE FAULT CONDITION

Notes on Table IV

1) The only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time (see Subclause 19.2*a)* and Figure 16).

2) EQUIPMENT which has no PROTECTIVELY EARTHED ACCESSIBLE PARTS and no means for the protective earthing of other EQUIPMENT and which complies with the requirements for the ENCLOSURE LEAKAGE CURRENT and for the PATIENT LEAKAGE CURRENT (if applicable).

Example:

Some computers with a screened MAINS PART.

3) EQUIPMENT specified to be permanently installed with a PROTECTIVE EARTH CONDUCTOR which is electrically so connected that the connection can only be loosened with the aid of a TOOL and which is so fastened or otherwise so secured mechanically at a specific location that it can only be moved after the use of a TOOL.

Examples of such EQUIPMENT are:

- Major components of an X-ray installation such as the X-ray generator, the examination or treatment table.
- EQUIPMENT with mineral insulated heaters.
- EQUIPMENT with an EARTH LEAKAGE CURRENT higher than stated in Table IV, first line, which is due to compliance with requirements for radio-interference suppression.

4) MOBILE X-ray EQUIPMENT and MOBILE EQUIPMENT with mineral insulation.

5) The maximum values for the a.c. component of the PATIENT LEAKAGE CURRENT and of the PATIENT AUXILIARY CURRENT specified in table IV refer to the a.c.-only component of the currents.

*See rationale for 19.3

19.4 *Tests*

**a) General*

1) The EARTH LEAKAGE CURRENT*, the* ENCLOSURE LEAKAGE CURRENT*, the* PATIENT LEAKAGE CURRENT *and the* PATIENT AUXILIARY CURRENT *are measured:*

– after the EQUIPMENT *has been brought up to operating temperature in accordance with the requirements of Section Seven, and*

– after the humidity preconditioning treatment as described in Sub-clause 4.10.

The measurements shall be carried out with the EQUIPMENT *located in an environment with a temperature approximately equal to t where t is the temperature of the humidity cabinet and a relative humidity between 45% and 65% and shall commence 1 h after the end of the humidity preconditioning treatment.*

The measurements which do not energize the EQUIPMENT *shall be made first.*

2) EQUIPMENT *is connected to a supply with a voltage equal to 110% of the highest* RATED MAINS VOLTAGE*.*

3) Three-phase EQUIPMENT *which is also suitable for single-phase supply is tested as single-phase* EQUIPMENT *with the three sections connected in parallel.*

4) Where examination of the circuit arrangement and the arrangement of components and material of EQUIPMENT *shows no possibility of any* SAFETY HAZARD*, the number of tests may be reduced.*

5) Not used.

**b) Measuring supply circuits*

1) EQUIPMENT *specified for connection to a* SUPPLY MAINS *which is approximately at earth potential on one side and* EQUIPMENT *for which the nature of the power supply is not specified, is connected to a circuit as shown in Figure 10.*

2) EQUIPMENT *specified for connection to a* SUPPLY MAINS *of which the voltages between the lines and the neutral are approximately equal and in opposition, is connected to a circuit as shown in Figure 11.*

3) Polyphase or single-phase EQUIPMENT*, specified for connection to a polyphase (for example, three-phase)* SUPPLY MAINS*, is connected to one of the circuits as shown in Figures 12 and 13.*

4) EQUIPMENT *specified for use with a specified Class I single-phase power supply, is connected to a circuit as shown in Figure 14.*

The switch S_8 shall be opened and closed in turn during the tests.

However, if the specified power supply has a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR*, the switch S_8 shall be left closed during tests.*

5) EQUIPMENT specified for use with a specified Class II single-phase power supply is connected to a circuit as shown in Figure 14, not using the protective earth connection S_8.

c) Connection of the EQUIPMENT to the measuring supply circuit

1) EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.

2) 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 by the manufacturer.

3) EQUIPMENT specified to be PERMANENTLY INSTALLED is tested while connected to the measuring supply circuit via the shortest possible connection.

**d) Measuring arrangement*

1) It is recommended to position the measuring supply circuit and the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following sub-clauses) to avoid placing the EQUIPMENT on or near a large earthed metal surface.

2) However, external parts of the APPLIED PART, including PATIENT cords (when present), shall 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.

e) Measuring device (MD)

1) The measuring device shall load the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c. and a.c. and for composite waveforms with frequencies up to and including 1 MHz.

2) The evaluation of current or current components according to Sub-clauses 19.3a) and b) is obtained automatically if a measuring device according to Figure 15 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.

If currents or current components with frequencies exceeding 1 kHz and a value exceeding 10 mA are likely to occur, these shall be measured by other appropriate means.

3) Not used.

**4) The measuring instrument as shown in Figure 15 shall have an impedance of approximately 1 MΩ or more for frequencies from d.c. up to and including 1 MHz. It shall indicate the true r.m.s. value of the voltage across the measuring impedance being d.c. or a.c. or a composite waveform having components with frequencies from d.c. up to and including 1 MHz, with an indicating error not exceeding ±5% of the indicated value.*

The scale may 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 Table IV.

The requirements for percentage-indicating error and for calibration may be limited to 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.

f) Measurement of the EARTH LEAKAGE CURRENT

1) CLASS I EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 16, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

2) EQUIPMENT specified for use with a specified Class I single-phase power supply is tested according to Figure 17, using the measuring supply circuit of Figure 14. If the EQUIPMENT is PROTECTIVELY EARTHED, the measurement with MD2 shall also be performed.

g) Measurement of the ENCLOSURE LEAKAGE CURRENT

1) CLASS I EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 18, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

Measure with MD1 between earth and each part of the ENCLOSURE which is not PROTECTIVELY EARTHED.

Measure with MD2 between parts of the ENCLOSURE which are not PROTECTIVELY EARTHED.

2) CLASS II EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 18 using one of the measuring supply circuits of Figures 10, 11, 12 or 13 as relevant, but without the protective earth connection and S_7.

Measure with MD1 between the ENCLOSURE and earth or between each part of the ENCLOSURE if more than one is present.

Measure with MD2 between parts of the ENCLOSURE or between any two ENCLOSURES if more than one is present.

3) EQUIPMENT specified for connection to an SELV-source and INTERNALLY POWERED EQUIPMENT are tested for ENCLOSURE LEAKAGE CURRENT flowing between different parts of the ENCLOSURE (measuring device applied as MD2 in Figure 18).

4) EQUIPMENT, with or without an APPLIED PART, specified for use with a specified Class I single-phase power supply is tested according to Figure 19, using the measuring supply circuit of Figure 14.

EQUIPMENT, with or without an APPLIED PART, specified for use with a specified Class II single-phase power supply shall be tested according to Figure 19 using the measuring supply circuit of Figure 14, but without the protective earth connection(s) and S_8.

The protective earth connection(s) to EQUIPMENT and S_8 are used only when the EQUIPMENT itself is of Class I.

Test a Class I power supply and/or CLASS I EQUIPMENT connected to it, as mentioned under "CLASS I EQUIPMENT" (see Sub-clause 19.4g) 1)).

Test a Class II power supply and EQUIPMENT not being Class I, connected to it, as mentioned under "CLASS II EQUIPMENT" (see Sub-clause 19.4g) 2)).

5) If EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm × 10 cm shall be applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.

To achieve this, it may be pressed against the insulating material with a PRESSURE of approximately 0,5 N/cm^2.

The metal foil is shifted, if possible, to determine the highest value of the ENCLOSURE LEAKAGE CURRENT. Care shall be taken that the metal foil does not touch any metal parts of the ENCLOSURE which are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE which are not PROTECTIVELY EARTHED may be covered partly or totally by the metal foil.

Where it is intended to measure the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION, the metal foil may be arranged to contact the metal part of the ENCLOSURE.

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR may be larger than that of a normal hand, the size of the foil is increased corresponding to the area of contact.

6) If applicable, the measurements according to Sub-clause 17g) are performed in addition to those mentioned above.

**h) Measurement of the PATIENT LEAKAGE CURRENT*

For connections to the APPLIED PART(S) see Sub-clause 19.1e) and Appendix K.

1) CLASS I EQUIPMENT with an APPLIED PART is tested according to Figure 20, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

2) CLASS I EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 21, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

SIGNAL INPUT and SIGNAL OUTPUT PARTS shall, if not already permanently earthed in the EQUIPMENT, be connected to earth.

The value of the voltage to be set at the transformer T_2 in Figure 21 shall be equal to 110% of the highest RATED MAINS VOLTAGE of the EQUIPMENT.

3) CLASS I EQUIPMENT with an APPLIED PART and a SIGNAL INPUT and/or SIGNAL OUTPUT PART, is, when required (see Sub-clause 19.2b)), additionally tested according to Figure 22, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

The value of the voltage set at the transformer T_2 shall be equal to 110% of the highest RATED MAINS VOLTAGE of the EQUIPMENT. The SIGNAL INPUT and SIGNAL OUTPUT PART is short-circuited unless a load is prescribed by the manufacturer, in which case the test voltage is applied in turn to all poles of the SIGNAL INPUT and SIGNAL OUTPUT PART.

4) CLASS II EQUIPMENT is tested as CLASS I EQUIPMENT mentioned in tests 1) to 3) above, but disregarding the protective earth connection(s) and S_7.

The PATIENT LEAKAGE CURRENT of CLASS II EQUIPMENT with an F-TYPE APPLIED PART and an external voltage on the APPLIED PART is measured with the metal ENCLOSURE (if present) connected to earth.

In the case of CLASS II EQUIPMENT with an ENCLOSURE made of insulating material, it 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.

5) EQUIPMENT with an APPLIED PART, specified for use with a specified single-phase power supply, is tested using the measuring supply circuit of Figure 14, but disregarding the protective earth connection(s) and S_8 if the specified single-phase power supply is of Class II.

– If EQUIPMENT itself is of Class I, it is tested as CLASS I EQUIPMENT mentioned in test 1) above.

– If EQUIPMENT itself is of Class II, it is tested as CLASS II EQUIPMENT mentioned in test 4) above.

– If the specified single-phase power supply is of Class I only S_8 shall be opened (SINGLE FAULT CONDITION) and closed during the measurement, while S_1, S_2, S_3 and S_{10} (when present) are closed.

6) INTERNALLY POWERED EQUIPMENT is tested according to Figure 23.

Where the ENCLOSURE is made of insulating material, metal foil as described in Sub-clause 19.4g) 5) shall be applied.

7) INTERNALLY POWERED EQUIPMENT provided with an F-TYPE APPLIED PART is additionally tested according to Figure 24. The value of the voltage to be set at the transformer T_2 shall be 250 V at the supply frequency (see Sub-clause 19.1b)).

For this test a metal ENCLOSURE of EQUIPMENT and the SIGNAL INPUT and SIGNAL OUTPUT PART is connected to earth.

An ENCLOSURE 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.

8) INTERNALLY POWERED EQUIPMENT provided with an APPLIED PART and a SIGNAL INPUT and/or SIGNAL OUTPUT PART is, if applicable according to Sub-clause 19.2b), additionally tested according to Figure 25. The value of the voltage to be set at the transformer T_1 shall be 250 V at the supply frequency (see Sub-clause 19.1b)).

For this test EQUIPMENT is positioned as in NORMAL USE as indicated in Sub-clause 19.4d) or as indicated in Sub-clause 19.4h) 7), whichever is less favourable.

9) An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under Sub-clause 19.4g) 5). Alternatively a saline solution may be used in which the APPLIED PART is immersed.

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm × 10 cm, the size of the foil is increased to correspond to the area of contact.

Such foil or saline solution shall be considered as the only PATIENT CONNECTION for the APPLIED PART concerned.

10) If loading of the APPLIED PART is specified by the manufacturer, the measuring device is connected in turn to all poles of the load (APPLIED PART).

11) If applicable, the measurements according to Sub-clause 17a) are performed in addition to those mentioned above.

j) Measurement of the PATIENT AUXILIARY CURRENT

For connections to the APPLIED PART(S) see Sub-clause 19.1e) and Appendix K.

1) CLASS I EQUIPMENT with an APPLIED PART is tested according to Figure 26, using one of the relevant measuring supply circuits of Figures 10, 11, 12 or 13.

2) CLASS II EQUIPMENT with an APPLIED PART is tested as CLASS I EQUIPMENT mentioned above, but disregarding the protective earth connection(s) and S_7.

3) EQUIPMENT with an APPLIED PART, and specified for use with a specified single-phase power supply is tested using the measuring supply circuit of Figure 14, but disregarding the protective earth connection and S_8, if the specified single-phase power supply is of Class II.

If EQUIPMENT itself is of Class I, it is tested as CLASS I EQUIPMENT mentioned under paragraph 1).

If EQUIPMENT itself is of Class II, it is tested as CLASS II EQUIPMENT mentioned under paragraph 2).

If the specified single-phase power supply is of Class I,

– S_8 shall be opened (SINGLE FAULT CONDITION) and S_1, S_2 and S_3 shall be closed;

– Additionally S_8 shall be closed and S_1, S_2 or S_3 shall be opened in turn (SINGLE FAULT CONDITION).

During the three measurement procedures described above S_5 and S_{10} shall be set in all possible combinations of positions.

4) INTERNALLY POWERED EQUIPMENT is tested according to Figure 27.

*See rationale for 19.4

19.5DV DR *Addition of 19.5DV.1 and 19.5DV.2:*

*See rationale for 19.5DV

19.5DV.1 In addition to the requirements in 19.1 – 19.4, the following requirements apply, except for X-ray EQUIPMENT and EQUIPMENT covered by note 3) on Table IV.

19.5DV.2 The LEAKAGE CURRENTS specified in Tables 19.5DV.1 and 19.5DV.2 are not to be exceeded when the EQUIPMENT is tested in accordance with Clause 19 except:

a) When the EQUIPMENT is to be connected to the highest RATED MAINS VOLTAGE[1)];

b) When the notes in Tables 19.5DV.1 and 19.5DV.2 apply.

[1)]Minimum 120 VAC and 240 VAC for EQUIPMENT and marked voltage ranges of 105 – 120 VAC and 210 – 240 VAC respectively.

Table 19.5DV.1 DR *Addition:*

Table 19.5DV.1 – PATIENT CARE EQUIPMENT[a)] maximum LEAKAGE CURRENT (microamperes)

Earth and ENCLOSURE[b)]					
CLASS I EQUIPMENT[c)]			CLASS II EQUIPMENT[d)]		
AC RMS	or	DC	AC RMS	or	DC
300 (500)[e)]			150 (250)[e)]		

[a)] See 2.12.19DV.

[b)] Metal ENCLOSURE or metal foil over insulating material as per 19.4 (g)(5).

[c)] Measured with and without the loss of PROTECTIVE EARTH with the supply conductors normal or reversed.

[d)] Measured with supply conductors normal and reversed. When measured with either BASIC or SUPPLEMENTARY INSULATION effectively bypassed, the allowable LEAKAGE CURRENT is twice that shown.

[e)] EQUIPMENT with all surfaces, likely to be contacted by someone in the PATIENT VICINITY (2.12.20DV), constructed of nonconductive materials may comply with the bottom number (in parentheses) instead of the top one.

When the EQUIPMENT is marked or identified in the installation instructions for use on a center-tapped, 240 V, single phase circuit, the LEAKAGE CURRENT may be measured from a center-tapped circuit.

Table 19.5DV.2 DR *Addition:*

Table 19.5DV.2 – Nonpatient EQUIPMENT maximum LEAKAGE CURRENT (microamperes)

Earth and ENCLOSURE[a)]					
CLASS I EQUIPMENT[b)]			CLASS II EQUIPMENT[c)]		
AC RMS	or	DC	AC RMS	or	DC
500			250		

[a)] Metal ENCLOSURE or metal foil over insulating material as per 19.4 (g)(5).

[b)] Measured with all combinations of:

– PROTECTIVE EARTH connection connected or not connected;

– One supply connection, at a time, connected or not connected;

– SUPPLY CONNECTIONS normal or reversed.

Table 19.5DV.2 – Nonpatient EQUIPMENT maximum LEAKAGE CURRENT (microamperes) Continued on Next Page

Table 19.5DV.2 – Nonpatient EQUIPMENT maximum LEAKAGE CURRENT (microamperes) Continued

Earth and ENCLOSURE[a)]	
CLASS I EQUIPMENT[b)]	CLASS II EQUIPMENT[c)]
[c)] Measured with all combinations of: **– One SUPPLY CONNECTION at a time connected or not connected;** **– SUPPLY CONNECTIONS normal or reversed;** **– When measured with either BASIC or SUPPLEMENTARY INSULATION effectively bypassed, the acceptable LEAKAGE CURRENT is twice that shown.** **When the EQUIPMENT is marked or identified in the installation instructions for use on a center-tapped, 240 V, single phase circuit, the LEAKAGE CURRENT may be measured from a center-tapped circuit.**	

20 Dielectric strength

Only insulation with a safety function need be subject to testing.

20.1 *General requirements for all types of EQUIPMENT*

The dielectric strength shall be tested (see also Appendix E):

A-a_1 Between LIVE parts and ACCESSIBLE METAL PARTS which are PROTECTIVELY EARTHED.

This insulation shall be BASIC INSULATION.

A-a_2 Between LIVE parts and parts of the ENCLOSURE not PROTECTIVELY EARTHED.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

A-b Between LIVE parts and conductive parts isolated from the LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION.

This insulation shall be BASIC INSULATION.

A-c Between the ENCLOSURE and conductive parts isolated from LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION.

This insulation shall be SUPPLEMENTARY INSULATION.

A-d Not used.

A-e Between LIVE parts not being parts of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS and SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS not PROTECTIVELY EARTHED.

Separation shall be achieved by one of the methods indicated in Items *g)* 1 to 5 of Clause 17.

No separate investigation is needed if the voltages appearing on the SIGNAL INPUT PART (SIP) and/or SIGNAL OUTPUT PART (SOP) in NORMAL and SINGLE FAULT CONDITIONS do not exceed SAFETY EXTRA LOW VOLTAGE.

*A-f Between parts of opposite polarity of the MAINS PART.

This insulation shall be equivalent to BASIC INSULATION.

Table Continued on Next Page

Table Continued

The electrical insulation of parts A-f shall be investigated only if, after inspection of insulation quantities and sizes, including CREEPAGE DISTANCES and AIR CLEARANCES according to Sub-clause 57.10, no complete compliance can be established.

If separation of circuits or protection of components, necessary for the investigation of parts A-f, is not possible without damage to EQUIPMENT, the manufacturer and the testing laboratory shall make an agreement as to any other method possible to fulfil the purpose of this investigation.

A-g Between a metal ENCLOSURE (or cover) lined internally with insulating material and a metal foil applied for testing purposes in contact with the interior surface of the lining. Such a lining may be applied where the distance, measured through the lining, between a LIVE part and the ENCLOSURE (or cover) is less than the AIR CLEARANCE required according to Sub-clause 57.10.

Where the ENCLOSURE (or cover) is PROTECTIVELY EARTHED, the required AIR CLEARANCE is that for BASIC INSULATION and the lining shall be treated as such.

Where the ENCLOSURE (or cover) is not PROTECTIVELY EARTHED, the required AIR CLEARANCE is that for REINFORCED INSULATION.

If the distance between the LIVE part and the interior surface of the lining is not less than the AIR CLEARANCE required for BASIC INSULATION, that distance shall be treated as BASIC INSULATION. The lining shall then be treated as SUPPLEMENTARY INSULATION.

Where the distance, as described before, is less than that required for BASIC INSULATION, the lining shall be treated as REINFORCED INSULATION.

A-h Not used.

A-j Between ACCESSIBLE PARTS not PROTECTIVELY EARTHED and likely to become LIVE in the event of failure of the insulation of the POWER SUPPLY CORD, and either metal foil wrapped around the POWER SUPPLY CORD inside inlet bushings, cord guards, cord anchorages and the like, or a metal rod having the same diameter as the POWER SUPPLY CORD, inserted in its place.

This insulation shall be SUPPLEMENTARY INSULATION.

A-k Between, in turn, a SIGNAL INPUT PART, a SIGNAL OUTPUT PART and ACCESSIBLE PARTS not PROTECTIVELY EARTHED.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

This insulation need not be investigated separately if at least one of the following conditions is satisfied:

a) The voltages appearing on the SIGNAL INPUT PART or SIGNAL OUTPUT PART in NORMAL USE do not exceed SAFETY EXTRA LOW VOLTAGE.

b) The LEAKAGE CURRENTS do not exceed the allowable values in SINGLE FAULT CONDITION in the event of any single component failure in the SIGNAL INPUT or SIGNAL OUTPUT PARTS.

c) The parts in question are effectively separated by a PROTECTIVELY EARTHED shielding or by a PROTECTIVELY EARTHED intermediate circuit.

d) The SIGNAL INPUT or SIGNAL OUTPUT PARTS are designated by the manufacturer for connection to EQUIPMENT in situations where no risk of external voltage exists (see IEC 601-1-1).

*See rationale for 20.1

20.2 *Requirements for EQUIPMENT with an APPLIED PART*

For EQUIPMENT with an APPLIED PART, the dielectric strength shall also be tested (see also Appendix E):

B-a Between the APPLIED PART (PATIENT CIRCUIT) and LIVE parts.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

This insulation need not be investigated separately if the parts in question are effectively separated as described in Sub-clause 17*a)* 1), 2) or 3). In this case the test is replaced by the tests of B-c and B-d.

Where the total separation between the APPLIED PART and the LIVE part consists of more than one circuit insulation, possibly of circuits with a substantially different operating voltage, care shall be taken that each part of the separation means is stressed with the proper test voltage derived from the relevant reference voltage. This may mean that the test B-a may have to be replaced by two or more tests on separate parts of the separation means.

B-b Between parts of the APPLIED PART and/or between APPLIED PARTS.

See Particular Standards.

B-c Between the APPLIED PART and parts not PROTECTIVELY EARTHED which are isolated from LIVE parts by BASIC INSULATION only.

This insulation shall be SUPPLEMENTARY INSULATION.

This insulation need not be investigated separately if the parts in question are effectively separated as described in Sub-clause 17*a)* 1), 2) or 3).

B-d Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS. See also Sub-clauses 20.3 and 20.4*j)*.

This insulation shall be BASIC INSULATION. See also B-e.

B-e Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE where the F-TYPE APPLIED PART contains voltages stressing the insulation to the ENCLOSURE in NORMAL USE including earthing of any part of the APPLIED PART.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

B-f Not used (see B-a).

20.3 **Values of test voltages*

The dielectric strength of the electrical insulation at operating temperature as well as following the humidity preconditioning treatment and after any required sterilization procedure, if applicable (see Sub-clause 44.7), shall be sufficient to withstand the test voltages as specified in Table V.

The reference voltage (*U*) as used in Table V is the voltage to which the relevant insulation is subjected in NORMAL USE and at RATED supply voltage or a voltage as specified by the manufacturer, whichever is the greater.

The reference voltage (*U*) for each part of a DOUBLE INSULATION is equal to the voltage to which that DOUBLE INSULATION is subjected in NORMAL USE, NORMAL CONDITION and RATED supply voltage, the EQUIPMENT being energized at the voltage defined in the preceding paragraph.

For reference voltages (*U*) involving an APPLIED PART not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.

For insulation between two isolated parts or between an isolated part and an earthed part, the reference voltage (*U*) is equal to the arithmetic sum of the highest voltages between any two points within both parts.

The reference voltage (*U*) between an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. However, the reference voltage (*U*) shall be not less than the highest RATED supply voltage or for polyphase EQUIPMENT, the phase to neutral supply voltage or for INTERNALLY POWERED EQUIPMENT 250 V.

For DEFIBRILLATION-PROOF APPLIED PARTS, the reference voltage *(U)* is determined without regard to the possible presence of defibrillation voltages (see also subclause 17 **h)*).

Table V
Test voltages

	Test voltages for reference voltage *U*(V)					
Insulation to be tested	***U*≤50**	**50<*U*≤150**	**150<*U*≤250**	**250<*U*≤1 000**	**1 000<*U*≤10 000**	**10 000<*U***
BASIC INSULATION	500	1 000	1 500	2*U* + 1 000	*U* + 2 000	[1]
SUPPLEMENTARY INSULATION	500	2 000	2 500	2*U* + 2 000	*U* + 3 000	[1]
REINFORCED and DOUBLE INSULATION	500	3 000	4 000	2(2*U* + 1 500)	2(*U* + 2 500)	[1]

[1] If necessary, to be prescribed by Particular Standards.

NOTES

1 Tables VI and VII, not used.

2 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 test voltage. In this case the value of the test voltage shall be determined from table V using a reference voltage *(U)* equal to the measured peak-to-peak voltage divided by 2√2.

*See rationale for 20.3

20.4 *Tests*

**a) The test voltage for single-phase EQUIPMENT and for three-phase EQUIPMENT (to be tested as single-phase EQUIPMENT) shall be applied to the insulation parts as described in Sub-clauses 20.1 and 20.2 for 1 min and according to Table V:*

– immediately after warming up to operating temperature and de-energizing the EQUIPMENT with an incorporated mains switch closed, or

– for heating elements after warming up to operating temperature and keeping the EQUIPMENT in operation by application of the circuit of Figure 28, and

– immediately after the humidity preconditioning treatment (as described in Sub-clause 4.10) with the EQUIPMENT de-energized during the test and kept in the humidity cabinet, and

– after any required sterilization procedure (see Sub-clause 44.7) with the EQUIPMENT de-energized.

Initially, not more than half the prescribed voltage shall be applied, then it shall be gradually raised over a period of 10 s to the full value, which shall be maintained for 1 min, after which it shall be gradually lowered over a period of 10 s to less than half the full value.

**b) The test voltage shall have a waveform and frequency such that the dielectric stress on the insulation is at least equal to that which would occur if the waveform and the frequency of the test voltage were equal to those of the voltage applied to the various parts in NORMAL USE.*

c) Not used.

d) Not used.

e) Not used.

f) During the test, no flashover or breakdown shall occur. Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, which must be higher, however, than the reference voltage (U) and provided that the discharges do not provoke a drop in test voltage.

**g) Care is taken that the voltage applied to a REINFORCED INSULATION does not overstress BASIC INSULATION or SUPPLEMENTARY INSULATION in the EQUIPMENT.*

h) Where metal foil is applied this is done according to Sub-clause 19.4g) 5).

Care is taken that the metal foil is positioned in such a manner that 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.

**j) Power-consuming voltage-limiting devices, in parallel with an insulation to be tested, are disconnected from the earthed side of the circuit.*

Lamps, electronic tubes, semiconductors or other automatic regulating devices may be removed or rendered inoperative if necessary to carry out the test.

Protective devices connected between the F-TYPE APPLIED PART and the ENCLOSURE are disconnected if they would become operative at the test voltage or below (see Sub-clause 59.3).

k) With the exception of the tests on the insulations described in Sub-clauses 20.1 A-b, 20.1 A-f, 20.1 A-g, 20.1 A-j and 20.2 B-b, the terminals of the MAINS PART, SIGNAL INPUT PART, SIGNAL OUTPUT PART and the APPLIED PART (if applicable) respectively are short-circuited during the test.

l) In the case of motors provided with capacitors where a resonance voltage U_c may 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, a test voltage equal to 2 U_c + 1 000 V shall be applied between the point where the winding and the capacitor are connected together and the ENCLOSURE or conductive parts separated from LIVE parts by BASIC INSULATION only.

During the test, parts not mentioned above are disconnected and the capacitor shall be short-circuited.

*See rationale for 20.4

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21 Mechanical strength

General

For general requirements on design and manufacture of EQUIPMENT see Clauses 3 and 54.

ENCLOSURES including any ACCESS COVERS forming part of them, with all components thereon, shall have sufficient strength and rigidity.

Compliance is checked by application of the following tests:

a) The rigidity of an ENCLOSURE or an ENCLOSURE part, and of any component thereon, is tested by application of an inward directed force of 45 N applied over an area of 625 mm^2 anywhere on the surface.

There shall not be any appreciable damage or reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in Sub-clause 57.10.

b) The strength of an ENCLOSURE or an ENCLOSURE part, and of any component thereon, is tested by application of blows with an impact energy of 0,5 J ± 0,05 J by means of the spring-operated impact test apparatus shown and described in Appendix G.

The release mechanism springs are adjusted so that they exert just sufficient PRESSURE to keep the release jaws in the engaged position.

The test apparatus is cocked by pulling the cocking knob until the release jaws engage with the groove in the hammer shaft. The blows are applied by pushing the release cone against the sample in a direction perpendicular to the surface at the point to be tested.

The PRESSURE is slowly increased so that the cone moves back until it is in contact with the release bars, which then move to operate the release mechanism and allow the hammer to strike.

The EQUIPMENT shall be rigidly supported and three blows shall be applied to every point of the ENCLOSURE that is likely to be weak. The blows shall also be applied to handles, levers, knobs, displays and the like, and to signal lamps and their covers, but only if the lamps or covers protrude from the ENCLOSURE by more than 10 mm or if their surface area exceeds 4 cm^2. Lamps within EQUIPMENT and their covers are tested only if they are likely to be damaged in NORMAL USE.

After the test, any damage sustained shall produce no SAFETY HAZARD; in particular, LIVE parts shall not have become accessible so as to cause non-compliance with the requirements of Section Three, Clause 44 and Sub-clause 57.10. If, as a result of the preceding test, the integrity of SUPPLEMENTARY or REINFORCED INSULATION is in doubt, the relevant insulation only (not the rest of the EQUIPMENT) shall be subjected to a dielectric strength test as specified in Clause 20.

Damage to the finish, small dents which do not reduce CREEPAGE DISTANCES and AIR CLEARANCES below the values specified in Sub-clause 57.10 and small chips which do not adversely affect the protection against electrical shock or moisture shall be ignored.

Cracks not visible to the naked eye and surface cracks in fibre reinforced mouldings and the like shall be ignored.

If a decorative cover is backed by an inner cover, fracture of the decorative cover shall be ignored if the inner cover withstands the test after removal of the decorative cover.

c) Carrying handles or grips furnished on PORTABLE EQUIPMENT shall withstand loading as described in the following test.

The handle and its means of attachment are subjected to a force equal to four times the weight of the EQUIPMENT.

The force is applied uniformly over a 7 cm length of the handle at the centre, without clamping, started at zero and gradually increased so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min.

If more than one handle is furnished on the EQUIPMENT, the force shall be distributed between the handles. The distribution of forces shall be determined by measuring the percentage of the EQUIPMENT mass sustained by each handle with the EQUIPMENT in the normal carrying position. If the EQUIPMENT is furnished with more than one handle but so designed that it may readily be carried by only one handle, each handle shall be capable of sustaining the total force. The handles shall not break loose from the EQUIPMENT and there shall not be any permanent distortion, cracking or other evidence of failure.

21.1 Not used.

21.2 Not used.

21.3 EQUIPMENT parts serving for support and/or immobilization of PATIENTS shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings.

Supporting parts for adult human PATIENTS shall be designed for a PATIENT having a mass of 135 kg (normal load).

Where manufacturers specify particular applications, such as paediatric use, the normal load shall be reduced.

Where breakdown of a PATIENT support constitutes a SAFETY HAZARD, the requirements of Clause 28 shall apply.

Compliance is checked by the following test:

A PATIENT support system shall be positioned horizontally and in the least favourable position consistent with the instructions for use and loaded with weight distributed evenly over the support surface, including any side rails. The weight shall be applied gradually to the system until the required load is in place.

During the test structural members not considered part of the system under test may be provided with additional support.

The weight shall be equal to the required SAFETY FACTOR (see Clause 28) times the specified normal load. Where no normal load is specified, a weight that exerts a force of 1,35 kN shall be considered the normal load for the test. The full load shall act on the support system for a period of 1 min.

There shall be no damage to parts of the support system such as chains, clamps, cords, cord terminations and connections, belts, axles, pulleys and the like that affect protection against a SAFETY HAZARD.

The support system shall be in equilibrium within 1 min after the application of the full test load.

Foot rests and chairs shall be tested by the same procedure, but the test force shall be twice the specified maximum normal load or, if such a load is not specified, the test force shall be 2,7 kN. The test force shall be evenly distributed over an area of 0,1 m^2 surface area for one minute.

At the completion of the test, foot rests and chairs shall show no damage resulting in a SAFETY HAZARD.

21.4 Not used.

21.5 *EQUIPMENT or EQUIPMENT parts which are hand held during NORMAL USE shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.

Compliance is checked by the following test:

The sample to be tested shall be allowed to fall freely once from each of three different starting attitudes from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood > 700 kg/m^3) which lies flat on a rigid base (concrete block).

After the test EQUIPMENT shall comply with the requirements of this Standard.

*See rationale for 21.5

21.6 *PORTABLE and MOBILE EQUIPMENT shall be capable of withstanding the stresses caused by rough handling.

Compliance is checked by the following tests:

a) PORTABLE EQUIPMENT is lifted to a height as indicated in Table VIII above a 50 mm thick hardwood board (see Sub-clause 21.5). The other dimensions of the board shall be at least 1,5 times those of the EQUIPMENT and it shall lie flat on a rigid (concrete) base. The EQUIPMENT is dropped three times from each attitude in which it may be placed in NORMAL USE.

Table VIII
Drop height

Mass of EQUIPMENT (kg)	*Drop height (cm)*
Up to and including 10	*5*
More than 10 up to and including 50	*3*
More than 50	*2*

After the test EQUIPMENT shall comply with the requirements of this Standard.

b) MOBILE EQUIPMENT is propelled, by a force acting at a point as near floor level as possible, in its normal direction of travel at a velocity of 0,4 m/s ± 0,1 m/s, or for self-propelled EQUIPMENT at its maximum velocity, over a descending step 20 mm high, which is rigidly attached to an otherwise flat floor.

The test is performed 20 times after which the EQUIPMENT shall comply with the requirements of this Standard.

This test need not be performed on EQUIPMENT and EQUIPMENT parts tested according to Sub-clauses 21.5 or 21.6 a).

*See rationale for 21.6

22 *Moving parts

*See rationale for 22

22DV D2 *Modification of 22 by adding 22DV.1 – 22DV.4:*

*See rationale for 22DV

22DV.1 Where a risk of injury to the PATIENT or OPERATOR can occur as a result of a moving part, in addition to the other requirements in this clause, there shall be end stops or other mechanical means to act as the ultimate travel limiting means (example: the end points of a movable ceiling suspension).

22DV.2 End stops or other mechanical means shall have the mechanical strength to withstand the conditions of maximum intended loading and reasonably foreseeable abusive operation.

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22DV.3 Compliance with these requirements shall be determined by the following tests.

22DV.4 The EQUIPMENT shall be loaded with (1) the maximum intended load, (2) unloaded, or (3) loaded to any intermediate level that is likely to provide the most severe test result. The moving part is to be driven against each end stop or other mechanical means for the number of cycles and conditions shown in Table 22DV.1. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the following tests.

Table 22DV.1 D2 *Addition:*

Table 22DV.1 – Number of Test Cycles

Construction	No. Cycles	Test Conditions
Motor driven		
1. No limit system provided[a]	**6 000**	**Run at maximum speed**
2. Non-independent limit system or systems provided[a,b]	**50**	**Defeat all switches simultaneously, and run at maximum speed**
3. Two or more independent limit systems[a,b]	**No Test**	
Manually driven or manually driven power assisted	**50**	**Run at any speed, including reasonable overspeed considered to be abusive**

[a] A 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.

[b] To qualify as an independent limit system, each system shall, in addition to the criteria in note[a], comply with both of the following:

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

2. The system provides a means by which a malfunction of one limit system is made obvious to the OPERATOR. This may be an audible, visual or otherwise discernible indicator.

22.1 Not used.

22.2 Moving parts which do not need to be exposed for the operation of EQUIPMENT and which, if exposed, constitute a SAFETY HAZARD shall:

a) in the case of TRANSPORTABLE EQUIPMENT, be provided with adequate guards which shall form an integral part of the EQUIPMENT, or

b) in the case of STATIONARY EQUIPMENT, be similarly guarded unless installation instructions provided by the manufacturer in the technical description require that such guarding or equivalent protection will be separately provided.

Compliance is checked by inspection.

22.3 Cords (ropes), chains and bands shall either be confined so that they cannot run off or jump out of their guiding devices, or a SAFETY HAZARD shall be prevented by other means. Mechanical means applied for this purpose shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

22.4 Movements of EQUIPMENT or EQUIPMENT parts which may cause physical injury to the PATIENT shall be possible only by the continuous activation of the control by the OPERATOR of these EQUIPMENT parts.

Compliance is checked by inspection.

22.4DV D2 *Modification of 22.4:*

In addition to "PATIENT" add "or OPERATOR" to the requirement in this sub-clause.

22.5 Not used.

22.6 Parts subject to mechanical wear likely to result in a SAFETY HAZARD shall be accessible for inspection.

Compliance is checked by inspection.

22.7

– If an electrically produced mechanical movement could cause a SAFETY HAZARD, readily identifiable and accessible means shall be provided for emergency switching of the relevant part of EQUIPMENT.

Such means shall only be recognized as a SAFETY DEVICE if the emergency situation becomes obvious to the OPERATOR and his reaction time is taken into account.

– Operation of an emergency switching or stopping means shall not introduce a further SAFETY HAZARD nor interfere with the complete operation necessary to remove the original SAFETY HAZARD.

– Devices for emergency stopping shall be able to break the full load current of the relevant circuit, taking into account possible stalled motor currents and the like.

– Means for stopping of movements shall operate as a result of one single action.

Compliance is checked by inspection.

22.7DV D2 *Modification to 22.7 by adding the following items:*

– A device intended to be designated as an emergency off, emergency switching or stopping device shall comply with each of the following:

a) The device shall be constructed in accordance with all of the following:

1) The device shall have an actuator, colored red as per 6.7, designed to be distinctive and easily identifiable from that of other controls, and that will open the circuit(s) when actuated,

2) The device, once actuated, shall maintain the EQUIPMENT in the off (open) condition until a deliberate action, different from that used to actuate it, is performed, and,

3) Actuators shall be readily accessible to the OPERATOR and positioned at each operating station.

b) An actuator that interrupts/opens mechanical movements shall be marked with the word "STOP" or with symbol 5110 from IEC 878 (shown below) on or immediately adjacent to, the face of the actuator and shall be marked in compliance with all the requirements (permanence, letter height, and the like) for cautionary markings in Clause 6. A switch need not be marked with the word "STOP" or the equivalent symbol, if the switch interrupts all movements, including the generation of X-rays and any other condition that could result in a risk of injury.

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– The emergency switching means, in the first dashed paragraph shall be separate and independent of the intended movement control.

23 Surfaces, corners and edges

Rough surfaces, sharp corners and edges which may cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection.

24 Stability in NORMAL USE

24.1 EQUIPMENT shall either not overbalance during NORMAL USE when tilted through an angle of 10°, or shall satisfy the requirements of Sub-clause 24.3.

24.2 Not used.

24.3 If EQUIPMENT overbalances when tilted through an angle of 10°, all the following requirements shall be met:

– EQUIPMENT shall not overbalance when tilted through an angle of 5° in any position of NORMAL USE, excluding transport.

– EQUIPMENT shall carry a warning notice stating that transport should only be undertaken in a certain position which shall be clearly described in the instructions for use or illustrated on the EQUIPMENT.

– In the position specified for transport, EQUIPMENT shall not overbalance when tilted to an angle of 10°.

Compliance is checked by application of the following tests, during which EQUIPMENT shall not overbalance.

a) 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 and ACCESSORIES.

EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.

The connection leads shall be laid down on the inclined plane (see tests b) and c)) in the position most unfavourable for stability.

b) If no special transport position with increased stability is specified, EQUIPMENT is placed in any possible position of NORMAL USE on a plane inclined at an angle of 10° to the horizontal plane.

If castors are present, they shall be temporarily fixed in their most disadvantageous position.

Doors and drawers and the like shall be placed in the most disadvantageous position.

c) If a special transport position with increased stability is specified and marked on EQUIPMENT, it is tested as described in the preceding sub-clause, but only in the prescribed transport position on a plane inclined at an angle of 10°.

Furthermore, such EQUIPMENT shall be tested in any possible position of NORMAL USE as described in this sub-clause, but the angle of inclination shall be restricted to 5°.

d) EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.

24.4 Not used.

24.5 Not used.

24.6 Grips and other handling devices

a) EQUIPMENT or EQUIPMENT parts with a mass of more than 20 kg and which need(s) to be handled in NORMAL USE shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where EQUIPMENT can be lifted safely or how it should be handled during assembly.

Where the method of handling is obvious and no SAFETY HAZARDS can develop when this is done, no particular construction or instruction is required.

Compliance is checked by weighing (if necessary) and by inspection of EQUIPMENT and/or the ACCOMPANYING DOCUMENTS.

b) EQUIPMENT specified by the manufacturer as PORTABLE EQUIPMENT with a mass of more than 20 kg shall have (a) carrying-handle(s) suitably placed which enable(s) the EQUIPMENT to be carried by two or more persons.

Compliance is checked by weighing (if necessary) and by carrying.

25 Expelled parts

25.1 Where expelled parts could constitute a SAFETY HAZARD protective means shall be provided.

Compliance is checked by inspection for the presence of protective means.

25.2 A graphical display vacuum tube whose maximum face dimension exceeds 16 cm shall either be intrinsically safe with respect to effects of implosion and to mechanical impact, or the ENCLOSURE of the EQUIPMENT shall provide adequate protection against the effects of an implosion of the tube.

A non-intrinsically safe tube shall be provided with an effective protective screen which cannot be removed without the use of a TOOL; if a separate screen of glass is used, it shall not be in direct contact with the surface of the tube.

The tube shall be tested as specified in IEC Publication 65, unless a certificate of the testing is provided.

26 *Vibration and noise

*See rationale for 26

No general requirement.

27 Pneumatic and hydraulic power

No general requirement.

28 Suspended masses

28.1 *General*

The following requirements concern EQUIPMENT parts suspending masses (including PATIENTS), where a mechanical defect of the means of suspension could constitute a SAFETY HAZARD.

Any moving part shall also comply with the requirements of Clause 22.

28.2 Not used.

28.3 *Suspension system with SAFETY DEVICES*

– Where the integrity of a suspension depends on parts, such as springs, which may, due to their manufacturing process, have hidden defects, or on parts having SAFETY FACTORS not complying with Sub-clause 28.4, a SAFETY DEVICE shall be provided, unless excess travel in the event of breakdown is limited.

– The SAFETY DEVICE shall have SAFETY FACTORS complying with Sub-clause 28.4.2.

– If EQUIPMENT can still be used after failure of suspension means and activation of a SAFETY DEVICE (for example a secondary rope), it shall become obvious to the OPERATOR that the SAFETY DEVICE has been activated.

28.3DV D2 ***Modification to 28.3 by adding the following item:***

– To comply with the requirements of 28.3, EQUIPMENT relying on a SAFETY DEVICE shall additionally be tested as follows:

A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hoses, or the like, employed to support a load, is to be defeated by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the EQUIPMENT. There shall be no evidence of damage to a safety catch or other restraining means that would affect its ability to perform its intended function. If it cannot be demonstrated that a safety catch or other restraining means can perform its intended function after the test, a permanent marking shall be provided in accordance with paragraph below. If the load is a PATIENT, the load is to be as specified by the manufacturer, or 1,33 kN or 136 kgf (300 lbf) if not specified.

The EQUIPMENT shall be marked with signal word "WARNING" and the following text or the equivalent – "For Continued Protection Against Injury to Persons, Repair or Replace Safety Catch (or specific restraining means, as appropriate) After It Has Been Activated. Refer to Instructions in the Service Manual Provided With the Equipment." The marking shall be readily visible during any approach to servicing or resetting of the safety catch. More than one such marking may be required.

28.4 *Suspension systems of metal without SAFETY DEVICES*

If a SAFETY DEVICE is not provided, the construction of the suspension shall comply with the following requirements:

1) The TOTAL LOAD shall not exceed the SAFE WORKING LOAD.

2) Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts shall not be less than 4.

3) Where impairment by wear, corrosion, material fatigue or ageing is expected, relevant supporting parts shall have a SAFETY FACTOR not less than 8.

4) Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTORS, as given in 2) and 3) above shall be multiplied by 1,5.

5) Sheaves, sprockets, bandwheels and guides shall be so designed and constructed that the SAFETY FACTORS of this sub-clause of the suspension system shall be maintained for a specified minimum life till replacement of the ropes, chains and bands.

Compliance with the requirements of Sub-clauses 28.3 and 28.4 is checked by inspection of the design data and any maintenance instructions.

28.4DV.1 D2 ***Modification of 28.4 by replacing the last paragraph with the following:***

Compliance with the requirements of 28.3 and 28.4 is checked by test performance, design data and inspection of any maintenance instructions. Where the complexity of the system is such that the design data can be reasonably evaluated so as to determine that

compliance is met, demonstration of test performance may not be necessary.

28.4DV.2 D2 ***Modification of 28.4 by adding the following:***

To comply with the required SAFETY FACTORS, the suspensions shall be subjected to a loading test. The suspension shall be loaded as in NORMAL USE with its SAFE WORKING LOAD multiplied by the applicable SAFETY FACTORS. There shall be no damage to structural parts that would create a risk of injury to a PATIENT or OPERATOR. The support system shall be in equilibrium one minute after application of the test load. The test may be conducted on previously untested samples.

28.5 ***Dynamic loads***

No general requirement.

*See rationale for 28.5

28.6 Not used.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

General

Radiation from MEDICAL ELECTRICAL EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision may exceed limits normally acceptable for the population as a whole.

Adequate provisions shall be made to protect the PATIENT, OPERATOR and other persons and sensitive devices in the vicinity of the EQUIPMENT from unwanted or excessive radiation from the EQUIPMENT.

Limits for EQUIPMENT intended to produce radiation for diagnostic or therapeutic purpose are specified in Particular Standards.

Requirements and tests will be found in Clauses 29 to 36.

29 X-Radiation

29DV DR ***Modification to 29 by adding the following:***

The requirements of 29.2 shall be considered when evaluating EQUIPMENT. The remaining SECTION FIVE items are considered the responsibility of the proper authorities. See 1.1DV.

29.1

– For diagnostic X-ray EQUIPMENT – See Collateral Standard IEC 601-1-3 (see Appendix L);

– For radiotherapy EQUIPMENT – No general requirement, see relevant Particular Standard.

29.2 For EQUIPMENT not intended to produce X-radiation for diagnostic and therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5 kV shall not produce an exposure exceeding 130 nC/kg (0,5 mR) in 1 h at a distance of 5 cm from any accessible surface of the EQUIPMENT.

Compliance is checked by measurements of exposure or exposure rate with a radiation detector suitable for the energy of the emitted radiation. In order to average the exposure of narrow beams over the appropriate area, the detector shall have an entry window with an area of approximately 10 cm^2.

Controls and adjustments, internal and external, provided for the purpose of altering the value of the relevant HIGH VOLTAGE source(s) in the EQUIPMENT, are set at the position resulting in the maximum emission of X-radiation. Single failures of components causing the least favourable conditions are simulated in turn.

Detailed requirements concerning failure of components may be specified in Particular Standards.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

No general requirement.

31 Microwave radiation

No general requirement.

32 Light radiation (including lasers)

No general requirement.

33 Infra-red radiation

No general requirement.

34 Ultraviolet radiation

No general requirement.

35 Acoustical energy (including ultra-sonics)

No general requirement.

36 *Electromagnetic compatibility

*See rationale for 36

See IEC 601-1-2 (see Appendix L).

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

NOTE – This section has been partly re-written and re-numbered.

37 Locations and basic requirements

37.1 Not used.

37.2 Not used.

37.3 Not used.

37.4 Not used.

37.5 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR: 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 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.

37.6 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE: A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a completely or partly enclosed 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.

37.7 EQUIPMENT or parts thereof specified for use in a location defined in Sub-clause 37.5 shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of Clauses 39 and 40.

37.8 EQUIPMENT or parts thereof specified for use in a location defined in Sub-clause 37.6 shall be CATEGORY APG EQUIPMENT and shall comply with the requirements of Clauses 39 and 41.

Parts of CATEGORY APG EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of Clauses 38, 39 and 40.

Compliance with the requirements of Sub-clauses 37.7 and 37.8 is checked by inspection and by the appropriate tests of Clauses 39, 40 and 41.

These tests shall be made after applicable tests according to Sub-clause 44.7.

38 Marking, ACCOMPANYING DOCUMENTS

38.1 Not used.

38.2 CATEGORY APG EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG", permanently affixed and clearly legible (see Appendix D and Clause 6). The length of the green-coloured band shall be at least 4 cm. The sizes of the marking shall 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.

38.3 Not used.

38.4 CATEGORY AP EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP", permanently affixed and clearly legible (see Appendix D and Clause 6).

The size of the marking shall 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.

38.5 The marking according to Sub-clauses 38.2 and 38.4 shall be present on the major part of the EQUIPMENT if this part is AP or APG. It need not be repeated on detachable parts which can only be used together with the marked EQUIPMENT.

38.6 ACCOMPANYING DOCUMENTS shall contain an indication for the USER enabling him to distinguish the parts of EQUIPMENT (see Sub-clause 38.7) that are categorized AP and APG.

Compliance is checked by inspection (see Sub-clause 6.8).

38.7 On EQUIPMENT in which only certain EQUIPMENT parts are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

Compliance is checked by inspection.

38.8 Not used.

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

39.1 *Electrical connections*

a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORDS shall be according to Sub-clause 57.10, Table XVI, values for SUPPLEMENTARY INSULATION.

b) Connections, except those in the circuits described in Sub-clauses 40.3 and 41.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection and/or disconnection can be performed only with the use of a TOOL.

c) CATEGORY AP EQUIPMENT and CATEGORY APG EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of Sub-clauses 40.3 or 41.3.

Compliance is checked by inspection and/or measurement.

39.2 *Construction details*

a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.

Compliance is checked by inspection.

b) To avoid the likelihood of arcing and sparking due to foreign objects penetrating the ENCLOSURE:

– top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;

– openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;

– openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.

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 shall not enter the ENCLOSURE when applied in all possible directions without appreciable force.

c) Where BASIC INSULATION of electrical conductors 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 SAFETY HAZARD in such a part (see Sub-clause 41.3*a)*).

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) shall be performed and the temperature in the relevant part shall 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.

39.3 *Prevention of electrostatic charges*

a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG EQUIPMENT by a combination of appropriate measures such as:

– the use of antistatic materials with a limited electrical resistance as specified in Sub-clause 39.3*b)*, and

– provision of electrically conductive paths from EQUIPMENT or EQUIPMENT 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.

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO Standard 2882.

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 471, ISO 1853 and ISO 2878.

39.3 *c)* to *j)* Not used.

39.4 *Corona*

Parts and components of EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. which are not included in ENCLOSURES in compliance with Sub-clauses 40.4 or 40.5 shall be so designed that corona cannot be produced.

Compliance is checked by inspection and measurement.

40 Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof

40.1 *General*

EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.

EQUIPMENT, EQUIPMENT parts or components complying with one of the Sub-clauses 40.2 to 40.5 are considered to comply with the requirement of this sub-clause.

EQUIPMENT, EQUIPMENT parts or components complying with the requirements of IEC Publication 79 for pressurized ENCLOSURES (79-2), for sandfilled ENCLOSURES (79-5) or for oil-immersed EQUIPMENT (79-6) as well as with the requirements of this Standard (excluding those of Sub-clauses 40.2 to 40.5), are considered to comply with the requirements for CATEGORY AP EQUIPMENT.

40.2 *Temperature limits*

EQUIPMENT, EQUIPMENT 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 Sub-clause 40.1.

The operating temperatures are measured during the tests mentioned in Section Seven.

40.3 **Low-energy circuits*

EQUIPMENT, EQUIPMENT parts or components which may produce sparks in NORMAL USE and NORMAL CONDITION of the EQUIPMENT (for example, switches, relays, plug connections which can be detached without the use of a TOOL, including connections inside EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of Sub-clause 40.2 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:

$U_{max} \leq U_{zR}$ with a given current I_{zR}, see Figure 29, and

$U_{max} \leq U_{zC}$ with a given capacitance C_{max}, see Figure 30, and

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure 29, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and a $U_{max} \leq 24$ V, see Figure 31.

– The graphs of Figures 29, 30 and 31 have been obtained with the test apparatus according to Appendix F with the most readily flammable mixtures of ether vapour with air (ether volume percentage 4,3 ± 0,2%) for an ignition probability (without SAFETY FACTOR) of 10^{-3}.

– Extrapolation of the graph of Figure 29 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50$ W.

Extrapolation for voltages of more than 42 V is not valid.

– Extrapolation of the graph of Figure 30 is allowed for combinations of capacitances and corresponding voltages within the limitations:

$$\frac{C}{2} U^2 \leq 1.2\,\text{mJ}$$

Extrapolation for voltages of more than 242 V is not valid.

If the equivalent resistance R is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– Extrapolation of the graph of Figure 31 is allowed for combinations of currents and corresponding inductances within the limitations

$$\frac{L}{2} I^2 \leq 0.3\,\text{mJ}$$

Extrapolation for inductances larger than 900 mH is not valid.

– 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 Sub-clause 10.2.2.

– 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 Sub-clause 10.2.2.

– Capacitance C_{max} and inductance L_{max} are taken as the values which occur at the component under investigation which produces sparks in the EQUIPMENT.

– If the circuit is supplied with a.c., the peak value is taken into account.

– 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.

Compliance is checked either by temperature measurement and determination of U_{max}, I_{max}, R, L_{max} and C_{max} and application of Figures 29, 30 and 31, or by examination of the design data.

*See rationale for 40.3

40.4 ***External ventilation with internal overpressure***

Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an ENCLOSURE with external ventilation by means of internal overpressure the following requirements shall apply:

a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR which might have penetrated into the ENCLOSURE of EQUIPMENT or of an EQUIPMENT part shall be removed by ventilation before the EQUIPMENT or EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the EQUIPMENT or the EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).

b) The overpressure inside the ENCLOSURE shall be at least 0,75 hPa 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 which are necessary for the normal operation of EQUIPMENT or of EQUIPMENT parts.

Energizing 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, EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

c) If the overpressure drops below 0,5 hPa during operation, ignition sources shall be de-energized automatically by means which either shall be located in a place where the requirements and tests of Clause 40 do not apply, or comply with the requirements of Clause 40.

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.

Compliance with the requirements of Sub-clauses 40.4a) to 40.4d) is checked by temperature, PRESSURE and flow measurements and inspection of the PRESSURE monitoring device.

*See rationale for 40.4

40.5 *ENCLOSURES with restricted breathing*

Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an ENCLOSURE with restricted breathing the following requirements shall apply:

*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.

b) If the required tightness is obtained by gaskets and/or sealing, the material used shall therefore be resistant to ageing.

Compliance is checked by application of test B-b of IEC Publication 68-2-2, Clause 15, temperature 70°C ± 2°C, duration 96 h.

c) If the ENCLOSURE contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending and/or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see Sub-clause 57.4*a)*).

Compliance with the requirements of Sub-clauses 40.5a), 40.5b) and 40.5c) is checked by application of the following tests:

After completion of the test of Sub-clause 40.5b) if relevant, an internal overpressure of 4 hPa is created and 30 pulls of the value shown in Table IX 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 shall not be reduced to less than 2 hPa.

Table IX
Gas-tightness of cord inlets

Mass of EQUIPMENT (kg)	Pull (N)
Up to and including 1	30
Over 1 up to and including 4	60
Over 4	100

When the ENCLOSURE of 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.

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 shall also be measured.

*See rationale for 40.5

41 Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof

41.1 *General*

EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES 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 Sub-clause 3.6.

EQUIPMENT, EQUIPMENT parts or components which do not comply with the requirements of Sub-clauses 41.3 are tested by a CONTINUOUS OPERATION test over a period of 10 min in an ether/oxygen mixture (ether volume percentage 12,2% ± 0,4%) after the thermal steady state condition has been attained, but not longer than 3 h after switching on.

41.2 **Power supply*

Parts or components of CATEGORY APG EQUIPMENT which operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source which is isolated from earth by at least BASIC INSULATION and from LIVE parts by DOUBLE or REINFORCED INSULATION.

Compliance is checked by inspection of circuit diagrams and measurement.

*See rationale for 41.2

41.3 **Temperatures and low-energy circuits*

EQUIPMENT, and EQUIPMENT parts or components are considered to comply with the requirements of Sub-clause 41.1 without being tested according to Sub-clause 41.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see Sub-clause 3.6):

a) no sparks are produced and no temperatures exceeding 90°C occur, or

b) a temperature limit of 90°C is not exceeded, EQUIPMENT or EQUIPMENT parts contain components which may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but 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}, comply with the following:

$U_{max} \leq U_{zR}$ with a given I_{zR}, see Figure 32, and

$U_{max} \leq U_{zC}$ with given C_{max}, see Figure 33, as well as

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure 32, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and $U_{max} \leq 24$ V, see Figure 34.

– The graphs in Figures 32, 33 and 34 have been obtained with the test apparatus according to Appendix F with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage 12,2 ± 0,4%) for an ignition probability of 10^{-3}. The maximum allowable values of I_{zR} (Figure 32), U_{zC} (Figure 33) and I_{zL} (Figure 34) include a SAFETY FACTOR 1,5.

– Extrapolation of the curves of Figures 32, 33 and 34 is limited to the areas indicated.

– 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 Sub-clause 10.2.2.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in Sub-clause 10.2.2.

– Capacitance C_{max} and inductance L_{max} are taken as values which occur in the relevant circuit.

– If the equivalent resistance R in Figure 33 is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– If the circuit is supplied with a.c., the peak value is taken into account.

– 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.

– If the energy produced in an inductance and/or capacitance in a circuit is limited by voltage-limiting and/or current-limiting devices preventing the limits of Figures 32 and/or 33 and/or 34 being exceeded, two independent components shall be applied, so that the required limitation of voltage and/or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components.

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.

Compliance is checked by inspection, temperature measurements, comparison with design data and/or by measurement of U_{max}, I_{max}, R, L_{max} and C_{max} and using Figures 32, 33 and 34.

*See rationale for 41.3

41.4 *Heating elements*

EQUIPMENT, EQUIPMENT parts and components which 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.

Compliance is checked by the corresponding test of Sub-clause 56.6a).

The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection.

41.5 *Humidifiers*

See ISO 8185.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures

42DV D2 ***Modification of 42 by adding the following:***

Insulating systems (such as on transformers, motors, solenoids, inductors and the like) where the measured temperatures exceed Class A (105°C) limits during NORMAL USE and NORMAL CONDITION shall comply with the requirements in the Standard for Systems of Insulating Materials – General, UL 1446.

*See rationale for 42DV

42.1 *EQUIPMENT parts having a safety function and their environment shall not attain temperatures exceeding the values given in Table XA during NORMAL USE and NORMAL CONDITION over the range of ambient temperatures specified in Sub-clause 10.2.1.

*See rationale for 42.1

Table XA
Allowable maximum temperatures[1)]

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material[2), 3)]	105
– of Class B material[2), 3)]	130
– of Class E material[2), 3)]	120
– of Class F material[2), 3)]	155
– of Class H material[2), 3)]	180
Air adjacent to switches and THERMOSTATS with *T* marking[4), 5)]	T
Natural rubber or polyvinyl chloride insulation of internal and external wiring and flexible cords with *T* marking[4),6)]	T
Motor capacitors with marking of maximum operating temperature (*tc*)	tc-10
Parts in contact with oil having a flash-point of *t*°C	t-25
Batteries (INTERNAL ELECTRICAL POWER SOURCE)	7)
Parts accessible without the use of a TOOL, except for heaters and their guards, lamps, and handles held in NORMAL USE by the OPERATOR	85
Accessible surfaces of handles, knobs, grips and the like of all EQUIPMENT, which in NORMAL USE are continuously held by the OPERATOR:	
– of metal	55
– of porcelain or vitreous material	65
– of moulded material, rubber or wood	75
Accessible surfaces of handles, knobs, grips and the like, which in NORMAL USE are held by the OPERATOR for short periods only (for example, switches):	
– of metal	60
– of porcelain or vitreous material	70
– of moulded material, rubber or wood	85
EQUIPMENT parts which may in NORMAL USE have a brief contact with a PATIENT	50

See explanations after Table XB.

42.2 *EQUIPMENT parts and their environment shall not attain temperatures exceeding the values as given in Table XB when the EQUIPMENT is operated during NORMAL USE and under NORMAL CONDITIONS at an ambient temperature of 25°C.

*See rationale for 42.1

Table XB
Allowable maximum temperatures[1)]

Parts	Maximum temperature °C
Pins of APPLIANCE INLETS:	
– for hot conditions [8)]	155
– for other conditions	65
All terminals for external conductors (see Sub-clause 57.5)[9)]	85
Air adjacent to switches, THERMOSTATS without *T* marking[4)]	55
Natural rubber or polyvinyl chloride insulation of internal and external wiring and flexible cords:	
– if flexing of wiring occurs or is likely	60
– if flexing does not occur or is unlikely	75
Natural rubber used for parts, the deterioration of which could have an effect on safety:	
– when used as SUPPLEMENTARY or REINFORCED INSULATION	60
– in other cases	75
Cord sheaths used as SUPPLEMENTARY INSULATION	60
Material used as electrical insulation other than for wires or windings:	
– impregnated or varnished textile, paper or press board:	95
– laminated bonded with:	
• melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins	110
• urea-formaldehyde resin	90
– mouldings of:	
• phenol-formaldehyde with cellulose fillers	110
• phenol-formaldehyde with mineral fillers	125
• melamine-formaldehyde	100
• urea-formaldehyde	90
– thermoplastic material[10)]	
– polyester with glass-fibre reinforcement	135
– silicone rubber and the like[11)]	
– polytetrafluorethylene	290
– pure mica and tightly sintered ceramic material when such products are used as SUPPLEMENTARY or REINFORCED INSULATION	425
– other materials[13)]	
Materials used as thermal insulation and in contact with hot metal:	
– laminates bonded with:	
• melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins	200
• urea-formaldehyde resin	175
– mouldings of:	
• phenol-formaldehyde with cellulose fillers	200
• phenol-formaldehyde with mineral fillers	225
• melamine-formaldehyde	175
• urea-formaldehyde	175
– other materials[13)]	
Wood in general[12)]	90
Electrolytic capacitors, without a marking for *tc*	65
Other capacitors, without a marking for *tc*	90
Supports, walls, ceiling and floor of the test corner as described in the test of Sub-clause 42.3	90

Explanations for Tables XA and XB:

1) It is recognized that higher maximum temperatures may be allowed for insulating materials under insulating oil and in the absence of air or oxygen.

2) The classification is in accordance with IEC Publication 85.

Examples of Class A material are:

– impregnated cotton, silk, artificial silk and paper; enamels based on oleo or polyamide resins.

Examples of Class B material are:

– glass fibre, melamine and phenol-formaldehyde resins.

Examples of Class E material are:

– mouldings with cellulose fillers, cotton fabric laminates and paper laminates, bonded with melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins;

– cross-linked polyester, cellulose triacetate films, polyethylene terephthalate films;

– varnished polyethylene terephthalate textile bonded with oil-modified alkyd resin varnish;

– enamels based on polyvinylformal, polyurethane or epoxy resins.

Examples of Class F material are:

– glass fibre;

– varnished glass, fibre textile, built-up mica (with or without supporting material), the foregoing impregnated or bonded with alkyd epoxy, cross-linked polyester and polyurethane resins with superior thermal stability or silicone-alkyd resins.

Examples of Class H material are:

– glass fibre;

– varnished glass fibre impregnated or bonded with appropriate silicone resins or silicone elastomer;

– built-up mica (with or without supporting materials), glass fibre laminates, the foregoing impregnated or bonded with appropriate silicone resins.

3) Motors are required to be marked with their insulation classes or certified by the manufacturer. Totally enclosed motors with insulation Class A, B, E, F and H may have maximum temperature values as indicated, plus 5°C.

4) *T* signifies the maximum operating temperature.

5) If so requested by the EQUIPMENT manufacturer switches and THERMOSTATS marked with the letter *T* followed by the value of the temperature limit are considered as being not marked. In this case Table XB applies.

6) This limit will only become applicable when IEC standards for high temperature wires and flexible cords are available.

7) The operating temperature of an INTERNAL ELECTRICAL POWER SOURCE shall not attain a value which causes a SAFETY HAZARD.

Such a value shall be established by consultation with the supplier of the INTERNAL ELECTRICAL POWER SOURCE.

8) The possibility of reducing the maximum temperature of the pins of APPLIANCE INLETS for hot conditions is under consideration. See also IEC Publication 320.

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9) Terminals of TRANSPORTABLE or HAND-HELD EQUIPMENT are excluded.

10) There is no specific limit for thermoplastic material which, however, must comply with the requirements for resistance to heat, fire or tracking, for which purpose the maximum temperature must be determined.

11) As specified by the supplier of the material.

12) The limit is concerned with the deterioration of wood and does not take into account deterioration of surface finishes.

13) Electrical or thermal insulating materials other than those given in Tables XA and XB may be used, subject to the production of evidence from the manufacturer of the suitability of such materials for their intended use.

42.3 APPLIED PARTS of EQUIPMENT not intended to supply heat to a PATIENT shall not have surface temperatures exceeding 41°C.

Compliance with the requirements of Sub-clauses 42.1 to 42.3 is checked by operation of EQUIPMENT and temperature measurements as follows:

1) Positioning and cooling

– Heating 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 shall be at least 115% of the linear dimensions of the EQUIPMENT under test.

The EQUIPMENT is positioned in the test corner as follows:

a) EQUIPMENT normally used on a floor or a table is placed as near to the walls as possible, provided that the manufacturer has not given special instructions concerning its use.

b) EQUIPMENT normally fixed 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, provided the manufacturer has not given special instructions concerning the installation.

c) EQUIPMENT normally fixed to a ceiling is fixed to the ceiling as near to the walls as is likely to occur in NORMAL USE, provided the manufacturer has not given special instructions concerning its installation.

d) Other EQUIPMENT shall be tested in the position of NORMAL USE.

- *HAND-HELD EQUIPMENT is suspended in its normal position, in still air.*
- *EQUIPMENT intended for installation in a cabinet or wall is built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.*

– Generally EQUIPMENT under test is operated at the prevailing ambient temperature, the value of which is measured. If the ambient temperature changes during the test, such a change shall be noted. Where doubts exist concerning the effectiveness of cooling

means the test may have to be conducted at the ambient temperature which represents the least favourable condition, provided that this temperature is within the ambient temperature range specified in Sub-clause 10.2 of this Standard. If cooling liquid is used during the test the conditions of Sub-clause 10.2 shall apply.

2) Supply

– 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.

– Motor operated 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.

– Combined heating and motor operated and other EQUIPMENT shall be tested both at 110% of the maximum RATED voltage and at 90% of the minimum RATED voltage.

3) DUTY CYCLE

The EQUIPMENT is operated:

– for the RATED operating time for EQUIPMENT for SHORT-TIME OPERATION;

– over consecutive cycles of operation until thermal-equilibrium conditions are established for EQUIPMENT for INTERMITTENT OPERATION, the "ON" and "OFF" periods being the RATED "ON" and "OFF" periods;

– for EQUIPMENT for CONTINUOUS OPERATION

a) until the temperature measured according to test 4) described below does not increase in 1 h by more than 2°C;

b) for 2.5 h, whichever is shorter.

4) Temperature measurement

The temperature of windings is determined by the resistance method unless the windings are non-uniform or severe complications are involved in making the necessary connections for the resistance measurement.

In this case the measurement is made by devices so chosen and positioned that they have a negligible effect on the temperature of the part under test.

Devices used for determining the temperature of surfaces of walls, ceiling and floor of the test corner shall be embedded in the surfaces or attached to the back of small blackened disks of copper or brass, 15 mm in diameter and 1 mm thick, which are flush with the surfaces.

As far as possible, EQUIPMENT is positioned so that parts likely to attain the highest temperatures touch the disks.

The value of the temperature rise of a copper winding is calculated from the formula:

$$\Delta t = \frac{R_2 - R_1}{R_1} (234.5 + t_1) - (t_2 - t_1)$$

where:

Δt *is the temperature rise in °C*

R_1 *is the resistance at the beginning of the test in* Ω

R_2 *is the resistance at the end of the test in* Ω

t_1 *is the room temperature at the beginning of the test in °C*

t_2 *is the room temperature at the end of the test in °C*

At the beginning of the test, windings are to be at room temperature. It is recommended that the resistance of windings at the end of the test be determined by taking resistance 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 resistance at the instant of switching off.

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, contact between LIVE *parts and* ACCESSIBLE METAL PARTS*, bridging of insulation or reduction of* CREEPAGE DISTANCES *or* AIR CLEARANCES *below the values specified in Sub-clause 57.10.*

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures may have to be measured.

5) Test criteria

During the test THERMAL CUT-OUTS *shall not be de-activated and shall not operate. At the end of the test the maximum temperature of the parts listed in Table XA is determined taking into account the ambient temperature of the test environment, the temperature of the parts tested and the ambient temperature range specified in Sub-clause 10.2.*

For the EQUIPMENT *parts listed in Table XB the temperatures measured during the test shall, if necessary, be corrected to determine the values which would correspond to operation at an ambient temperature of 25°C.*

42.4 Not used.

42.5 *Guards*

Guards intended to prevent contact with hot accessible surfaces shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

43 Fire prevention

43.1 *Strength and rigidity*

EQUIPMENT shall have the strength and rigidity necessary to avoid a fire hazard which may occur as a result of a total or partial collapse caused by the abuses to which it is liable to be subjected in NORMAL USE.

Compliance is checked by the mechanical strength test for ENCLOSURES (see Clause 21).

43.2 **Oxygen enriched atmospheres*

No general requirement.

*See rationale for 43.2

43.2DV D2 ***Modification of 43.2 by adding 43.2DV.1 – 43.2DV.9.5:***

*See rationale for 43.2DV

43.2DV.1 These requirements only apply to EQUIPMENT that is normally used or recommended for use with oxygen or oxygen enriched atmospheres and for which no particular requirements exist that address the EQUIPMENT'S use with oxygen or oxygen enriched atmospheres. Sub-clause 43.2DV.9 is relevant to installation and the product's end use and can be addressed by their inclusion in the product's operation and installation manual. The manual's reference should cover those details needed to reduce the risk of oxygen related hazards.

43.2DV.2 In order to reduce the risk of fire caused by electrical components which might be a source of ignition in oxygen enriched atmospheres, at least one of the following requirements shall be satisfied in enclosed compartments of EQUIPMENT containing such atmospheres:

– Electrical components shall be separated from compartments in which accumulation of oxygen can occur, by a barrier complying with the requirements of 43.2DV.3 – 43.2DV.3.2.

– Compartments containing electrical components shall be ventilated according to the requirements of 43.2DV.4 – 43.2DV.4.2.

– Electrical components which, in NORMAL USE or SINGLE FAULT CONDITIONS can be a source of ignition, shall comply with the requirements of 43.2DV.5 – 43.2DV.5.2.

43.2DV.2.1 EQUIPMENT that is marked as specified in 43.2DV.7 and 43.2DV.8 or does not contain an oxygen enriched environment within the EQUIPMENT need not comply with 43.2DV.2 – 43.2DV.6.1 and 43.2DV.9.

43.2DV.3 Any barrier required under the provision of 43.2DV.2 and 43.2DV.2.1 shall be sealed at all joints and at any holes for cables, shafts or for other purposes.

43.2DV.3.1 Compliance is checked by inspection and, if applicable, by the compliance test described in 40.5, for ENCLOSURES with restricted breathing.

43.2DV.3.2 The internal overpressure of 4 hPa specified in 40.5 is not applicable when, in NORMAL CONDITION, a PRESSURE difference exists between the spaces separated by the barrier. In such cases the compliance test of 43.2DV.4 – 43.2DV.4.2 applies.

43.2DV.4 The ventilation required under the provisions of 43.2DV.2 and 43.2DV.2.1 shall be such that the oxygen content in the compartment containing electrical components shall not exceed 4 percent volume above the ambient level. If this requirement is met by forced ventilation a ventilation failure alarm shall be provided.

43.2DV.4.1 Compliance is checked by the following test:

43.2DV.4.2 The oxygen concentration is measured under the following conditions and for such a period that the highest possible concentration of oxygen occurs:

– SINGLE FAULT CONDITION.

– The oxygen flow shall be equal to the maximum set-point value in NORMAL USE.

– Selection of the least favorable control settings.

– Mains supply voltage deviations of ±10 percent.

– The measurements shall be repeated after 18 h during which the time the supply voltage shall have been switched off and the gas supply shall have remained on.

– The rate of air exchange in the test room shall be between 3 and 10 times per hour.

43.2DV.5 Electrical circuits which can produce sparks or generate increased surface temperatures or which might otherwise be a source of ignition shall be so designed that no ignition occurs. At least the following requirements shall be satisfied in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS:

– The product of the value of the rms no load voltage and the rms value of the short circuit current shall not exceed 10 VA.

– The surface temperature of components shall not exceed 300°C.

43.2DV.5.1 Compliance is checked by the following test:

43.2DV.5.2 Voltages and currents in steady-state condition are measured or calculated and surface temperatures shall be measured in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

Note – Short- and open-circuiting of resistors, capacitors and inductances complying with the requirements of IEC Publication 65, fourth edition, Clause 14, shall not be considered as SINGLE FAULT CONDITIONS.

43.2DV.6 External exhaust gas outlets shall be located at least 20 cm from any electrical component mounted on the outside of the EQUIPMENT which can spark in NORMAL CONDITION or SINGLE FAULT CONDITION.

43.2DV.6.1 Compliance is checked by inspection and/or measurement.

43.2DV.7 Hospital beds intended for use with oxygen administering EQUIPMENT shall be marked with the following notice or equivalent wording: ″CAUTION – Possible fire hazard when used with oxygen administering equipment of other than the nasal, mask or 1/2 bed length tent type. Oxygen tent should not extend below mattress support level″. An additional statement ″Lock hand control at foot of bed when using oxygen administrating equipment,″ or similar wording shall be included where applicable (see 43.2DV.5 – 43.2DV.5.2). The letter height shall not be less than 2,8 mm (7/64 inch) for the word ″CAUTION″ and not less than 2,4 mm (3/32 inch) for the remainder of the notice. The marking shall be located on the outside vertical surface of the foot panel of the bed where readily visible.

43.2DV.8 When provided on beds intended for use with oxygen administering EQUIPMENT, pendant controls for PATIENT use which have not been found suitable for use in oxygen atmosphere shall be marked ″CAUTION – Possible fire hazard if hand control is not locked at foot of bed when using oxygen administering equipment″, or with an equivalent wording. The letter height shall not be less than 2,8 mm (7/64 inch) for the word ″CAUTION″ and not less than 2,4 mm (3/32 inch) for the remainder of the notice.

43.2DV.9 Installation related items

43.2DV.9.1 The use of oxygen in therapy requires that special care be taken to prevent fire. Any materials which will burn in air and some that will not are easily ignited and burn rapidly in high concentrations of oxygen. Accordingly, for safety it is necessary that all sources of ignition be kept away from EQUIPMENT, such as an incubator, and preferably out of the room in which it is being used. ″NO SMOKING″ signs should be prominently displayed.

43.2DV.9.2 A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under PRESSURE. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen EQUIPMENT.

43.2DV.9.3 On high PRESSURE oxygen cylinders, use only approved reducing or regulating valves marked for oxygen service. Do not use these valves for air or gases other than oxygen, since they may be hazardous when returned to oxygen service. Such EQUIPMENT must be operated strictly in accordance with manufacturer's directions.

43.2DV.9.4 In view of these considerations, and to avoid the necessity for handling heavy cylinders in the nursery, it is recommended that wherever possible, the high PRESSURE oxygen EQUIPMENT be located outside the nursery. In any event, cylinders in use should be fixed in place so they will not be knocked over, and should be located as far as practicable from the incubator.

43.2DV.9.5 Mixtures of oxygen and flammable vapors, such as alcohol, ether, ethylene and cyclopropane may explode if ignited. Such mixtures may be ignited by electrical static spark discharges, or high temperature surfaces, in addition to all other more common sources of ignition. Only EQUIPMENT designed for use in hazardous locations should be used in operating and delivery rooms. Refer to Article 517 of the ANSI/NFPA 70, National Electrical Code, for the use of flammable anesthetics.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

44.1 *General*

The construction of EQUIPMENT shall ensure a sufficient degree of protection against SAFETY HAZARDS caused by overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection.

44.2 *Overflow*

If 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 electrical safety insulation which is liable to be adversely affected by such a liquid, nor shall a SAFETY HAZARD be created. Unless restricted by a marking or by the instructions for use, no SAFETY HAZARDS shall develop if TRANSPORTABLE EQUIPMENT is tilted through an angle of 15°.

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.

TRANSPORTABLE EQUIPMENT is subsequently tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

After these procedures, EQUIPMENT shall show no signs of wetting of uninsulated LIVE parts or electrical insulation of parts which may cause a SAFETY HAZARD. For electrical insulation in case of doubt the EQUIPMENT shall be subjected to the dielectric strength test as described in Clause 20.

44.3 *Spillage*

EQUIPMENT requiring the use of liquids in NORMAL USE shall be so constructed that spillage does not wet parts which may cause a SAFETY HAZARD.

Compliance is checked by the following test:

The EQUIPMENT is placed according to subclause 4.6 a). A quantity of 200 ml of normal tap water is poured steadily on an arbitrary point on the top surface of the EQUIPMENT, for approximately 15 s, from a height not exceeding 5 cm.

After the test, the EQUIPMENT shall comply with all the requirements of this Standard for NORMAL CONDITION.

44.4 **Leakage*

EQUIPMENT shall be so constructed that liquid which might escape in a SINGLE FAULT CONDITION does not cause a SAFETY HAZARD (see also subclause *52.4.1).

Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

Compliance is checked by the following test:

By means of a pipette, drops of water shall be applied to couplings, to seals and to hoses which might rupture, moving parts being in operation or at rest, whichever is least favourable.

After these procedures, the EQUIPMENT shall comply with all the requirements of this Standard for SINGLE FAULT CONDITIONS.

*See rationale for 44.4

44.5 *Humidity*

EQUIPMENT, including any detachable parts, shall be sufficiently proofed against the effects of humidity to which it is liable to be subjected in NORMAL USE.

Compliance is checked by the preconditioning treatment and tests (see Sub-clause 4.10).

44.6 *Ingress of liquids*

ENCLOSURES designed to give a specified degree of protection against harmful ingress of water shall provide this protection in accordance with the classification of IEC Publication 529.

Compliance is checked by the tests of IEC 529.

EQUIPMENT shall withstand the dielectric strength test specified in clause 20. Inspection shall show that water which may have entered EQUIPMENT can have no harmful effect; in particular, there shall be no trace of water on insulation for which CREEPAGE DISTANCES are specified in subclause 57.10.

44.7 *Cleaning, sterilization and disinfection*

For EQUIPMENT parts which come in contact with the PATIENT in NORMAL USE, see Sub-clause 6.8.2*d)*.

EQUIPMENT or EQUIPMENT parts, including APPLIED PARTS and parts into which PATIENTS may exhale, shall be capable of withstanding without damage or deterioration of safety provisions the cleaning, sterilization or disinfection processes which are likely to be encountered in NORMAL USE or which are specified by the manufacturer in the instructions for use.

Should the instructions for use restrict cleaning, sterilization or disinfection to specific methods for the EQUIPMENT as a whole or for parts of it, then only these specified methods shall be applied. See also Sub-clause 6.8.2*d)*.

Compliance is checked by sterilizing or disinfecting the EQUIPMENT or EQUIPMENT parts 20 times in accordance with the methods specified. If no special method of sterilization or disinfection is specified, the test is made with saturated steam at 134°C ± 4°C for 20 cycles, each of 20 min duration (with intervals until EQUIPMENT has cooled to room temperature). There shall be no appreciable signs of deterioration. At the end of the treatment and after an adequate cooling and drying period, EQUIPMENT or parts of it shall withstand the dielectric strength test specified in Clause 20.

44.8 ***Compatibility with substances used with the EQUIPMENT*

No general requirement.

*See rationale for 44.8

45 *PRESSURE vessels and parts subject to PRESSURE

*See rationale for 45

The requirements of this clause apply to vessels and parts subject to PRESSURE, the rupture of which could cause a SAFETY HAZARD.

45.1 Not used.

45.2 *If a PRESSURE vessel has a PRESSURE volume greater than 200 kPa × l, and PRESSURE greater than 50 kPa, it shall withstand the HYDRAULIC TEST PRESSURE.

Compliance is checked by the following tests:

The test PRESSURE shall be the MAXIMUM PERMISSIBLE WORKING PRESSURE multiplied by a factor obtained from Figure 38.

The PRESSURE is raised gradually to the specified test value and shall be held at that value for 1 min. The sample shall not burst nor suffer from permanent (plastic) deformation nor leak. 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.

No leakage is allowed for PRESSURE vessels intended for toxic, flammable or otherwise hazardous substances.

Where pipework and fittings (e.g. of steel and copper) made to relevant National Standards are provided, these may be considered to have adequate strength.

Where unmarked PRESSURE vessels and pipes cannot be hydraulically tested, integrity shall be verified by other suitable tests, e.g. pneumatic using suitable media, at the same test PRESSURE as for the hydraulic test.

*See rationale for 45.2

45.3 *The maximum PRESSURE to which a part can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part.

The maximum PRESSURE in use shall be considered to be whichever is the highest of the following:

a) the RATED maximum supply PRESSURE from an external source;

b) the PRESSURE setting of a PRESSURE-relief device provided as part of the assembly;

c) the maximum PRESSURE that can be developed by an air compressor that is part of the assembly, unless the PRESSURE is limited by a PRESSURE-relief device.

Compliance is checked by inspection.

*See rationale for 45.3

45.4 Not used.

45.5 Not used.

45.6 Not used.

45.7 EQUIPMENT shall incorporate PRESSURE-relief device(s) where excessive PRESSURE could otherwise occur.

A PRESSURE-relief device shall comply with all of the following requirements:

a) it shall be connected as close as possible to the PRESSURE vessel or parts of the system that it is intended to protect;

b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;

c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;

d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;

e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts which may cause a SAFETY HAZARD;

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;

g) there shall be no shut-off valve between a PRESSURE-relief device and the parts that it is intended to protect;

h) the minimum number of cycles of operation shall be 100 000, except for bursting disks.

Compliance is checked by inspection and functional test.

The control device responsible for limiting the PRESSURE in the vessel 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.

45.8 Not used.

45.9 Not used.

45.10 Not used.

46 *Human errors

*See rationale for 46

Not used.

47 Electrostatic charges

Not used.

48 Biocompatibility

Parts of EQUIPMENT and ACCESSORIES intended to come into contact with biological tissues, cells or body fluids, shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Compliance is checked by inspection of the information provided by the manufacturer.

49 *Interruption of the power supply

*See rationale for 49

49.1 THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used if they may cause a SAFETY HAZARD by such resetting.

Compliance is checked by a functional test.

49.2 *EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a SAFETY HAZARD other than interruption of its intended function.

Compliance is checked by interruption and restoration of relevant power supplies.

*See rationale for 49.2

49.3 Means shall be provided to allow the mechanical constraints on a PATIENT to be removed in the event of failure of the SUPPLY MAINS.

Compliance is checked by functional testing.

49.4 Not used.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data

50.1 *Marking of controls and instruments*

Not used. See Sub-clause 6.3.

50.2 *Accuracy of controls and instruments*

Not used.

51 Protection against hazardous output

51.1 ***Intentional exceeding of safety limits***

No general requirement.

*See rationale for 51.1

51.2 ***Indication of parameters relevant to safety***

No general requirement.

*See rationale for 51.2

51.3 *Reliability of components*

Not used (see also Sub-clause 3.6*f*)).

51.4 *Accidental selection of excessive output values*

Where EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, appropriate steps shall be taken to minimize the possibility of a high intensity output being selected accidentally e.g. interlocks in order to achieve deliberate action, separated output terminals.

Compliance is checked by inspection.

51.5 ***Incorrect output***

No general requirement.

*See rationale for 51.5

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

Note – The content of this Section has been augmented and rearranged, to include a wider range of hazards and their possible causes.

52 Abnormal operation and fault conditions

52.1 EQUIPMENT shall be so designed and manufactured that even in SINGLE FAULT CONDITION no SAFETY HAZARD exists (see Sub-clause 3.1 and Clause 13). Additionally the safety of EQUIPMENT incorporating programmable electronic systems is checked by applying the rules of the future IEC Collateral Standard 601-1-4 (see Appendix L).

It is assumed that EQUIPMENT is operated according to the conditions of NORMAL USE, unless specified otherwise in the following tests.

Compliance is fulfilled if:

The introduction of any of the SINGLE FAULT CONDITIONS described in Sub-clause 52.5, one at a time, does not lead directly to any of the SAFETY HAZARDS described in Sub-clause 52.4.

52.2 Not used.

52.3 Not used.

52.4 The following SAFETY HAZARDS shall be taken into consideration:

52.4.1 *

– emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;

– deformation of ENCLOSURES to such an extent that compliance with this Standard is impaired;

– temperatures exceeding the maximal values shown in table XI, during the tests of sub-clauses 52.5.10 *d)* through 52.5.10 *h)*. These temperatures apply for an ambient temperature of 25°C.

Table XI
Maximum temperatures under fault conditions

Parts	Maximum temperatures °C
Walls, ceiling and floor of the test corner[1)]	175
Supply cord[1)]	175
SUPPLEMENTARY and REINFORCED INSULATION other than thermoplastic materials	1,5 times the values shown in Table XB minus 12,5°C
[1)] For motor operated EQUIPMENT without heaters, these temperature measurements are not made.	

Temperatures shall be measured as prescribed in Sub-clause 42.3 *4)*.

The requirements of Sub-clause 52.1 and the corresponding tests shall not be applied to components the construction or the supply circuit of which limits the power dissipation in SINGLE FAULT CONDITION to 15 W or less.

After the test of Sub-clauses 52.5.10*d)* through 52.5.10*h)*, the insulation between the MAINS PART and the ENCLOSURE, when cooled down to approximately room temperature, shall withstand relevant dielectric strength tests.

However the tests according to this sub-clause shall be performed in the sequence indicated in Appendix C (C23, C25, C26, C27).

For SUPPLEMENTARY and REINFORCED INSULATION of thermoplastic materials, the ball-PRESSURE test specified in Sub-clause 59.2*b)* is carried out at a temperature 25°C higher than that measured during these tests.

For EQUIPMENT which is immersed in, or filled with, conducting liquid in NORMAL USE, the sample is immersed in or filled with the conducting liquid or water, as appropriate, for 24 h before the dielectric strength test is made.

After the tests of this section THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

*See rationale for 52.4.1

52.4.1DV DE ***Modification of 52.4.1 by replacing the second paragraph with the following text:***

The requirements of 52.1 and the corresponding tests shall not be applied to components when their construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to 15 W or less.

52.4.2

– Exceeding of the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in Sub-clause 19.3, Table IV;

– Exceeding of the voltage limits in case of a SINGLE FAULT CONDITION (in a BASIC INSULATION) for the parts indicated in Sub-clause 16*a)* 5).

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52.4.3 Starting, interrupting or locking of movements, particularly for EQUIPMENT (parts) supporting, lifting or moving masses (including PATIENTS) and suspension systems of masses in the vicinity of PATIENTS. See also Clauses 21, 22 and 49.

52.5 The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests:

During the insertion of only one fault at a time, AIR CLEARANCES and CREEPAGE DISTANCES for which requirements are specified in this Standard but are less than the specified value shall be short-circuited simultaneously or consecutively in a combination which produces the less favourable result. See also Sub-clauses 17*a)* and 17*g)*.

52.5.1 Overloading of mains supply transformers in EQUIPMENT

Tests are described in Sub-clause 57.9.

52.5.2 Failure of THERMOSTATS

THERMOSTATS are short-circuited or interrupted, whichever is less favourable. See also Sub-clauses 52.5.10 and 56.6 for overloading situations.

52.5.3 Short-circuiting of either constituent part of a DOUBLE INSULATION

Each constituent part of a DOUBLE INSULATION is short-circuited independently.

52.5.4 Interruption of the PROTECTIVE EARTH CONDUCTOR

Tests are described in Sub-clause 19.4.

52.5.5 Impairment of cooling

Contrary to possible statements in the instructions for use impairments of cooling which may occur in practice are simulated, for example:

– single ventilation fans are locked consecutively;

– ventilation through openings in top and sides is impaired by,

- *covering of openings in the top of the ENCLOSURE, or*
- *positioning of EQUIPMENT against walls;*

– blocking of filters is simulated;

– the flow of a cooling agent is interrupted.

Temperatures shall not exceed 1,7 times the values of Clause 42, Tables XA and XB, minus 17,5°C. Test conditions of Clause 42 are applied as far as possible.

52.5.6 Locking of moving parts

Moving parts are locked if EQUIPMENT:

– has accessible moving parts liable to be jammed, or

– is liable to be operated while unattended (this includes EQUIPMENT which is automatically or remotely controlled), or

– has one or more motors with a locked rotor torque smaller than the full load torque.

If EQUIPMENT has more than one moving part as described above, only one part at a time is locked. For further test requirements see Sub-clause 52.5.8.

52.5.7 *Interruption and short-circuiting of motor capacitors

Motors with a capacitor in the circuit of an auxiliary winding are operated with a locked rotor, with the capacitor short-circuited or open-circuited in turn.

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC Publication 252 and EQUIPMENT is not intended for unattended use (including automatic or remote control).

For further tests, see Sub-clause 52.5.8.

*See rationale for 52.5.7

52.5.8 *Additional tests for motor operated EQUIPMENT

For every test in the SINGLE FAULT CONDITION of Sub-clauses 52.5.6 and 52.5.7, taking into account the exemptions stated in Sub-clause 52.4.1, motor-operated EQUIPMENT shall be operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:

a) 30 s for:

– HAND-HELD EQUIPMENT,

– EQUIPMENT which has to be kept switched on by hand,

– EQUIPMENT which has to be kept under physical load by hand;

b) 5 min for other EQUIPMENT not intended for unattended use;

c) for the maximum period of a timer, if such a device terminates the operation, for EQUIPMENT not listed under a) or b);

d) as long as necessary, to establish steady thermal conditions for all the remaining EQUIPMENT.

Note – EQUIPMENT which is automatically or remotely controlled is regarded as EQUIPMENT for unattended use.

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.

Temperatures are measured as specified in subclause 42.3 4).

Temperatures shall not exceed the limits of Table XII.

Table XII
Temperature limits of motor windings, in °C

Type of EQUIPMENT	Insulation class				
	Class A	Class B	Class E	Class F	Class H
EQUIPMENT provided with a timer and not intended for unattended use and EQUIPMENT to be operated for 30 s or 5 min	200	225	215	240	260
Other EQUIPMENT					
– if impedance-protected, maximum value	150	175	165	190	210
– if protected by protection devices which operate during the first hour, maximum value	200	225	215	240	260
– after the first hour, maximum value	175	200	190	215	235
– after the first hour, arithmetic average	150	175	165	190	210

*See rationale for 52.5.8

52.5.9 *Failure of components*

Failure of one component at a time, which failure could cause a SAFETY HAZARD as mentioned in Sub-clause 52.4, is simulated.

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

Capacitors (X1 and X2) complying with IEC 384-14, which are connected between parts of opposite polarity of the MAINS PART, are exempted from this requirement. Thus, failure of such capacitors shall not be simulated.

NOTE – For information concerning X1 and X2, see IEC 384-14, subclause 1.5.3.

52.5.10 *Overload*

a) EQUIPMENT having heating elements is checked for compliance as follows:

1) for thermostatically controlled EQUIPMENT having heating elements, which is intended for built-in or for unattended operation, or which has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of Sub-clauses 52.5.10c) and 52.5.10d);

2) for EQUIPMENT having heating elements with short-time rating:

by the tests of Sub-clauses 52.5.10c) and 52.5.10e);

3) for other EQUIPMENT having heating elements:

by the test of Sub-clause 52.5.10c).

If more than one of the tests is applicable to the same EQUIPMENT, these tests shall be made consecutively.

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 steady conditions are 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 shall be 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. Both samples shall comply with the conditions specified in Sub-clause 52.4.1.

b) EQUIPMENT having motors is checked for compliance as follows:

1) for the motor part of the EQUIPMENT, by the tests of Sub-clauses 52.5.5 through 52.5.8 and 52.5.10f) through 52.5.10h), as applicable;

2) for EQUIPMENT containing motors as well as heating parts, the tests shall be performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition;

3) if more than one of the tests is applicable for the same EQUIPMENT, these tests are made consecutively.

c) EQUIPMENT having heating elements is tested under the conditions specified in Clause 42, but without adequate heat discharge, the supply voltage being 90% or 110% of the RATED supply voltage, whichever is the least favourable.

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before steady thermal conditions are established, the operating period is ended. If interruption of the current does not occur, EQUIPMENT shall be switched off as soon as steady thermal conditions are established and shall be allowed to cool to approximately room temperature.

For EQUIPMENT with short-time rating, the duration of the test shall be equal to the RATED operating time.

d) Heating parts of EQUIPMENT are tested under all of the following conditions:

1) as specified in Clause 42;

2) with the EQUIPMENT operated in NORMAL CONDITION;

3) with a supply voltage being 110% of the RATED supply voltage;

4) disabling any control which serves to limit the temperature required in Section Seven, except a THERMAL CUT-OUT;

5) if the EQUIPMENT is provided with more than one control, they are disabled in turn.

e) Heating parts of EQUIPMENT are additionally tested under all of the following conditions:

1) as specified in Clause 42;

2) with the EQUIPMENT operated in NORMAL CONDITION;

3) with a supply voltage being 110% of the RATED supply voltage;

4) without any control which serves to limit the temperature required in Section Seven disabled;

5) until steady thermal conditions are established, irrespective of the RATED operating time.

f) Motors are checked for running overload protection if they are:

1) intended to be remotely controlled or automatically controlled, or

2) liable to be operated continuously whilst unattended,

by operating EQUIPMENT under normal load conditions at RATED voltage or at the maximum of the RATED voltage range, until steady thermal conditions are achieved (see Section Seven).

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.

When steady thermal conditions are 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.

The motor winding temperature is determined during each steady period and the maximum value recorded shall not exceed:

Insulation class	A	B	E	F	H
Maximum temperature °C	140	165	155	180	200

If the load cannot be changed in appropriate steps in EQUIPMENT, the motor is removed from the EQUIPMENT in order to perform the test.

g) EQUIPMENT RATED for SHORT-TIME or INTERMITTENT OPERATION other than:

– HAND-HELD EQUIPMENT;

– EQUIPMENT which has to be kept switched on by hand;

– EQUIPMENT which has to be kept under physical load by hand;

– EQUIPMENT with a timer and a back-up system;

is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until steady thermal conditions are established, or until the protective device operates.

Motor winding temperatures are determined when steady thermal conditions are established or immediately before the operation of the protective device and shall not exceed the values specified in Sub-clause 52.5.8.

If in NORMAL USE a load-reducing device in EQUIPMENT operates, the test is continued with EQUIPMENT running idle.

h) EQUIPMENT with three-phase motors is operated with normal load, connected to a three-phase (SUPPLY MAINS) with one phase disconnected. Periods of operation shall be according to Sub-clause 52.5.8.

53 ENVIRONMENTAL TESTS

See Sub-clause 4.10 and Clause 10.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

54 *General

*See rationale for 54

The following requirements in Section Ten specify details of the electrical and mechanical construction insofar as the safety of EQUIPMENT is concerned.

The aim is to specify requirements in such a manner as to allow manufacturers the widest possible choice in design and construction.

As allowed in Sub-clause 3.4, a manufacturer may make use of materials and constructions differing from those detailed in this Section, if an equivalent degree of safety is obtained. The requirements of this Section are considered as not more than one means of achieving the required degree of safety and the term ″shall″, where used, should be understood accordingly.

54DV DE *Modification of 54 by replacing the second sentence of the third paragraph with the following text:*

The requirements of this section are not to be considered the only means of achieving the required degree of safety and the term ″shall,″ where used, should be understood accordingly.

54.1 * *Arrangements of functions*

Not used.

*See rationale for 54.1

54.2 ***Serviceability***

Not used.

*See rationale for 54.2

54.3 ***Inadvertent changing of settings***

Not used.

*See rationale for 54.3

55 ENCLOSURES and covers

Not used. See Clauses 16, 21 and 24.

55DV D2 *Addition of 55DV.1 – 55DV.5:*

*See rationale for 55DV

55DV.1 The following requirements are additionally used to evaluate polymeric ENCLOSURES and covers:

No Text on This Page

55DV.2 Conductive coatings applied to nonmetallic surfaces shall comply with the applicable requirements in the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C, unless it can be determined by investigation that flaking or peeling of the coating does not result in the reduction of spacings or the bridging of LIVE parts that may present a risk of injury.

55DV.3 Flame Spread

55DV.3.1 An external surface of combustible material having an area of more than 9,47 m^2 (100 ft^2) or a single dimension of 3,7 m (12 ft) – including a diagonal – shall have a flame spread rating of 75 or less when subjected to the Steiner Tunnel Test in ASTM E 84, Test Method for Surface Burning Characteristics of Building Materials).

55DV.3.2 An external surface of combustible material having an area of more than 4,74 m^2 (50 ft^2) but not exceeding 9,47 m^2 (100 ft^2) shall have a flame spread rating of 75 or less when subjected to the radiant panel test (ASTM E 162, Test Method for Surface Flammability of Materials Using a Radiant Heat Energy Source), or the steiner tunnel test (ASTM E 84, Test Method for Surface Burning Characteristics of Building Materials).

55DV.4 Flammability, Mechanical Abuse and Mold Stress Relief

55DV.4.1 In addition to the other requirements in this Standard, flammability, mechanical abuse and mold stress tests shall be conducted. Polymeric ENCLOSURES and covers shall comply with the requirements for resistance to impact and drop as indicated below, and the requirements for mold stress release distortion, in the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C. The minimum flammability rating for TRANSPORTABLE EQUIPMENT shall be V-2, and V-0 for FIXED EQUIPMENT or STATIONARY EQUIPMENT.

55DV.4.2 Flammability tests are not required for ENCLOSURES housing only circuits supplied from a source, which is separated from the SUPPLY MAINS, by one of the methods described in 17 g), and where the available power does not exceed 15 W.

55DV.4.3 The top, sides, and front of the ENCLOSURE shall withstand a single impact of 6,78 N·m (5 ft-lb) without exposing LIVE electrical components or connections or developing a risk of electric shock, fire, or injury to persons. The impact applied is to be obtained from a solid, smooth, steel sphere 50,8 mm (2 inch) in diameter and weighing approximately 0,535 kg (1,18 lb). The sphere is allowed to fall freely from rest through the distance required to cause it to strike the top of the ENCLOSURE with an impact of 6,78 N·m (5 ft-lb). For surfaces other than the top of the ENCLOSURE the sphere is to be suspended by a cord and allowed to fall as a pendulum through the distance required to strike the surface with the specified impact. The ENCLOSURE is placed so that the surface tested is vertical and in the same vertical plane as the point of support of the pendulum. Parts of the ENCLOSURE that may interfere with the cord of the pendulum are to be removed.

55DV.4.4 An appliance intended to be hand-held or hand-guided shall withstand a drop test without exposing LIVE electrical components or connections or developing a risk of electric shock, fire, or injury to persons. Each of three samples of the appliance is to be dropped three times from a height of 1,22 m (4 ft) onto a tile covered concrete surface, in such manner as to test the component whose failure would create a risk of fire or electric shock in the most severe manner.

55DV.5 See also Clause 16, Clause 21 and subclause 59.2.

55.1 ***Materials***

Not used.

*See rationale for 55.1

55.2 ***Mechanical strength***

Not used.

*See rationale for 55.2

55.3 *ACCESS COVERS*

Not used.

55.4 *Grips and other handling devices*

Not used. Moved to Sub-clauses 21*c)* and 24.6.

56 Components and general assembly

56.1 *General*

a) Not used.

**b) Marking of components*

Ratings of components shall not conflict with the conditions of use in EQUIPMENT.

All components in the MAINS PART and in the APPLIED PART shall be marked or otherwise identified so that their ratings can be ascertained.

The markings may be integral with the parts themselves, or made available by reference to construction drawings, parts lists, or in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ratings of components to ascertain that no conflict exists with the condition of use in EQUIPMENT.

c) Supporting of components

Not used.

d) Component fixing

Components, the unwanted movement of which could result in a SAFETY HAZARD, shall be mounted securely to prevent such movement.

Compliance is checked by inspection.

e) Resistance of components to vibration.

Not used.

f) Fixing of wiring

Conductors and connectors shall be so secured and/or insulated that accidental detachment shall not result in a SAFETY HAZARD. 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 giving rise to a SAFETY HAZARD.

One instance of breaking free shall be considered to be a SINGLE FAULT CONDITION.

Compliance is checked by inspection.

*See rationale for 56.1

56.2 *Screws and nuts*

Not used.

56.3 *Connections – General*

For connections and connectors in the MAINS PART see Sub-clauses 57.2 and 57.5.

a) Construction of connectors

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 SAFETY HAZARD may be caused.

– Connectors shall comply with Sub-clause 17*g).*

– Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets on the same EQUIPMENT intended for other functions, unless it can be proven that no SAFETY HAZARD can result.

– Medical gas connections on EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also Sub-clause 6.6 and ISO Recommendation R407.

Compliance is checked by inspection, if possible by interchanging of connections, to establish the absence of a SAFETY HAZARD (LEAKAGE CURRENT exceeding the values in NORMAL CONDITION, movement, temperature, radiation, etc.).

b) Connections between different parts of EQUIPMENT. See also Clause 58.

Detachable flexible cords used for interconnection of different parts of EQUIPMENT shall be provided with means for connection such that ACCESSIBLE METAL PARTS cannot become LIVE when a connection is loosened or broken due to the disengagement of one of the connecting means.

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to Sub-clause 16a).

*c) Any connector in a lead having a CONDUCTIVE CONNECTION to a PATIENT shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that part of the said connector which is remote from the PATIENT can contact earth or possibly hazardous voltages.

Compliance is checked by inspection and by applying to the CONDUCTIVE CONNECTION *of that part of the connector identified above those of the following tests which are applicable:*

– the said part shall not come into contact with a flat conductive surface of not less than 100 mm diameter;

– for single-pole connectors, the straight unjointed test finger with the same dimensions as the standard test finger of figure 7 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 ± 2 N;

– 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.*

*See rationale for 56.3

56.3DV DR *Modification of item (a) by adding 56.3DV.1 and 56.3DV.2:*

*See rationale for 56.3DV

56.3DV.1 A connector, plug, pin, or the like that is attached to a PATIENT-connected lead or contact shall be constructed so that it cannot engage any part on the EQUIPMENT – including a separable cord set – that can introduce a risk of electric shock, fire, or injury to persons.

56.3DV.2 In addition to the above requirement, a connector, plug, pin or the like that is attached to a PATIENT-connected lead or contact, and that is used with a product that may be used without professional supervision, shall be constructed so that it cannot be inserted or otherwise manipulated to make contact with the LIVE parts of a power receptacle outlet or separable cord set.

56.4 **Connections of capacitors*

– Capacitors shall not be connected between LIVE parts and non-PROTECTIVELY EARTHED ACCESSIBLE PARTS where the failure of such a capacitor could result in ACCESSIBLE PARTS becoming LIVE.

– Capacitors connected directly between the MAINS PART and PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS shall comply with the requirements of IEC Publication 384-14 or equivalent.

– The enclosure of capacitors connected to the MAINS PART and providing only BASIC INSULATION shall not be secured directly to non-PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS.

– Capacitors or other spark-suppression devices shall not be connected between the contacts of THERMAL CUT-OUTS.

Compliance is checked by inspection.

*See rationale for 56.4

56.5 *Protective devices*

EQUIPMENT shall not be fitted with protective devices which cause disconnection of the EQUIPMENT from the SUPPLY MAINS by producing a short-circuit which results in operation of an overcurrent protection device. See also Sub-clause 59.3.

Compliance is checked by inspection.

56.6 *Temperature and overload control devices*

a) Application

– THERMAL CUT-OUTS with a safety function which have to be reset by a soldering operation which may affect the operating value shall not be fitted in EQUIPMENT.

– Thermal SAFETY DEVICES shall be provided where necessary to prevent operating temperatures exceeding the limits specified in Section Nine and in Sub-clause 57.9.

– Where a failure of a THERMOSTAT could constitute a SAFETY HAZARD 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 but shall be within the safe temperature limit for its intended function.

– Where the consequent loss of function of EQUIPMENT caused by operation of a THERMAL CUT-OUT presents a SAFETY HAZARD, an audible warning shall be given.

Compliance is checked by inspection and, if applicable, by the following tests:

Thermal SAFETY DEVICES may be tested separately from EQUIPMENT.

THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be tested by operating the EQUIPMENT under the conditions described in Section Nine.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES shall be caused to operate 200 times.

Non-self resetting OVER-CURRENT RELEASES shall be caused to operate 10 times.

During the tests, forced cooling and resting periods may be introduced to prevent damage to the EQUIPMENT. After the tests, the samples shall show no damage impairing their further use.

EQUIPMENT which incorporates a fluid filled container having heating facilities shall be provided with a SAFETY DEVICE to safeguard against overheating in the event of the heater being switched on with the container empty, if dangerous overheating can occur in the absence of fluid.

Compliance is checked by operating the relevant EQUIPMENT with an empty container. No overheating shall occur which causes damage to the EQUIPMENT resulting in a SAFETY HAZARD.

b) Temperature settings

– Where means are provided for varying the temperature setting of THERMOSTATS, the temperature setting shall be clearly indicated.

– The operating temperature of THERMAL CUT-OUTS shall be clearly indicated.

Compliance is checked by inspection.

56.7 *Batteries*

a) Housing

Housings containing batteries from which gases can escape during charging or discharging shall be ventilated to minimize the risk of accumulation and ignition.

Battery compartments shall be designed to prevent the risk of accidentally short-circuiting the battery where such short circuits could result in a SAFETY HAZARD.

Compliance is checked by inspection.

b) Connection

If a SAFETY HAZARD might develop by the incorrect connection or replacement of a battery, EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also Sub-clause 6.2*d)*.

Compliance is checked by:

1) Establishing whether there is a possibility of making an incorrect battery connection.

2) Where such a possibility exists, establishing the effect of an incorrect battery connection.

**c) Battery state*

No general requirement.

*See rationale for 56.7

56.8 *Indicators*

Unless indication is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided:

– to indicate that EQUIPMENT is energized (see subclause 6.3 *a)*).

– On EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operative if a SAFETY HAZARD could result.

This does not apply to heated stylus-pens for recording purposes.

– To indicate that an output exists where an inadvertent or prolonged operation of the output circuit could constitute a SAFETY HAZARD.

Colours, of indicator lights are described in Sub-clause 6.7.

In EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE the charging mode shall be visibly indicated to the OPERATOR.

No Text on This Page

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

56.9 *Pre-set controls*

Not used.

56.10 *Actuating parts of controls*

a) Protection against electric shock

ACCESSIBLE PARTS of electrical controls shall comply with the requirements of Sub-clause 16*c)*.

b) Fixing, prevention of maladjustment

– All actuating parts shall be so secured that they cannot be pulled off or work loose during NORMAL USE.

– Controls, the adjustment of which can present a SAFETY HAZARD to the PATIENT or OPERATOR while EQUIPMENT is in use, shall be so secured that the indication of any scale always corresponds with the position of the control.

The indication in this case refers to ″On″ or ″Off″ position, scale markings or other indications of position.

– 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.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table XIII shall be applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test shall be repeated 10 times.

The knob shall not rotate with respect to the shaft.

If an axial pull is likely to be applied 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.*

Table XIII
Test torques for rotating controls

Gripping diameter of control knob (mm)	Torque (Nm)
10≤d<23	1,0
23≤d<31	1,8
31≤d<41	2,0
41≤d<56	4,0
56≤d≤70	5,0

c) Limitation of movement

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a SAFETY HAZARD.

Compliance is checked by inspection and manual tests. For rotating controls the torques as shown in Table XIII shall be applied for not less than 2 s in each direction alternately. The test shall be repeated 10 times.

No SAFETY HAZARD shall develop if an axial pull is likely to be applied in NORMAL USE. Compliance shall be checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

56.11 *Cord-connected hand-held and foot-operated control devices*

a) Limitation of operating voltages

Hand-held and foot-operated control devices and associated connection cords shall contain only conductors and components operating at voltages not exceeding 25 V a.c. or 60 V d.c. or peak value in circuits isolated from the MAINS PART by one of the means specified in Sub-clause 17*g)*.

Compliance is checked by inspection and, if necessary, voltage measurements.

b) Mechanical strength

– Hand-held control devices shall comply with the requirement and test of Sub-clause 21.5.

– Foot-operated control devices shall be able to support the weight of an adult human being.

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 625 mm^2. There shall be no damage to the device resulting in a SAFETY HAZARD.

c) Inadvertent operation

Hand-held and foot-operated control devices shall not change their control setting when inadvertently placed in an abnormal position.

Compliance is checked by turning the device in all possible abnormal positions and placing it as such on a supporting surface. There shall not be any inadvertent change of control setting resulting in a SAFETY HAZARD.

d) Entry of liquids

– Foot-operated control devices shall be at least IPX1 according to IEC 529.

Compliance is checked by the tests of IEC 529.

– The electrical switching parts of foot-operated control devices of EQUIPMENT, specified by the manufacturer for use in operating rooms, shall be IPX8 according to IEC 529.

Compliance is checked by the tests of IEC 529.

e) Connection cords

The connection and anchorage of a flexible cord to a hand-held or foot-operated control device at the entry point to the control device shall comply with the requirements specified for POWER SUPPLY CORDS in Sub-clause 57.4.

Compliance is checked by performance of the tests of Sub-clause 57.4.

57 MAINS PARTS, components and layout

57DV DR *Modification to 57 by adding the following:*

*See rationale for 57DV

57DV.1 General

57DV.1.1 Permanently connected EQUIPMENT shall have provision for the connection of one of the wiring systems that is in accordance with the National Electrical Code, ANSI/NFPA 70.

57DV.1.2 Fixed and stationary X-ray EQUIPMENT supplied from a branch circuit RATED at 30 A or less, and EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord – such as Type S, or the equivalent, for supply connection.

57.1 *Isolation from the SUPPLY MAINS*

a) Isolation

– EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously. This isolation shall include each LIVE supply conductor, except that PERMANENTLY INSTALLED EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device which does not interrupt the neutral conductor, but only if local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed extra-low voltage.

– Means for isolation shall either be incorporated in EQUIPMENT or, if external, shall be specified in the ACCOMPANYING DOCUMENTS (see Sub-clause 6.8.3).

b) Not used.

c) Not used. See Sub-clause 57.1*a)*.

d) Switches that are used to comply with Sub-clause 57.1*a)* shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC Publication 328.

e) Not used.

f) Mains switches shall not be incorporated in a POWER SUPPLY CORD or any other external flexible lead.

g) The directions of movement of the actuators of switches that are used to comply with Sub-clause 57.1*a)* shall comply with IEC Publication 447.

h) In non-PERMANENTLY INSTALLED EQUIPMENT a suitable plug device used to isolate EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of Sub-clause 57.1*a)*.

APPLIANCE COUPLERS and flexible cords with MAINS PLUGS are suitable plug devices.

j) Not used. See Sub-clause 57.1*a)*.

k) Not used.

l) Not used.

m) Fuses and semiconductor devices shall not be used as isolating devices in the sense of this sub-clause.

Compliance is checked by inspection.

Table XIV. Not used.

57.2 *MAINS CONNECTORS, APPLIANCE INLETS and the like*

a) Not used.

**b) Construction*

No general requirement.

c) Not used.

d) Not used.

*e) AUXILIARY MAINS SOCKET OUTLETS on non-PERMANENTLY INSTALLED EQUIPMENT, intended for the provision of mains supply to other EQUIPMENT, or to separated parts of EQUIPMENT shall be of a type that cannot accept a MAINS PLUG. See also Sub-clause 56.3.

This requirement does not apply to EMERGENCY TROLLEYS, on which however the number of such sockets shall be limited to 4.

These AUXILIARY MAINS SOCKET-OUTLETS shall be properly marked (see Sub-clause 6.1 *k)*).

Compliance is checked by inspection.

f) Not used.

*g) Except where a functional earth needs to be provided, CLASS I APPLIANCE INLETS shall not be used in CLASS II EQUIPMENT.

*See rationale for 57.2

57.2DV D1 *Modification of 57.2 by adding 57.2DV.1 – 57.2DV.6:*

*See rationale for 57.2DV

57.2DV.1 For PATIENT care EQUIPMENT, where a "Hospital Grade" or "Hospital Only" MAINS PLUG exists for the particular electrical rating in question, the MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT with a protective earth connection shall comply with the requirements for a hospital grade attachment plug (MAINS PLUG) or the non-hazardous location locking type designated "Hospital Only" as specified in the Standard for Attachment Plugs and Receptacles, UL 498 and the product shall comply with 57.2DV.2.

57.2DV.2 Cord connected EQUIPMENT employing ″Hospital Only″ or ″Hospital Grade″ attachment plugs shall be provided with instructions to indicate that grounding reliability can only be achieved when the EQUIPMENT is connected to an equivalent receptacle marked ″Hospital Only″ or ″Hospital Grade″. The necessary instructions shall be included on the EQUIPMENT itself or on a tag attached to the supply cord of the EQUIPMENT.

57.2DV.3 For EQUIPMENT intended for radiography and in which the plug constitutes the control-disconnecting means, the attachment plug shall be acceptable for a current not less than 50 percent of the maximum current input to the EQUIPMENT for radiographic settings.

57.2DV.4 Except for X-ray EQUIPMENT, the attachment plug shall be acceptable for use with a current not less than 125 percent of the RATED current, when measured at a voltage equal to the RATED voltage of the EQUIPMENT (corresponding to the plug cap configuration). If the EQUIPMENT is intended for being adapted for use on two or more different values of voltage by field alteration of internal connections, the attachment plug provided with the EQUIPMENT shall be acceptable for the voltage for which the EQUIPMENT is configured to be connected when shipped from the factory.

57.2DV.5 When a polarized attachment plug is used, the circuit conductors in the flexible cord shall be connected to the plug and to the wiring in the EQUIPMENT so that any of the following devices used in the primary circuit shall be connected in an ungrounded side of the line: the center contact of an edison-base lampholder, a single pole switch, an automatic control with a marked off position, a solitary fuseholder, and any other single-pole overcurrent protective device.

57.2DV.6 When a second fuseholder or other overcurrent protective device is provided in the application, it may be placed in the grounded side of the line.

57.3 *POWER SUPPLY CORDS*

a) Application

– EQUIPMENT shall not be provided with more than one connection to a particular SUPPLY MAINS.

– If a facility for alternative connection to a different supply system, e.g. external battery, is provided no SAFETY HAZARD shall occur when more than one connection is made simultaneously.

– MAINS PLUGS shall not be fitted with more than one POWER SUPPLY CORD.

– EQUIPMENT which is not intended to be permanently connected to fixed wiring shall be provided with either a POWER SUPPLY CORD or an APPLIANCE INLET.

Compliance is checked by inspection.

b) Types

POWER SUPPLY CORDS shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC Publication 245, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC Publication 227, designation 53).

Polyvinyl chloride insulated POWER SUPPLY CORDS shall not be used for EQUIPMENT having external metal parts with a temperature exceeding 75°C and which may be touched in NORMAL USE by the cord, unless it is RATED for that temperature (see also Table XB).

Compliance is checked by inspection and measurement.

c) Cross-sectional area of conductors

The NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS shall be not less than that shown in Table XV.

Compliance is checked by inspection.

Table XV
NOMINAL cross-sectional area of POWER SUPPLY CORDS

RATED current of EQUIPMENT (A)	NOMINAL cross-sectional area (mm^2 Cu)
Up to and including 6	0,75
over 6 up to and including 10	1
over 10 up to and including 16	1,5
over 16 up to and including 25	2,5
over 25 up to and including 32	4
over 32 up to and including 40	6
over 40 up to and including 63	10

d) Preparation of conductors

Stranded conductors shall not be soldered if fixed by any clamping means.

Compliance is checked by inspection.

57.3DV D2 ***Modification of 57.3 by replacing the text of items (b) and (c) with the following:***

b) Types

A DETACHABLE POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected EQUIPMENT) shall be of a type that can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a SAFETY HAZARD to a PATIENT or OPERATOR. A POWER SUPPLY CORD shall comply with the following requirements:

1) The flexible cord shall be of a type that is acceptable for the particular application. It shall be acceptable for use at a voltage not less than the RATED voltage of the appliance and shall have an ampacity, as given in the National Electrical Code, ANSI/NFPA 70, not less than the current rating of the appliance. It shall be constructed in accordance with the Standard for Flexible Cords and Fixture Wire, UL 62, or the equivalent Appliance Wiring Material (AWM).

2) The flexible cord shall be not smaller than No. 18 AWG, and the mechanical serviceability shall be:

i) Not less than that of Type SJE, SJT, SJO, or equivalent cord, for TRANSPORTABLE EQUIPMENT such as hospital beds and instrument carts; and

ii) Not less than that of Type SV for light-duty EQUIPMENT where extreme flexibility or weight is a factor. EQUIPMENT weighing 567 g (1-1/4 lb) or less would qualify for consideration.

iii) An oil-resistant cord is required if the EQUIPMENT is likely to be subjected to grease or oil.

*See rationale for 57.2DV

57.4 *Connection of POWER SUPPLY CORDS*

a) Cord anchorages

– EQUIPMENT and MAINS CONNECTORS provided with POWER SUPPLY CORDS shall have cord anchorages such that the conductors are relieved from strain, including twisting, where they are connected within the EQUIPMENT and within the MAINS CONNECTOR and the insulation of the conductors is protected from abrasion.

Strain relief methods, such as tying the cord into a knot or tying the ends with string, shall not be used.

– Cord anchorages of POWER SUPPLY CORDS shall be made:

1) of insulating material, or

2) of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by SUPPLEMENTARY INSULATION, or

3) of metal provided with an insulating lining, if otherwise a total insulation failure of the POWER SUPPLY CORD could render LIVE conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED. This lining shall be fixed to the cord anchorage, unless it is a flexible bushing which forms part of the cord guard specified in this sub-clause, and shall comply with the requirements for BASIC INSULATION.

– Cord anchorages of POWER SUPPLY CORDS shall be so designed that the cord is not clamped by a screw which bears directly on the cord insulation.

– Screws, if any, which have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.

– 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.

Compliance is checked by inspection and by the following tests:

EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the manufacturer.

The POWER SUPPLY CORD conductors should, if possible, be disconnected from the mains terminals or from the MAINS CONNECTOR of the EQUIPMENT.

The cord shall be subjected 25 times to a pull on the sheath of the value shown in Table XVIII. The pulls shall be applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord shall be subjected for 1 min to a torque of the value shown in Table XVIII.

Note – Table XVII not used. Table XVI incorporates (see Sub-clause 57.10a)) Tables XVI and XVII of the first edition.

Table XVIII
Testing of cord anchorages

Mass of EQUIPMENT (kg)	Pull (N)	Torque (Nm)
Up to and including 1	30	0,1
over 1 up to and including 4	60	0,25
over 4	100	0,35

After the tests, the cord sheath shall not have been longitudinally displaced by more than 2 mm and the conductor ends shall not have moved over a distance of more than 1 mm from their normally connected position.

CREEPAGE DISTANCES and AIR CLEARANCES shall not be reduced below the values specified in Sub-clause 57.10.

For the measurement of the longitudinal displacement, while the cord is subjected to the pull, a mark is made on the cord at a distance of approximately 2 cm from the cord anchorage or other suitable point, before starting the tests.

After the tests, the displacement on the cord sheath in relation to the cord anchorage or the above other suitable point while the cord is subjected to the pull, is measured.

It shall not be possible to push the cord into EQUIPMENT to such an extent that the cord, or internal parts of the EQUIPMENT, could be damaged.

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b) Cord guards

POWER SUPPLY CORDS of other than STATIONARY EQUIPMENT shall be protected against excessive bending at the inlet opening of EQUIPMENT by means of a cord guard of insulating material.

Alternatively, an opening in EQUIPMENT shall be so shaped that the applied POWER SUPPLY CORD, even if not provided with a guard, passes the following flexing test.

Compliance is checked by inspection, by measurement and by the following test(s):

EQUIPMENT designed for a POWER SUPPLY CORD is fitted with a cord guard or opening and the POWER SUPPLY CORD shall have an exposed length of approximately 100 mm. The EQUIPMENT is so held that the axis of the cord guard, where the cord leaves it, projects upward at an angle of 45° to the horizontal when the cord is free from stress.

A mass equal to 10 D^2g is then attached to the free end of the cord, D being the overall diameter, in millimetres, or, for flat cords, the minor overall dimensions of the POWER SUPPLY CORD delivered with the EQUIPMENT.

If the cord guard is temperature sensitive, the test is made at 23°C ± 2°C.

Flat cords are bent in a direction perpendicular to the plane containing the axis of the cores.

Immediately after the mass has been attached, the curvature of the cord shall nowhere be less than 1,5 D, being checked by a cylindrical rod with a diameter of 1,5 D.

Guards which fail the above dimensional test shall have to pass the test described in IEC 60335-1, Amendment 6, 1988, subclause 25.10.

c) Accessibility of the connection

The space inside 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 risk of damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the cover is fitted.

Compliance is checked by inspection and by an installation test.

57.5 *MAINS TERMINAL DEVICES and wiring of MAINS PART*

**a) General requirements for MAINS TERMINAL DEVICES*

EQUIPMENT intended to be permanently connected to fixed wiring and EQUIPMENT intended to be connected by means of rewirable non-DETACHABLE POWER SUPPLY CORDS shall be provided with MAINS TERMINAL DEVICES in which connection shall be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods.

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 between LIVE parts and other conductive parts cannot be reduced to less than the values specified in Sub-clause 57.10, should the conductor break away.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this sub-clause and are properly marked according to Sub-clauses 6.2*h)*, *j)* and *k)*.

Screws and nuts which 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.

Compliance is checked by inspection.

b) Arrangement of MAINS TERMINAL DEVICES

– For 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.

– For details of PROTECTIVE EARTH CONDUCTOR connections see Clause 58.

– For marking of MAINS TERMINAL DEVICES see Sub-clause 6.2.

– MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL, even if their LIVE parts are not accessible.

Compliance is checked by inspection.

– MAINS TERMINAL DEVICES shall be so located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact between LIVE parts and ACCESSIBLE PARTS and, for CLASS II EQUIPMENT, between LIVE parts and conductive parts separated from ACCESSIBLE PARTS by SUPPLEMENTARY INSULATION only.

Compliance is checked by inspection and, in case of doubt, by the following test:

The end of a flexible conductor having the NOMINAL cross-sectional area specified in Sub-clause 57.3c) (Table XV) is stripped of its insulation for a length of 8 mm.

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.

The free wire of a conductor connected to a LIVE *terminal shall not come into contact with any* ACCESSIBLE PARTS *or parts connected to* ACCESSIBLE PARTS*, or, for* CLASS II EQUIPMENT*, parts which are separated from* ACCESSIBLE PARTS *by* SUPPLEMENTARY INSULATION *only.*

The free wire of a conductor connected to a PROTECTIVE EARTH TERMINAL *shall not come into contact with any* LIVE *part (see Sub-clause 57.5a)).*

c) Fixing of mains terminals

Terminals of EQUIPMENT shall be so fixed 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 Sub-clause 57.10.

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.

**d) Connections to mains terminals*

– For EQUIPMENT with rewirable flexible cords to be connected by clamping means the cord terminals shall not require special preparation of the conductor in order to effect correct connection, and they shall be so designed or placed that the conductor is not damaged and cannot slip out when the clamping screws or nuts are tightened.

– For further requirements limiting conductor preparation in POWER SUPPLY CORDS and DETACHABLE POWER SUPPLY CORDS see Sub-clause 57.3*d)*.

Compliance is checked by inspection of the terminals and of the conductors after the test of Sub-clause 57.5c).

e) Fixing of wiring

Not used. See Sub-clause 56.1*f)*.

*See rationale for 57.5

57.5DV D2 *Modification of 57.5 by adding the following to item b):*

– If leads are provided for connection to the branch circuit and one end of the lead terminates in a wire binding screw, a terminal block, or the like within the EQUIPMENT, the free end shall be in a compartment separate from that containing the wire binding screws, terminal block, or the like. This may be in a separate wiring compartment provided as part of the EQUIPMENT, a separate recessed mounted splice (junction) box described in the installation instructions, or the like. See Figure 52DV.

– The free length of a lead inside an outlet box or field-wiring compartment shall be 152 mm (6 inches) or more. A lead may be less than 152 mm (6 inch) in length if it is evident that the use of a longer lead might result in a risk of fire or electric shock.

*See rationale for 57.2DV

57.6 *Mains fuses and* OVER-CURRENT RELEASES

Fuses or OVER-CURRENT RELEASES shall be provided in each supply lead for CLASS I EQUIPMENT and CLASS II EQUIPMENT having a functional earth according to Sub-clause 18*l)* and in at least one supply lead for other single-phase CLASS II EQUIPMENT.

The current rating of mains fuses and OVER-CURRENT RELEASES shall be such that they reliably carry the normal operating current and shall not be greater than the current rating of any component in the mains circuit carrying the mains supply current.

– A PROTECTIVE EARTH CONDUCTOR shall not be fused.

– For PERMANENTLY INSTALLED EQUIPMENT the neutral conductor shall not be fused.

Compliance is checked by inspection.

57.7 ***Location of interference suppressors in the** *MAINS PART*

Not used.

*See rationale for 57.7

57.8 *Wiring of the* MAINS PART

a) Insulation

The insulation of an individual conductor in the MAINS PART shall be at least electrically equivalent to that of the individual conductors of POWER SUPPLY CORDS complying with IEC 227 or 245, or that conductor shall be considered to be a bare conductor.

Compliance is checked by the following test:

The insulation is regarded to be electrically equivalent, if it withstands a dielectric strength test of 2 000 V for 1 min. The test voltage is applied to a sample of the wire between the conductor and aluminum foil wrapped around the insulation for a length of 10 cm.

b) Cross-section

– Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in Sub-clause 57.3*c)*.

Compliance is checked by inspection.

– The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits shall be sufficient to prevent any fire hazard in case of possible fault currents.

If any doubt exists concerning the adequacy of incorporated overcurrent protection, compliance is checked by connecting the 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. No SAFETY HAZARD shall arise.

57.9 ***Mains supply transformers***

*See rationale for 57.9

Mains supply transformers shall comply with the following requirements:

57.9.1 *Overheating*

– Mains supply transformers used in MEDICAL ELECTRICAL EQUIPMENT shall be protected against overheating of BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION in the event of short-circuit or overload on any output winding.

Compliance is checked by the tests described in Sub-clauses 57.9.1a) and 57.9.1b).

– Where protective devices external to the transformer or transformer ENCLOSURE provide the protection against overheating, e.g. fuses, OVER-CURRENT RELEASES, THERMAL CUT-OUTS, these devices shall be connected in such a way that failure of any component other than wiring interposed between the protective devices and the transformer cannot render the protective devices inoperative.

Compliance is checked by inspection.

Table XIX
Maximum allowable temperatures at 25°C ambient temperature of mains supply transformer windings under overload and short-circuit conditions

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material	150
– of Class B material	175
– of Class E material	165
– of Class F material	190
– of Class H material	210

a) Short-circuit

Compliance is checked by application of the following tests under the conditions specified in Clause 42:

– Mains supply transformers, provided with a protective device for limitation of the winding temperatures, are connected to a supply voltage which is the least favourable within the limits of 90% of the lowest to 110% of the highest RATED supply voltage or the RATED supply voltage range. Each secondary winding is short-circuited in turn, all other windings, except the primary winding, being loaded as in NORMAL USE.

– Any protective device for a secondary winding shall be operative.

– The protective device shall operate before the maximum temperatures of Table XIX are exceeded.

– Where a primary protective device does not operate, the maximum temperatures of Table XIX shall not be exceeded in steady thermal condition.

b) Overload

Mains supply transformers including their protective devices, if any, are tested in conditions of normal operation:

– under the conditions specified in Clause 42 until steady thermal conditions are obtained;

– the supply voltage being maintained at 90% or 110% of RATED supply voltage or at 110% of the highest value of the RATED supply voltage range, whichever is the least favourable;

– the tests are made on each winding or section in turn, the other windings or sections being loaded as in the relevant EQUIPMENT in NORMAL USE;

– the section or winding of the transformer under overload is loaded as follows:

• Mains supply transformers having fuses in accordance with IEC Publications 127 and 241 as protective devices, are loaded for 30 min and 1 h respectively, so that the test current in the fused circuit is in accordance with Table XX with the fuses replaced by links of negligible impedance.

• Mains supply transformers having fuses deviating from IEC Publications 127 and 241 as protective devices, are loaded for 30 min so that the test current in the fused circuit is as high as possible according to the characteristics supplied by the fuse manufacturer, but does not cause the fuse to operate. The fuses shall be replaced by links of negligible impedance.

Table XX
Test current for mains supply transformers

Marked value of RATED current of protecting fuse-link (A)	*Ratio between test current and RATED current of the fuse-link*
Up to and including 4	*2,1*
over 4 up to and including 10	*1,9*
over 10 up to and including 25	*1,75*
over 25	*1,6*

• If the current under short-circuit condition is smaller than the test current specified above, the transformer section or winding is short-circuited until steady thermal condition is attained.

• Mains supply transformers having THERMAL CUT-OUTS as protective devices are loaded so that the current through the transformer section or winding is the maximum which does not cause the cut-out to operate, the test being continued until steady thermal condition is attained.

• Mains supply transformers having OVER-CURRENT RELEASES as protective devices are loaded so that the test current in the circuit is as high as possible according to the trip current stated by the manufacturer of the OVER-CURRENT RELEASES but

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does not cause the releases to operate, the test being continued until a steady thermal condition is obtained. The OVER-CURRENT RELEASES shall be replaced by links of negligible impedance.

• On mains supply transformers not provided with a protective device for limitation of the winding temperature, the output terminals of the secondary winding or of a section of such a winding which gives the least favourable results shall be short-circuited. The test shall be continued until steady thermal condition is attained.

For the purpose of these tests, the tripping current is for:

– an OVER-CURRENT RELEASE without time-delay: the lowest current which causes the release to operate;

– an OVER-CURRENT RELEASE with delay: the current which causes the release, starting from room temperature, to operate with maximum delay or after 1 h, whichever is the shorter period.

During the tests, the temperature shall not exceed the value given in Table XIX.

57.9.1DV D2 *Modification of 57.9.1 by adding 57.9.1DV.1 and 57.9.1DV.2:*

*See rationale for 57.9.1DV

57.9.1DV.1 For an electronic circuit used to comply with the requirements of this sub-clause, a fuse or manual reset protector may be left in the circuit. If such components have not been investigated (such as those not investigated for calibration of opening for time vs. current or temperature) and functions to terminate the test, the test shall be repeated two additional times. For the overload test the maximum loading not resulting in the circuit switching to its limiting mode is to be used until the ultimate results. This requirement is not an alternative to enable the use of fuses, breakers, and the like that do not comply with 3.10DV.

57.9.1DV.2 A positive temperature coefficient resistive device (PTC) is to be left in the circuit for the short circuit test until ultimate results. For the overload test the maximum loading not resulting in the PTC switching to its high resistance mode is to be used until ultimate results are known.

57.9.2 *Dielectric strength*

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 EQUIPMENT as described in Clause 20. They shall not be repeated.

The dielectric strength of the electrical insulation between turns and layers of the primary and secondary windings of a mains supply transformer shall be such that after the humidity preconditioning treatment (see Sub-clause 4.10) it passes the following tests:

– Transformers not having any winding with a RATED voltage exceeding 500 V 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.

– Transformers having any winding with a RATED voltage exceeding 500 V 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.

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer shall be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the voltage specified in Sub-clause 20.3, Table V, BASIC INSULATION, if the RATED voltage of such a winding is considered as reference voltage U. If this should occur, the test voltage on the primary winding shall be reduced accordingly. The test frequency may be adapted to produce in the core approximately the magnetic induction present in NORMAL USE.

– Three-phase transformers may be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.

– The value of the test voltage with respect to the core and to any screen between primary and secondary windings shall be 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 shall be 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.

If such a connection point has not been identified, each side of the primary winding in turn shall be 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) shall be connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

– During the test, all windings not intended for connection to the SUPPLY MAINS shall be left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a point nearly at earth potential shall have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.

To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

– Initially not more than half the prescribed voltage shall be applied, then it shall be raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage shall be reduced gradually and switched off.

– Tests are not conducted at resonant frequencies.

– During the test, no flashover or breakdown of any part of the insulation shall occur. There shall be no detectable deterioration of the transformer after the test.

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 reference voltage (U) and that the discharges do not provoke a drop in test voltage.

57.9.3 *Housing*

Not used.

57.9.4 *Construction*

a) The separation of primary and secondary windings having a CONDUCTIVE CONNECTION to APPLIED PARTS or to ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED shall be achieved by one of the following methods:

– wound on separate bobbins or formers;

– wound on one bobbin or former with an imperforate insulating partition between windings;

– wound on one bobbin or former with concentric windings and having an imperforate protective copper screen with a thickness of not less than 0,13 mm;

– concentrically wound on one bobbin with windings separated by DOUBLE or REINFORCED INSULATION.

Compliance is checked by inspection.

b) Not used.

c) Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.

d) 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.

e) In transformers with REINFORCED INSULATION or DOUBLE INSULATION the insulation between the primary and secondary winding shall consist of:

– one insulation layer having a thickness of at least 1 mm, or

– at least two insulation layers with a total thickness of not less than 0,3 mm, or

– three layers provided that each combination of two layers can withstand the dielectric strength test for REINFORCED INSULATION.

f) For transformers complying with Sub-clause 57.9.4*a)* the CREEPAGE DISTANCES between the primary and secondary windings shall comply with the requirements for REINFORCED INSULATION (A-e, Table XVI, Sub-clause 57.10) with the following allowances:

– enamel or lacquer of winding wires are considered as contributing 1 mm each to these CREEPAGE DISTANCES.

– CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:

• either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

• 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.

– 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.

g) The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for DOUBLE INSULATION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding.

Compliance with the requirements of Sub-clauses 57.9.4c) through 57.9.4g) is checked by inspection.

57.10 ***CREEPAGE DISTANCES** and AIR CLEARANCES*

*See rationale for 57.10

a) Values

– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with at least the values of Table XVI.

For a number of insulations Sub-clauses 20.1 and 20.2 apply.

– The value of the reference voltage (*U*) is as given in Sub-clause 20.3. In case the reference voltage has a value between those given in Table XVI, the higher of the two values shall be applied.

Values for reference voltages above 1 000 V a.c. or 1 200 V d.c. are under consideration.

– For slot insulation of motors a reduction to 50% of the values of Table XVI for CREEPAGE DISTANCES shall be allowed, with a minimum of 2 mm at 250 V.

– Between DEFIBRILLATION-PROOF APPLIED PARTS and other parts, CREEPAGE DISTANCES and AIR CLEARANCES shall be not less than 4 mm.

b) Application

– For insulation in the MAINS PART between parts of opposite polarity (see Sub-clause 20.1 A-f) the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short-circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not produce a SAFETY HAZARD.

Operation of a protective device shall not be considered as a SAFETY HAZARD.

– The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figures 39 through 47).

The AIR CLEARANCES required between LIVE parts shall not apply to the air gap between the switching contacts of THERMOSTATS, THERMAL CUT-OUTS, OVER-CURRENT RELEASES, switches of microgap construction and the like, or to the air gap between the current-carrying parts of such devices where the clearance varies with the movement of the contacts and where adequacy of ratings has been proved.

– When assessing CREEPAGE DISTANCES and AIR CLEARANCES, the effect of insulating linings of metal enclosures or covers shall be taken into consideration.

– AIR CLEARANCE alone is only acceptable for isolation between LIVE parts and APPLIED PARTS and ACCESSIBLE PARTS not PROTECTIVELY EARTHED if the relative positioning is such that the relevant parts are rigid and located by mouldings or the design is otherwise such that there is no likelihood of a distance being reduced by deformation or movement of the parts.

Where limited movement of one of the relevant parts is normal or likely, this shall be taken into account when computing the minimum clearance.

c) Not used.

d) Measurement of CREEPAGE DISTANCES and AIR CLEARANCES

Compliance is checked by measurement taking into account the rules in Figures 39 through 47.

For EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified and also without conductors.

Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.

AIR CLEARANCES and CREEPAGE DISTANCES between terminals and ACCESSIBLE PARTS are also measured with the screws or nuts unscrewed as far as possible, and the AIR CLEARANCES shall then be not less than 50% of the values shown in Table XVI.

CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts shall be measured to the standard test finger of figure 7.

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.

The force is applied by means of a standard test finger having a tip as shown in Figure 7 and having a value of:

2 N for bare conductors;

30 N for ENCLOSURES.

Table XVI
CREEPAGE DISTANCES and AIR CLEARANCES in millimetres[1)]

	d.c. voltage	15	36	75	150	300	450	600	800	900	1 200	
	a.c. voltage	12	30	60	125	250	400	500	660	750	1 000	
Equivalent to BASIC INSULATION between parts of opposite polarity	A-f	0,4	0,5	0,7	1	1,6	2,4	3	4	4,5	6	AIR CLEARANCES
		0,8	1	1,3	2	3	4	5,5	7	8	11	CREEPAGE DISTANCES
BASIC INSULATION or SUPPLEMENTARY INSULATION	A-a1, A-b, A-c, A-j	0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
	B-d, B-c	1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES
DOUBLE INSULATION or REINFORCED INSULATION	A-a2, A-e, A-k	1,6	2	2,4	3,2	5	7	9	12	13	18	AIR CLEARANCES
	B-a, B-e	3,4	4	4,6	6	8	12	16	21	24	32	CREEPAGE DISTANCES

[1)] This table replaces Tables XVI and XVII of the first edition.

58 Protective earthing – Terminals and connections

58.1 The clamping means of the PROTECTIVE EARTH TERMINAL for fixed supply conductors or POWER SUPPLY CORDS shall comply with the requirements of Sub-clause 57.5*c)*. It shall not be possible to loosen it without the aid of a TOOL. Screws for internal protective earthing connections shall be completely covered or protected against inadvertent loosening from the outside of EQUIPMENT.

58.2 For internal protective earthing connections, clamping by means of a screw, soldering, crimping, wrapping, welding or a reliable PRESSURE contact are allowed.

58.2DV D2 ***Modification of 58.2 by adding the following:***

Soldering alone shall not be used. Connections shall be made mechanically secure as well as being soldered.

*See rationale for 58.2DV

58.3 Not used. See Sub-clause 57.5*b)*.

58.4 Not used.

58.5 Not used.

58.6 Not used.

58.7 Where an APPLIANCE INLET forms the supply connection to EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

58.8 The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

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58.9 *Protective earth connection*

Where the connection between mains supply conductors and EQUIPMENT or between separated parts of EQUIPMENT which can be operated by the OPERATOR 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 connected to protective earth. See also Sub-clauses 57.1, 57.2 and 57.3.

Compliance with the requirements of Clause 58 is checked by inspection of materials and construction, by manual tests and by the test of Sub-clause 57.5.

59 Construction and layout

59.1 *Internal wiring*

For fixing of wiring in the APPLIED PART and the MAINS PART, see Sub-clause 56.1*f)*.

a) Mechanical protection

– Cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges, if there is a relative movement between the part and cords or wiring.

– Wiring having BASIC INSULATION only shall be protected by additional fixed sleeving or by other similar means where it is in direct contact with metal parts and where such wiring is subject to a relative movement in NORMAL USE during which it is in direct contact with metal parts.

– EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged in the normal process of assembly or replacement of covers or the opening or closing of inspection doors.

Compliance is checked by inspection and, where appropriate, by manual test.

b) Bending

Guiding rollers of leads shall be constructed in such a manner that movable leads in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.

Compliance is checked by inspection and measurement of the relevant dimensions.

c) Insulation

– If insulating sleeving is needed on internal wiring, it shall be adequately secured. Sleeving is regarded as adequately secured if it can only be removed by breaking or cutting or if it is secured at both ends.

– Inside EQUIPMENT the sheath of a flexible cord shall be used as SUPPLEMENTARY INSULATION only where it is not subject to undue mechanical or thermal stresses and if its insulation properties are not less than those specified in IEC Publications 227 or 245.

– Insulated conductors which in NORMAL USE are subject to temperatures exceeding 70°C shall have an insulation of heat-resistant material if compliance with this Standard is likely to be impaired by deterioration of the insulation.

Compliance is checked by inspection and, if necessary, by special tests. Temperatures shall be determined as indicated in Clause 42.

Compliance of the sheath mentioned in the second dash is checked as follows:

The insulation shall withstand a dielectric strength test of 2 000 V for 1 min. The test voltage is applied between a metal rod inserted into a sample of the sheath and metal foil wrapped around the insulation for a length of 10 cm.

d) Materials

Aluminum wires of less than 16 mm^2 cross-section shall not be used.

Compliance is checked by inspection.

**e) Separation of circuits*

Not used. See Clause 17.

f) Applicable requirements

Connecting cords between EQUIPMENT parts, e.g. parts of an X-ray installation or a PATIENT monitoring installation or a data-processing installation or combinations thereof shall be considered as belonging to the EQUIPMENT and not be subject to requirements for wiring of electrical installations (in hospitals or otherwise).

Compliance is checked by application of the relevant tests of this Standard.

*See rationale for 59.1

59.1DV DR *Modification of 59.1 by replacing the text contained in item (f) with the following:*

The installation of connecting cords between EQUIPMENT parts shall meet the requirements of the National Electrical Code, ANSI/NFPA 70, as applicable. In addition to the requirements in this standard, a cable used as external interconnection between units shall be as follows:

1) If exposed to abuse, the cable shall be Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.

2) If not exposed to abuse, the cable shall be as indicated in item (1) above or shall be:

i) Type SPT-2, SP-2, or SPE-2, or equivalent,

ii) Type SVT, SVTO, SVE, or equivalent flexible cord or similar multiple-conductor appliance-wiring material, or

iii) An assembly of insulated wires each with a NOMINAL insulation thickness of 0,8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a NOMINAL wall thickness of 0,8 mm (1/32 inch) or more.

iv) Interconnecting cables operating at a voltage not exceeding 25 Vac (RMS) or 60 Vdc or peak supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in Subclause 17(g).

If exposed to abuse, flexible cord or cable is considered protected from abuse from a rolling table or similar EQUIPMENT at a time when such EQUIPMENT is likely to be used in the vicinity of the EQUIPMENT if one or more of the following conditions are met:

a) The entire cord or cable is 914 mm (3 ft) or more above the floor.

b) The cord or cable is guarded from contact by such EQUIPMENT. A cord or cable that may touch the floor under any condition of intended use is to be considered exposed to abuse, or

c) The entire cord or cable, which may be a retractable helically coiled type constructed so as to retain its retractability, supplies a hand-held device. The cord length is limited so that the unstretched cord does not contact the floor while the control device is in stored position or while the control device is positioned 610 mm (2 ft) above the floor.

*See rationale for 59.1DV

59.2 *Insulation*

This sub-clause refers to parts of EQUIPMENT other than wire insulation which is covered in Sub-clause 59.1*c)*.

a) Fixing

Not used.

**b) Mechanical strength and resistance to heat and fire*

The insulating characteristics, mechanical strength and resistance to heat and fire shall be retained by all types of insulation, including insulating partition walls, even in the case of extended use.

Compliance is established by inspection and, if necessary, in conjunction with the following tests:

– resistance to moisture, etc. (see Clause 44);

– dielectric strength (see Clause 20);

– mechanical strength (see Clause 21).

Resistance to heat is established by the following tests which need not be performed if satisfactory evidence of compliance is provided:

1) For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could influence the safety of the EQUIPMENT, by the ball-PRESSURE test:

ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords, are subjected to a ball-PRESSURE test using the test apparatus shown in Figure 48. 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 made in a heating cabinet at a temperature of 75°C ± 2°C or at a temperature of 40°C ± 2°C plus the temperature rise of the relevant part of insulating material measured during the test of Clause 42, whichever is the higher.

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. It shall be not greater than 2 mm. The test is not made on parts of ceramic material.

2) For parts of insulating material which support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the EQUIPMENT, by the ball-PRESSURE test:

A test is made as described in Item 1), but at a temperature of 125°C ± 2°C or at a temperature of 40°C ± 2°C plus the temperature rise which was determined during the test of Clause 42 of the relevant part, whichever is the higher.

The test is not made on parts of ceramic material, insulating parts of commutators, brush-caps and the like, on coil formers not used as REINFORCED INSULATION and the insulation of cords.

Note – For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also Sub-clause 52.4.1.

c) Protection

BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION shall be so designed or protected that they are not likely to be impaired by deposition of dirt or by dust resulting from wear of parts within the EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in Sub-clause 57.10.

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION.

Parts of natural or synthetic rubber used as SUPPLEMENTARY INSULATION in CLASS II EQUIPMENT shall be resistant to ageing and be so arranged and dimensioned that CREEPAGE DISTANCES are not reduced below the values specified in Sub-clause 57.10 whatever cracks may occur.

Insulating material in which heating conductors are embedded shall be considered as BASIC INSULATION and shall not be used as REINFORCED INSULATION.

Compliance is checked by inspection, by measurement and for rubber by the following test:

Parts of 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 ten times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97% pure, to a PRESSURE of 210 ± 7 N/cm^2.

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 and shall show no crack visible to the naked eye.

*See rationale for 59.2

59.3 *Excessive current and voltage protection*

– See Sub-clause 57.6.

– An INTERNAL ELECTRICAL POWER SOURCE in EQUIPMENT shall be provided with an appropriately RATED device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to the occurrence of a fire hazard in case of a short circuit.

Compliance is checked by inspection for the presence of protective means and if necessary by inspection of the design data.

– Fuse elements replaceable without opening the ENCLOSURE of the EQUIPMENT shall be fully enclosed in a fuseholder. When fuse replacement can be carried out without the use of a TOOL, uninsulated LIVE parts associated with the fuseholder shall be shielded to enable fuse replacement without a SAFETY HAZARD.

Compliance is checked by inspection and by the use of the standard test finger.

– Protective devices connected between 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.

Compliance is checked by testing the operating voltage of the protective devices.

– For THERMAL CUT-OUTS and OVER-CURRENT RELEASES see Sub-clause 56.6*a)*.

59.4 *Oil containers*

– Oil containers in PORTABLE EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.

Oil containers in MOBILE EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a PRESSURE-release device which can operate during NORMAL USE.

– Partially sealed oil-filled EQUIPMENT or EQUIPMENT parts shall be provided with means for checking the oil level.

Compliance is checked by inspection of EQUIPMENT and technical description, and by manual test.

60DV D2 ***Addition:***

*See rationale for 60DV

60DV.1 Separate power units

60DV.1.1 General

*See rationale for 60DV.1.1

60DV.1.1.1 A separate power unit (adapter, power supply, battery charger, or the like) employing a separable connector for supplying the EQUIPMENT shall be, (a) packaged with the EQUIPMENT, or, (b) be referenced by the following or equivalent marking on the EQUIPMENT: ″_____ (equipment descriptive name) _____ Model _____.″ ″Use only with (manufacturer's name or equivalent) Model ____ Adapter (power supply, battery charger, or the like)″, or ″Use only with adapters (or the like) noted in the instruction manual.″ If a reference is made to a manual, the manual shall be provided with the EQUIPMENT and shall clearly tabulate the adapters (or the like) with which the EQUIPMENT is intended to be used by manufacturer's name and model number. Also, the EQUIPMENT shall be marked with Symbol 14 of Table DI in Appendix D, if a reference is made to a manual.

60DV.1.2 Direct plug-in units

60DV.1.2.1 These requirements supplement the requirements in this Standard.

60DV.1.2.2 Construction

60DV.1.2.2.1 A direct plug-in unit shall comply with the mechanical assembly, ENCLOSURE, input connections, accessibility of LIVE parts, and grounding requirements specified in the Standard for Class 2 Power Units, UL 1310.

60DV.1.2.3 Performance

60DV.1.2.3.1 A direct plug-in unit shall comply with the direct plug-in requirements for blade secureness, security of input contacts, and abuse tests specified in the Standard for Class 2 Power Units, UL 1310.

60DV.1.2.3.2 During the tests specified in Sub-clause 57.9.1 a) and 57.9.1 b), the external ENCLOSURE temperature rise of a direct plug-in unit shall not exceed 65°C, except a temperature rise of 125°C is acceptable if the unit permanently opens within one hour after initiation of the test.

60DV.1.2.4 Markings

60DV.1.2.4.1 A direct plug-in unit provided with a mounting tab shall be marked in accordance with the requirements for semipermanent mounted units specified in the Standard for Class 2 Power Units, UL 1310.

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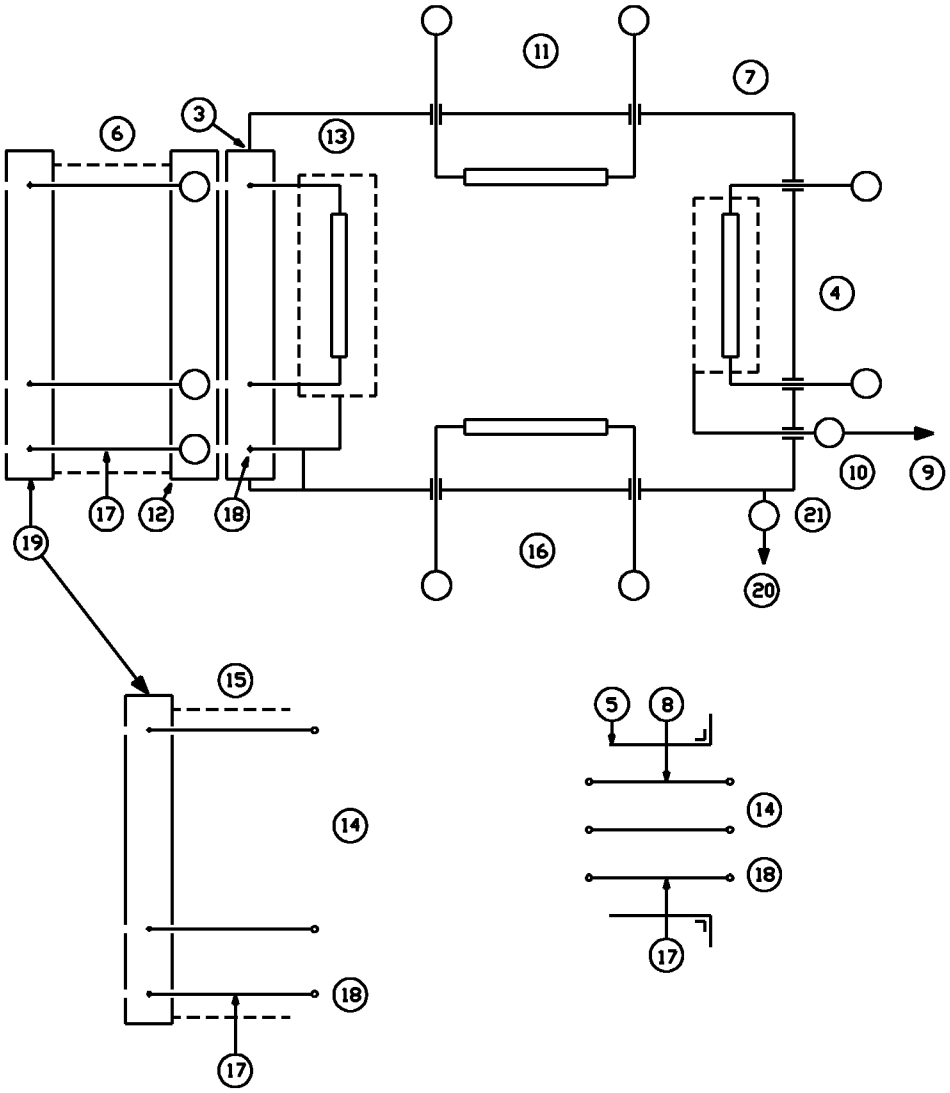
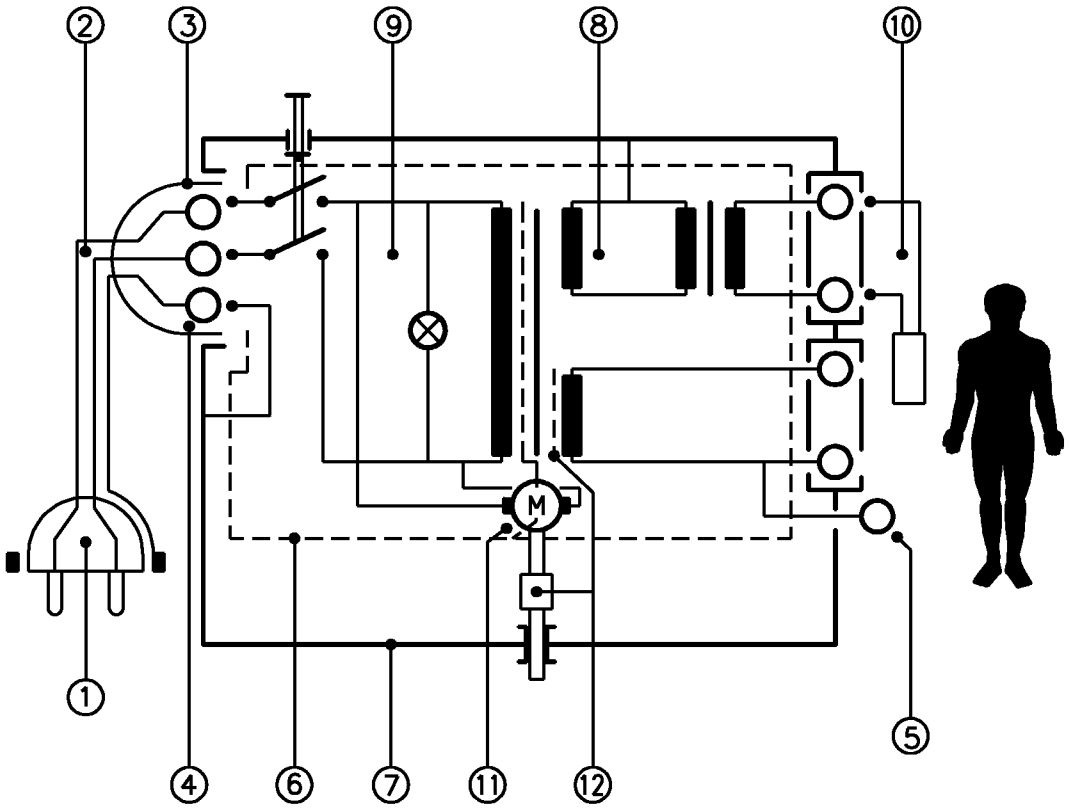
Figure 1 – Example of the defined terminals and conductors (see Clause 2).



(3) APPLIANCE INLET (see also Figure 5)
(4) APPLIED PART
(5) Conduit
(6) DETACHABLE POWER SUPPLY CORD
(7) ENCLOSURE
(8) Fixed wiring
(9) FUNCTIONAL EARTH CONDUCTOR
(10) FUNCTIONAL EARTH TERMINAL
(11) SIGNAL INPUT PART
(12) MAINS CONNECTOR
(13) MAINS PART
(14) MAINS TERMINAL DEVICE
(15) POWER SUPPLY CORD
(16) SIGNAL OUTPUT PART
(17) PROTECTIVE EARTH CONDUCTOR
(18) PROTECTIIVE EARTH TERMINAL
(19) MAINS PLUG
(20) POTENTIAL EQUALIZATION CONDUCTOR
(21) Means for the connection of a POTENTIAL EQUALIZATION CONNECTOR

SM948

Figure 2 – Example of a CLASS I EQUIPMENT (see Sub-clause 2.2.4).



① Plug with protective earthing contact

② DETACHABLE POWER SUPPLY CORD

③ APPLIANCE COUPLER

④ Protective earth contact and pin

⑤ FUNCTIONAL EARTH TERMINAL

⑥ BASIC INSULATION

⑦ ENCLOSURE

⑧ Intermediate Circuit

⑨ MAINS PART

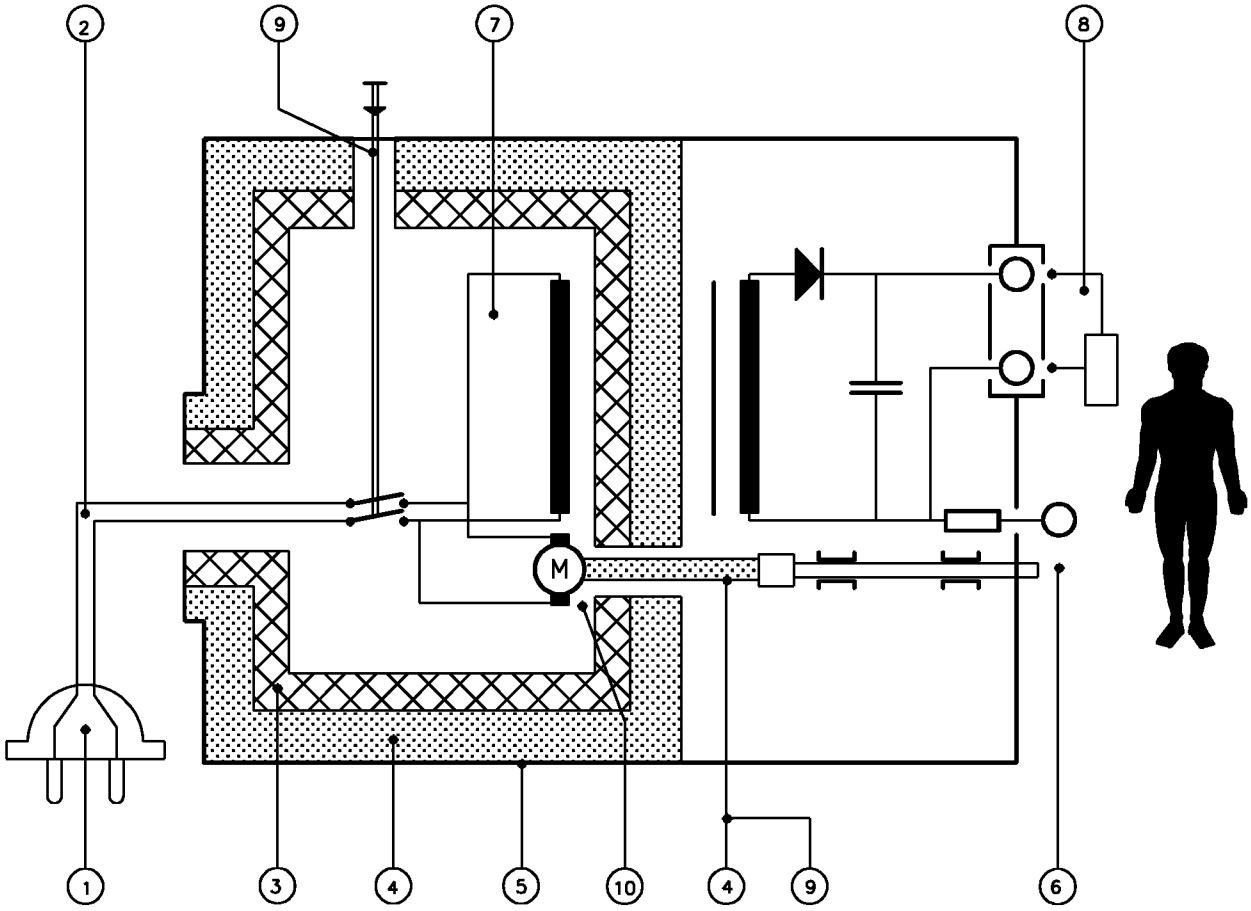
⑩ APPLIED PART

⑪ Motor with accesible shaft

⑫ SUPPLEMENTARY INSULATION or PROTECTIVELY EARTHED screen

SM902B

Figure 3 – Example of a metal-enclosed CLASS II EQUIPMENT (see Sub-clause 2.2.5).



(1) MAINS PLUG

(2) POWER SUPPLY CORD

(3) BASIC INSULATION

(4) SUPPLEMENTARY INSULATION

(5) ENCLOSURE

(6) FUNCTIONAL EARTH TERMINAL

(7) MAINS PART

(8) APPLIED PART

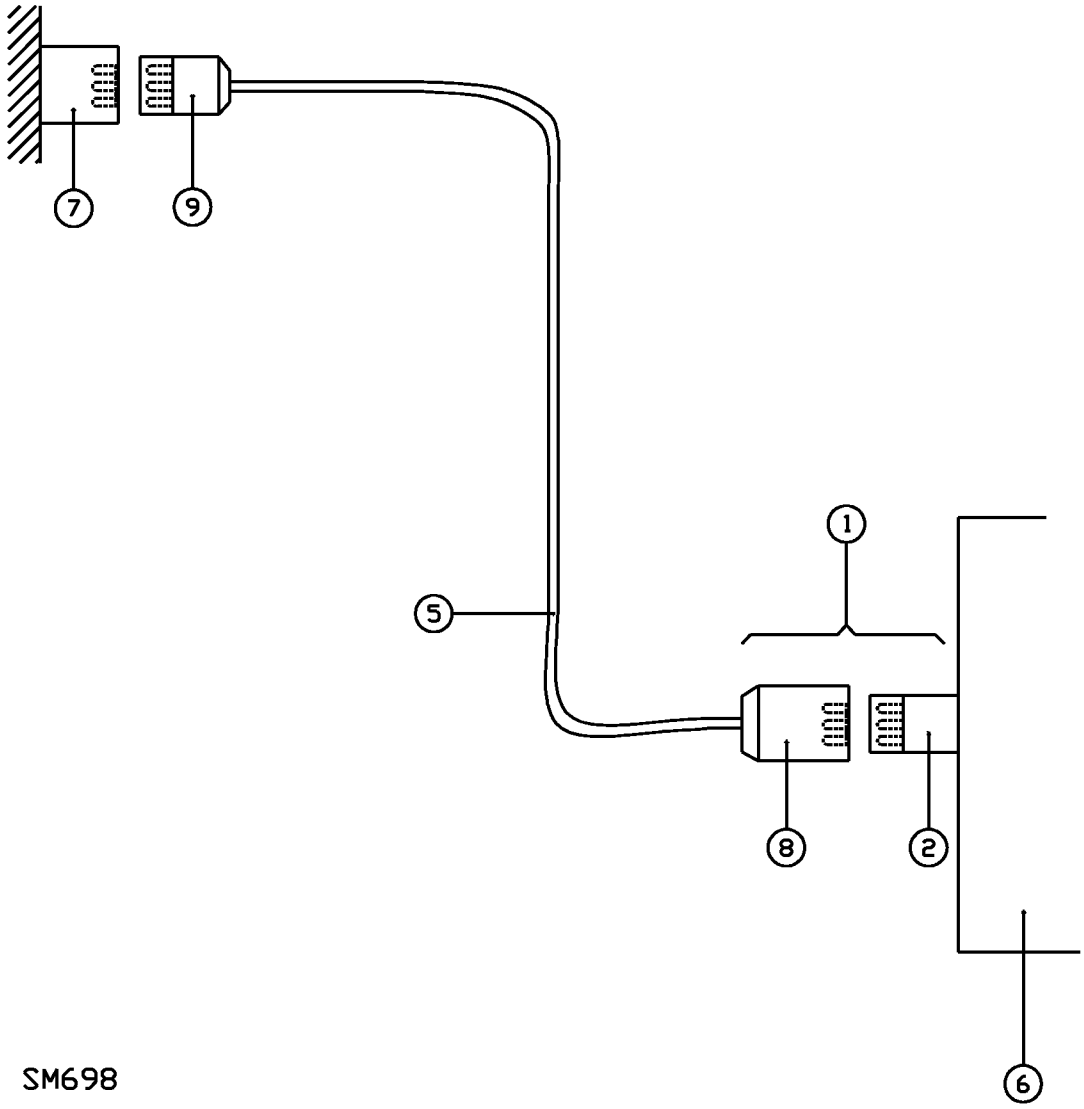
(9) REINFORCED INSULATION

(10) Motor with accessible shaft

SM979

Figure 4 – Not used.

Figure 5 – Detachable mains connection (see Clause 2).



1 APPLIANCE COUPLER

2 APPLIANCE INLET

5 DETACHABLE POWER SUPPLY CORD

6 EQUIPMENT

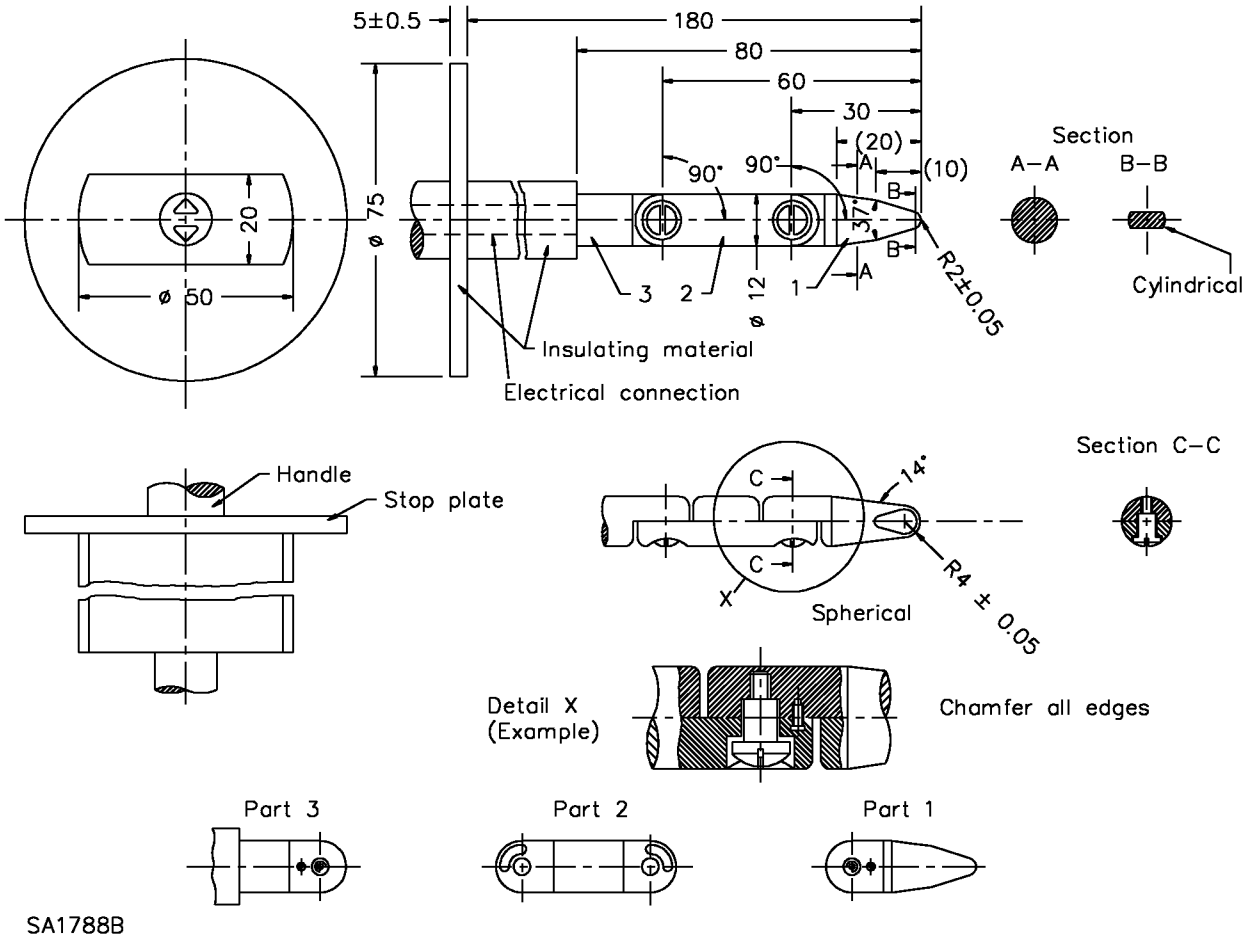
7 FIXED MAINS SOCKET-OUTLET

8 MAINS CONNECTOR

9 MAINS PLUG

Figure 6 – Not used.

Figure 7 – Standard test finger (see Clause 16).



Linear dimensions in millimetres

Tolerances on dimensions without specific tolerance:

on angles: +0/−10°

on linear dimensions:

up to 25 mm: +0/−0,05

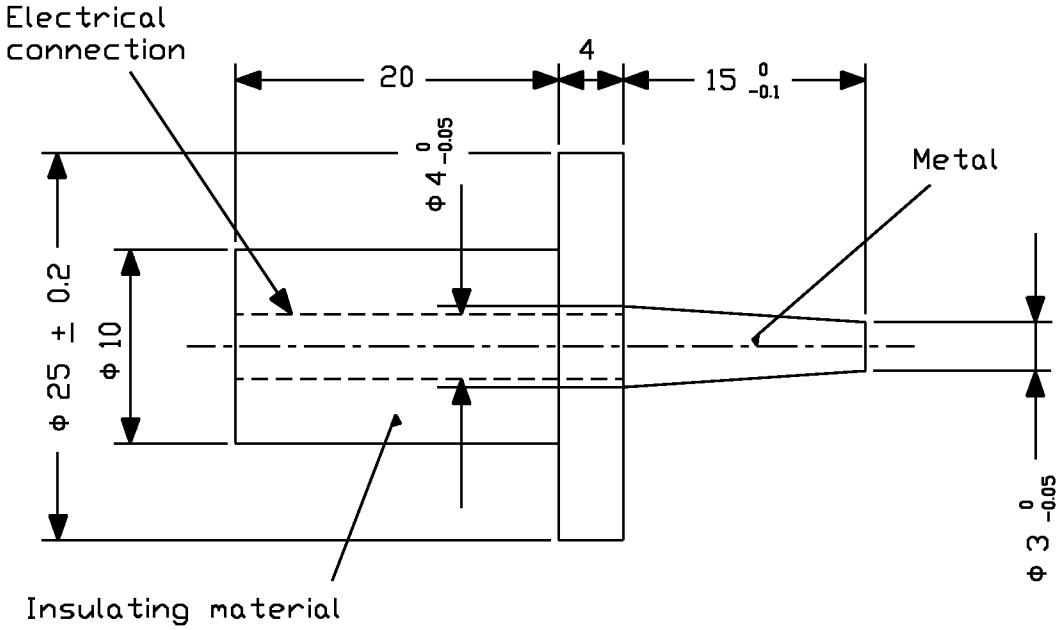
over 25 mm: ±0,2

Material of parts 1, 2 and 3 metal (e.g. heat-treated steel)

Both joints of this finger may be bent through an angle of 90 (+10°/0) but in one and the same direction only.

Using the pin and groove solutions 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 ensure a 90° bending angle with a 0 to +10° tolerance.

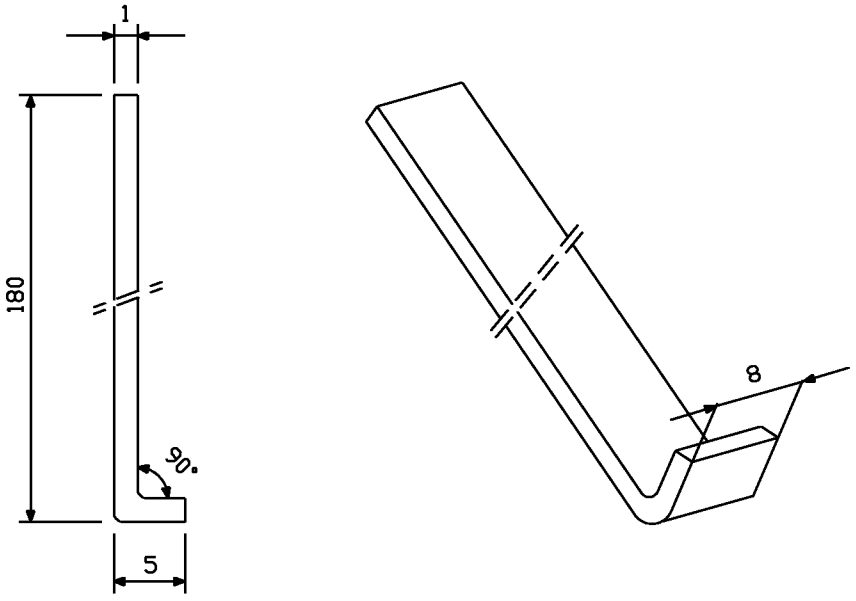
Figure 8 – Test pin (see Clause 16).



Dimensions in millimetres

SM973A

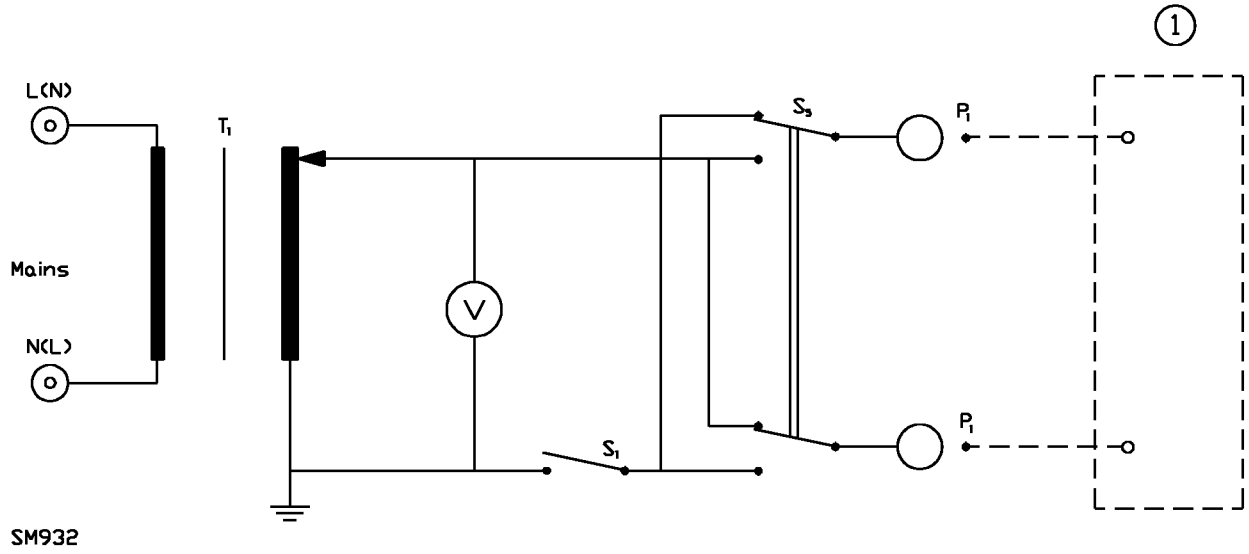
Figure 9 – Test hook (see Clause 16).



Dimensions in millimetres, material: steel

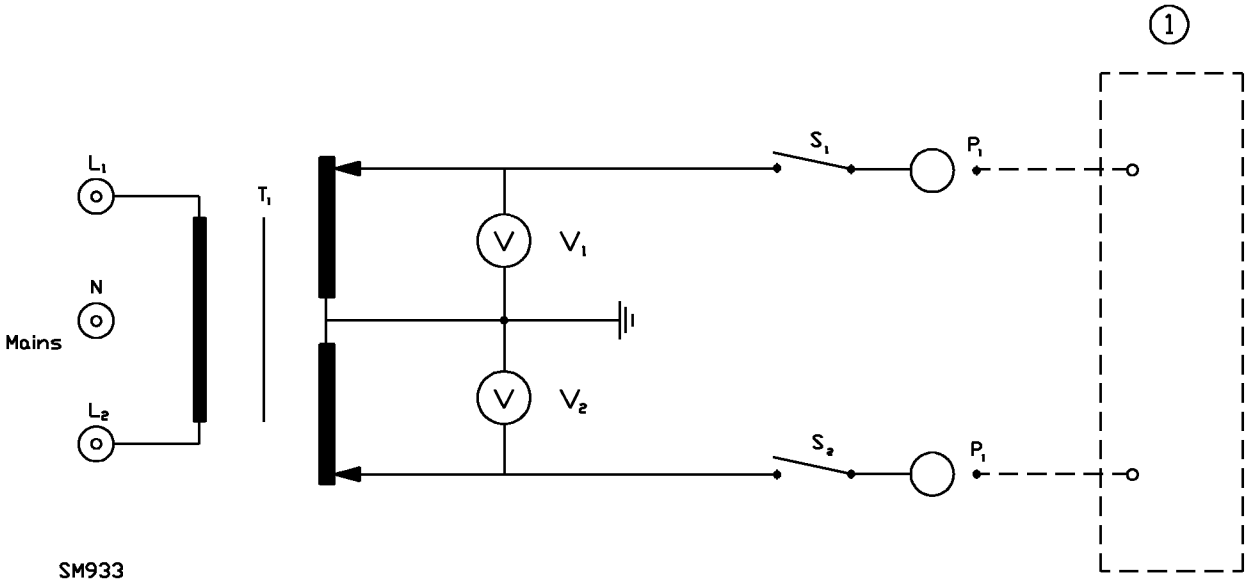
SM976

Figure 10 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential (see Sub-clause 19.4*b*)).



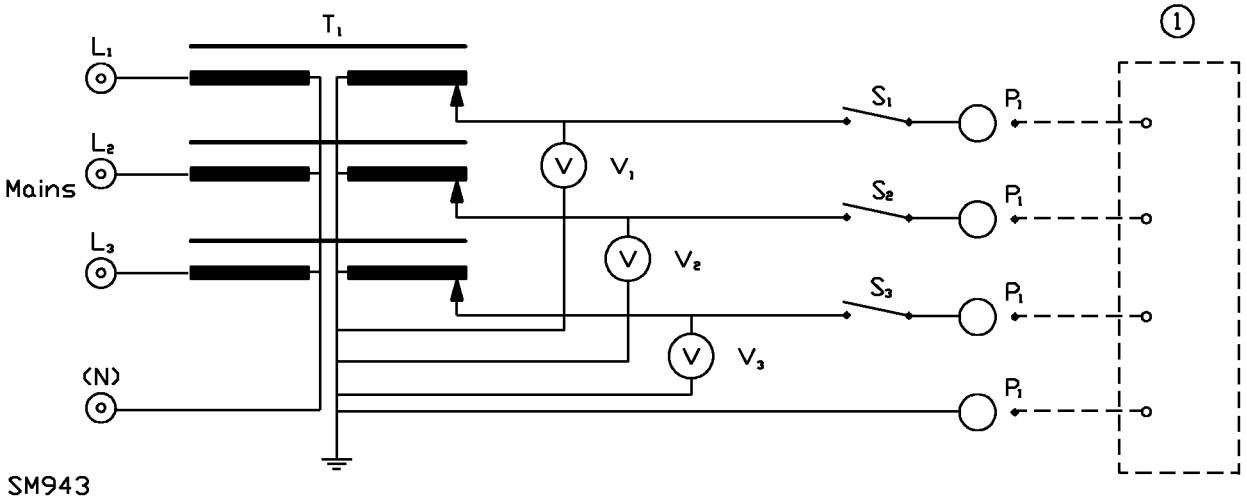
See legends after Figure 27

Figure 11 – Measuring supply circuit with the SUPPLY MAINS approximately symmetrical to earth potential (see Sub-clause 19.4*b*)).



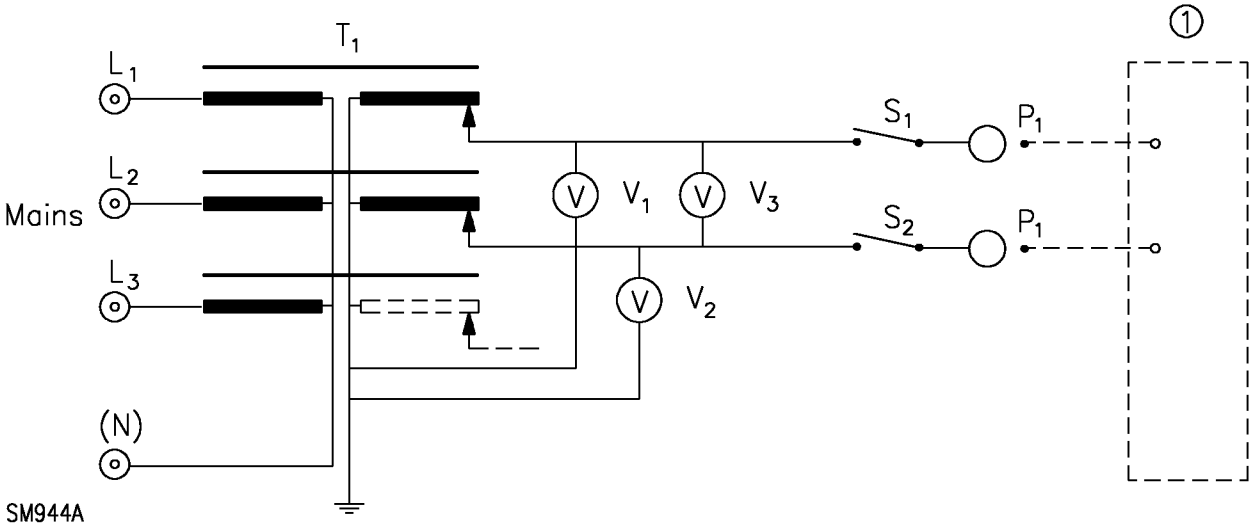
See legends after Figure 27

Figure 12 – Measuring supply circuit for polyphase EQUIPMENT specified for connection to a polyphase SUPPLY MAINS (see Sub-clause 19.4*b*)).



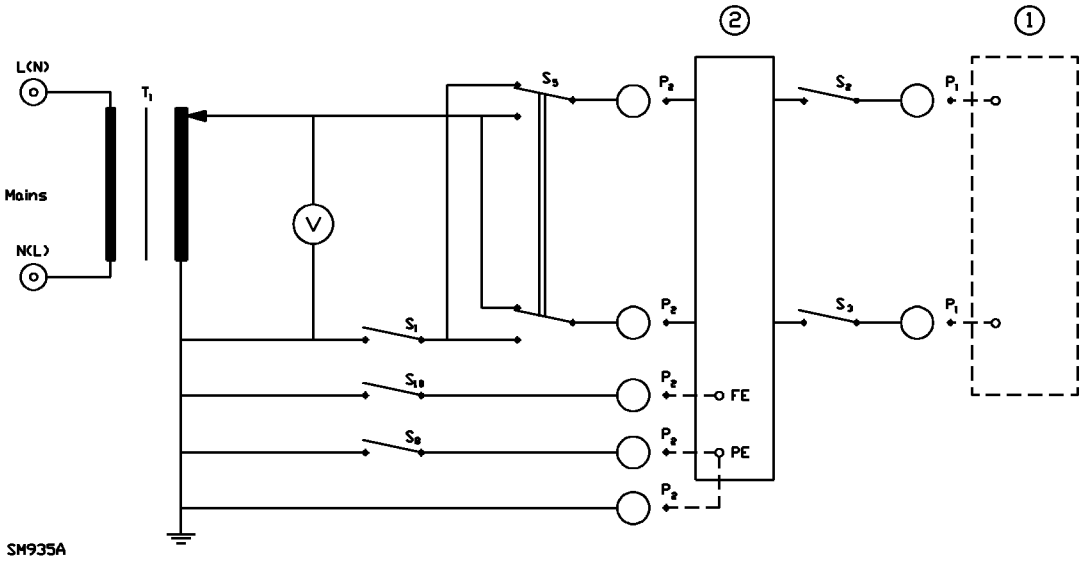
See legends after Figure 27

Figure 13 – Measuring supply circuit for single-phase EQUIPMENT specified for connection to a polyphase SUPPLY MAINS (see Sub-clause 19.4*b*)).



See legends after Figure 27

Figure 14 – Measuring supply circuit for either EQUIPMENT supplied from a specified class I single-phase power supply or for EQUIPMENT supplied from a specified class II single-phase power supply, not using in this case the protective earth connection and S_8 (see Sub-clause 19.4*b)*).



See legends after Figure 27

Figure 15 – Example of a measuring device and its frequency characteristic (see Sub-clause 19.4*e*)).

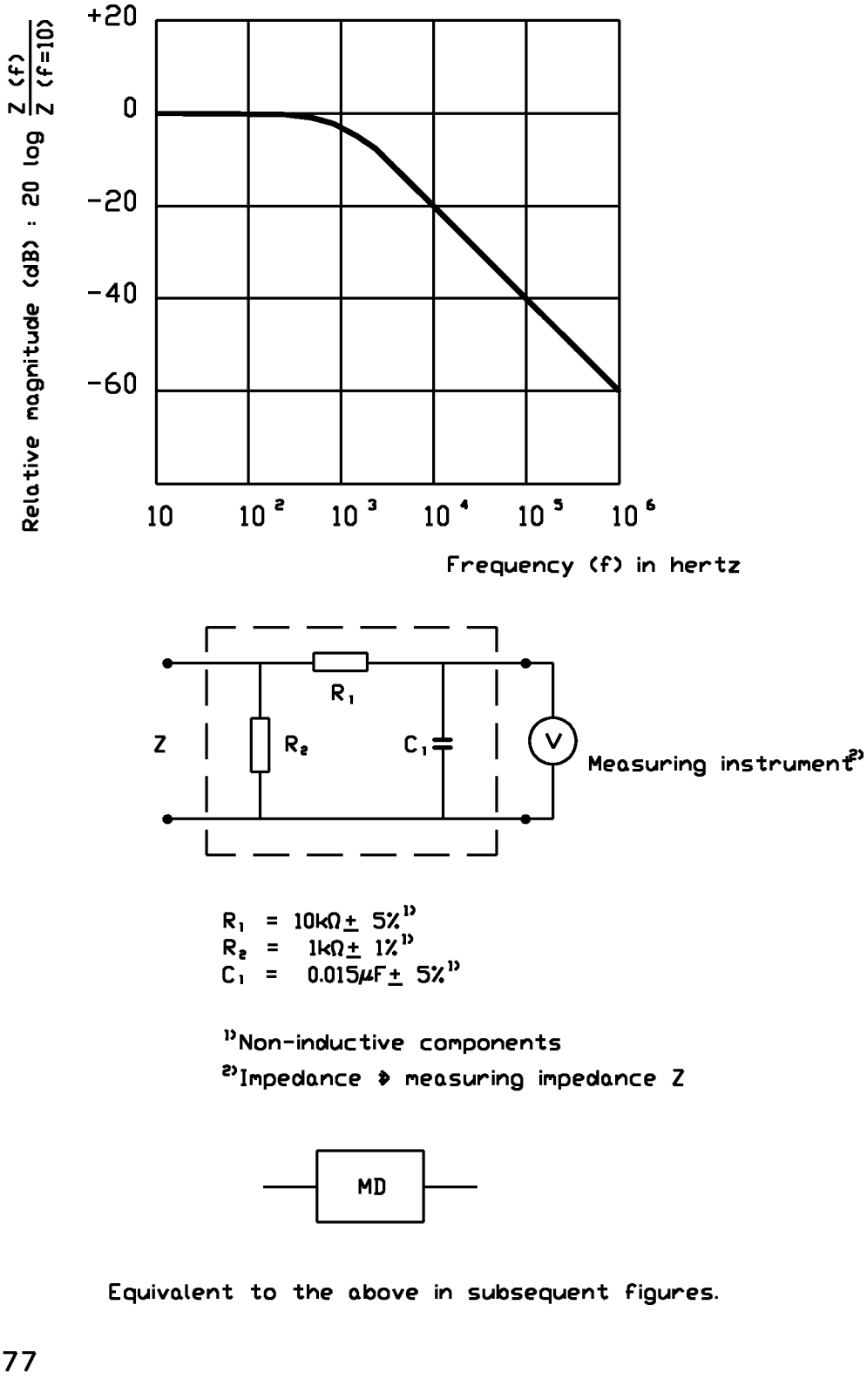
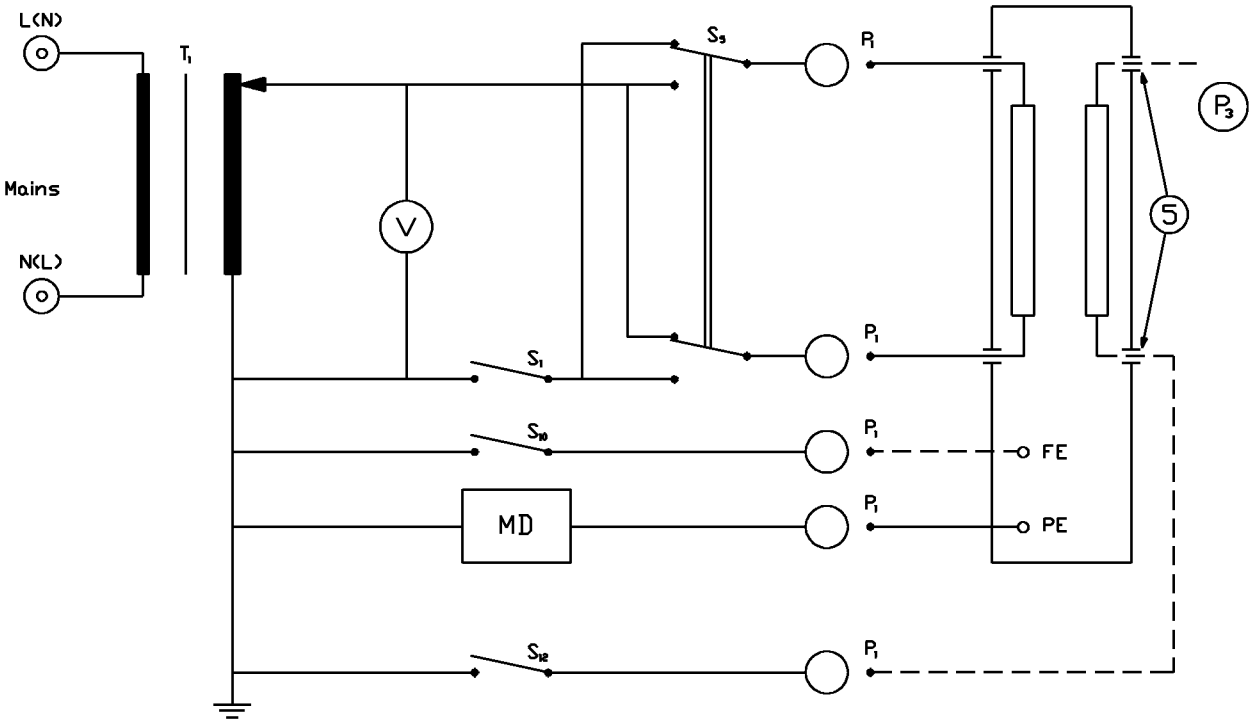


Figure 16 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I EQUIPMENT, with or without APPLIED PART (see Sub-clause 19.4*f)* and notes to Table IV). Example with the measuring supply circuit of Figure 10.



See legends after Figure 27

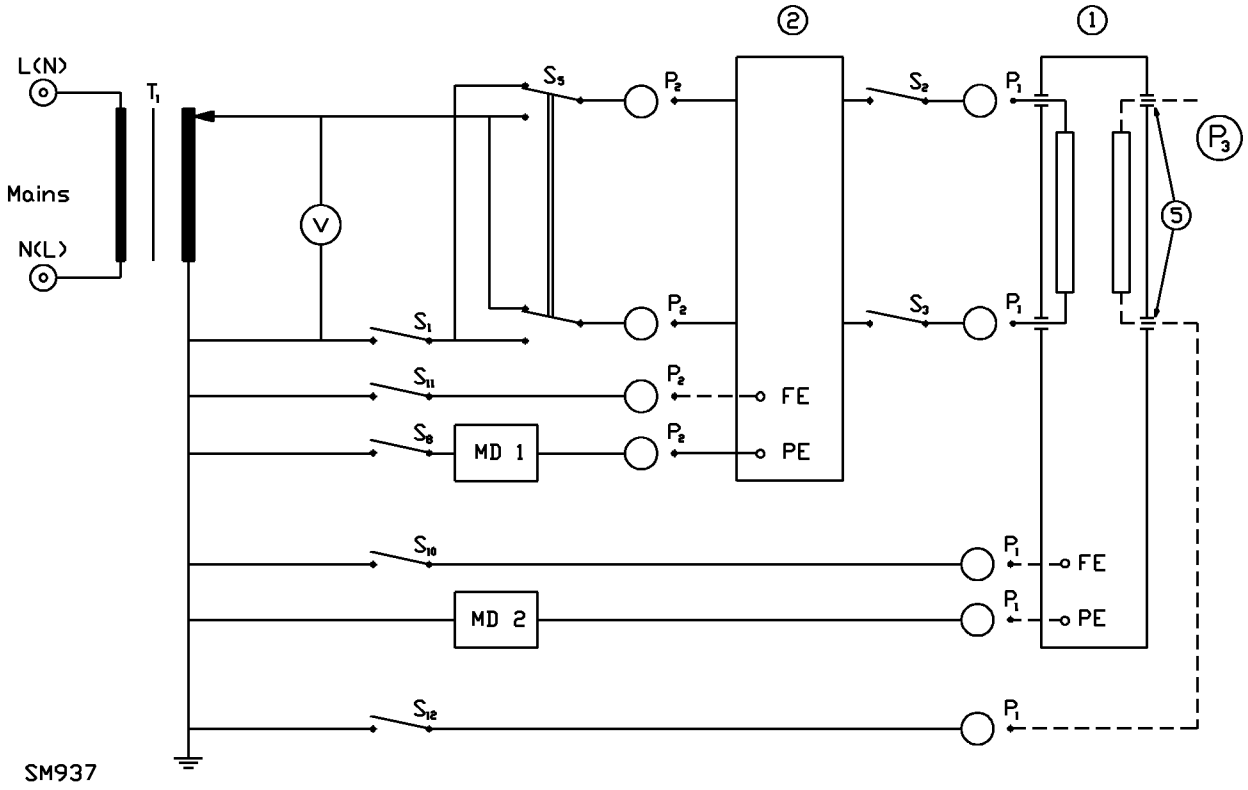
Measure in all possible combinations of positions of S_5, S_{10} and S_{12} with:

S_1 closed (NORMAL CONDITION), and

S_1 open (SINGLE FAULT CONDITION) and for measurement in accordance with Sub-clause 19.4*a)*, Table IV, notes 1 up to and including 4

S_1 open (SINGLE FAULT CONDITION)

Figure 17 – Measuring circuit for the EARTH LEAKAGE CURRENT of EQUIPMENT, with or without APPLIED PART, specified for use with a specified class I single-phase power supply using the measuring supply circuit of Figure 14 (see Sub-clause 19.4*f)* and notes of Table IV).



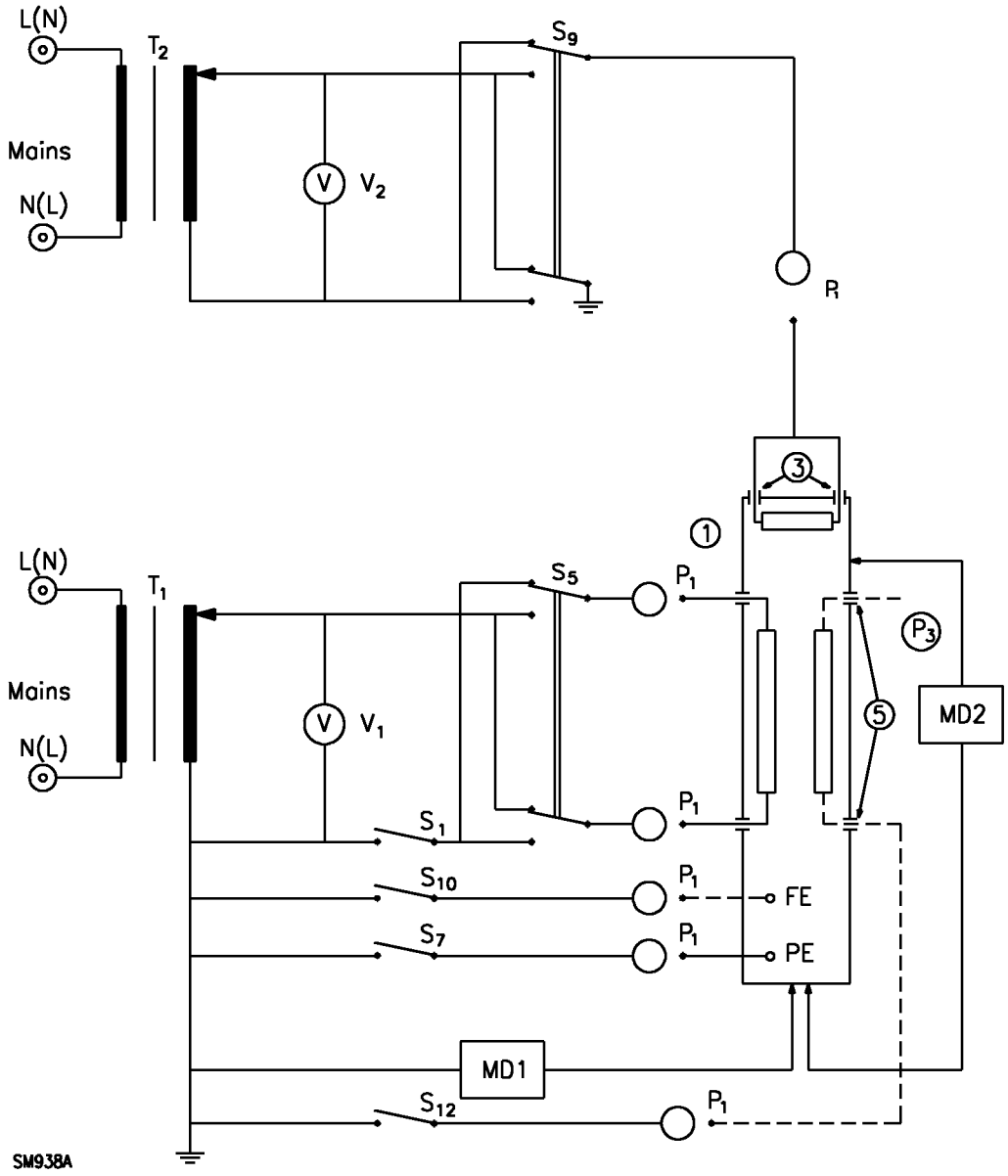
See legends after Figure 27

Measure with MD1 and MD2, with S_8 closed and S_1, S_2 and S_3 closed and under all possible combinations of positions of S_5, S_{10}, S_{11} and S_{12} (NORMAL CONDITION).

Measure with MD2, with S_8 open (SINGLE FAULT CONDITION) if the specified power supply is PROTECTIVELY EARTHED and with S_1, S_2 and S_3 closed under all possible combinations of positions of S_5, S_{10}, S_{11} and S_{12}.

Additionally, with S_8 closed and one of the switches S_1, S_2 or S_3 opened in turn (SINGLE FAULT CONDITION) but only for measurements in accordance with notes to Table IV.

Figure 18 – Measuring circuit for the ENCLOSURE LEAKAGE CURRENT. For CLASS II EQUIPMENT the protective earth connection and S_7 are not used. Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*g*)).



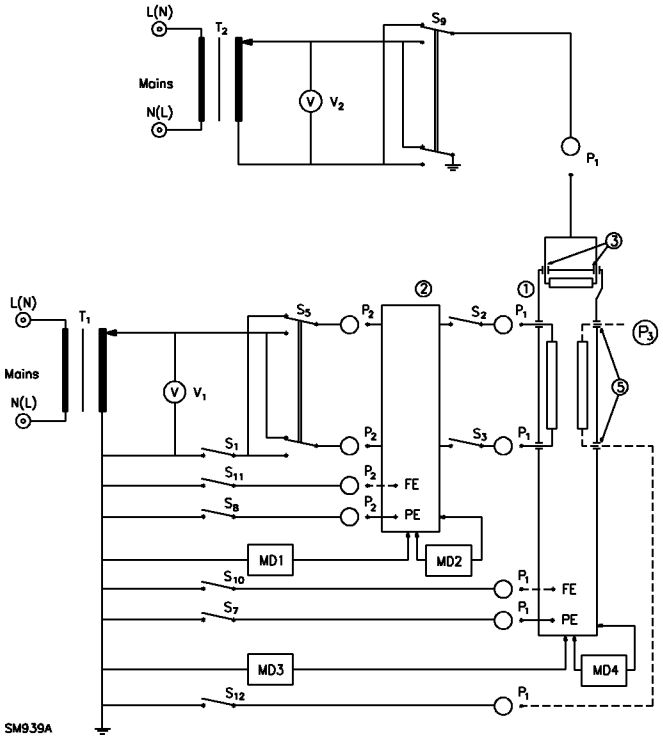
See legends after Figure 27

Measure (with S_7 closed if CLASS I EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_9, S_{10} and S_{12}. S_1 open is SINGLE FAULT CONDITION.

Class I only:

Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{12}.

Figure 19 – Measuring circuit for the ENCLOSURE LEAKAGE CURRENT of EQUIPMENT with or without APPLIED PART, intended only for use with a specified single-phase power supply. For a specified single-phase supply circuit of Class II, the protective earth connection and S_7 are not used. Example with measuring supply circuit of Figure 14 (see Sub-clause 19.4*g*)).



See legends after Figure 27

Measure with MD1 and MD2 (with S_8 closed if specified power supply is of class I) under all possible combinations of positions of S_1, S_5, S_9 and S_{11}. S_1 open is SINGLE FAULT CONDITION.

Specified power supply of class I only:

Measure with MD1 and MD2 with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_9 and S_{11}.

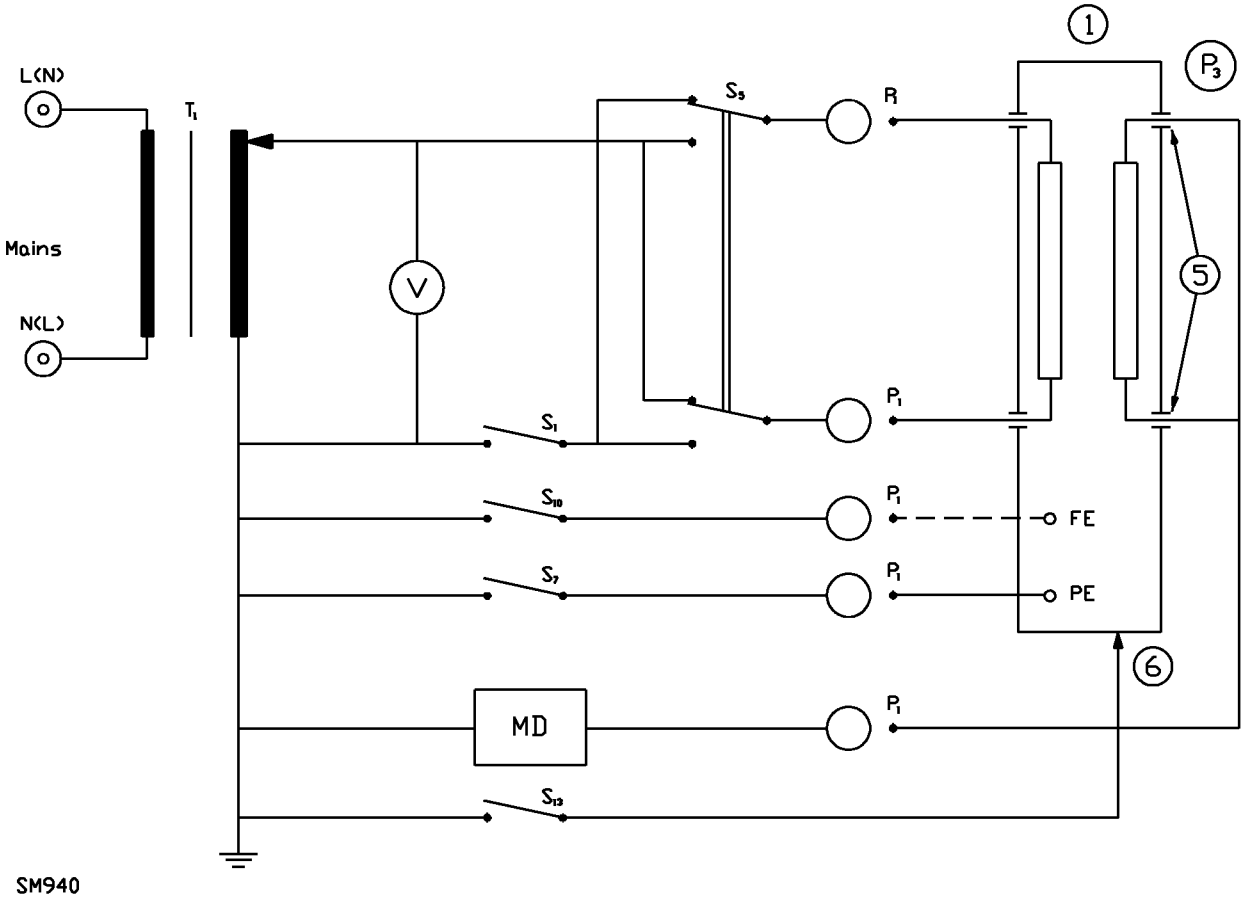
Measure with MD3 and MD4 (with S_7 closed if the EQUIPMENT itself is of Class I and with S_8 closed if the specified power supply is of class I) with:

- S_1, S_2 and S_3 closed (NORMAL CONDITION), and
- S_1 or S_2 or S_3 open (SINGLE FAULT CONDITION) under all possible combinations of positions of S_5 and of S_9, S_{10}, S_{11} and S_{12}.

Measure with MD3 and MD4 with either (SINGLE FAULT CONDITION):

- S_7 open (when the EQUIPMENT is of Class I) or
- S_8 open (when the specified power supply is of class I) and with S_1, S_2 and S_3 closed under all possible combinations of positions of S_5 and of S_9, S_{10}, S_{11} and S_{12}.

Figure 20 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth. For CLASS II EQUIPMENT, the protective earth connection and S_7 are not used. Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h*)).



See legends after Figure 27

Measure (with S_7 closed if Class I) under all possible combinations of positions of S_1, S_5 and of S_{10}.

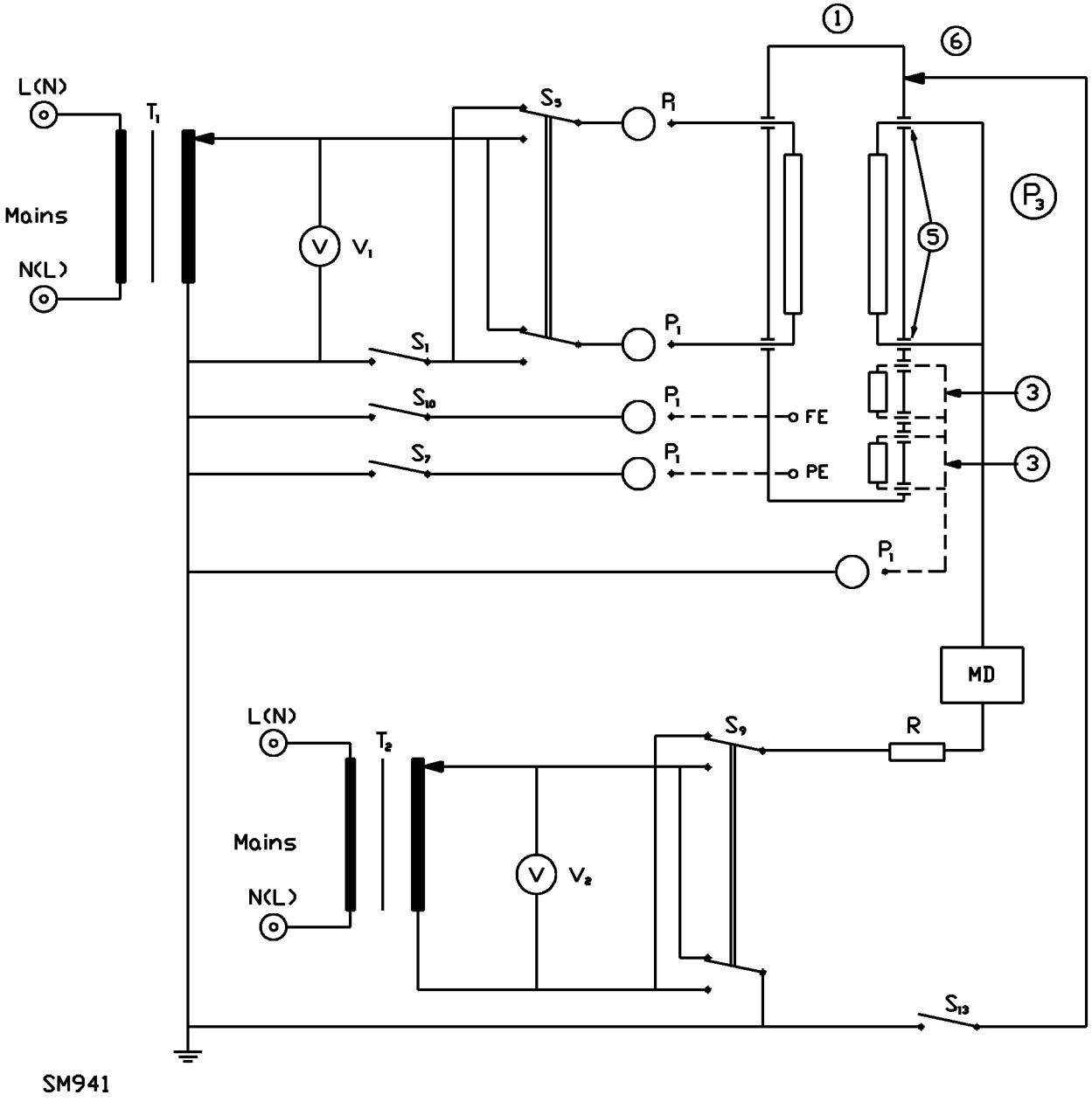
S_1 open is SINGLE FAULT CONDITION.

Class I only:

Perform, if applicable, the test of Sub-clause 17*a)* (SINGLE FAULT CONDITION).

Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_{10} and S_{13}.

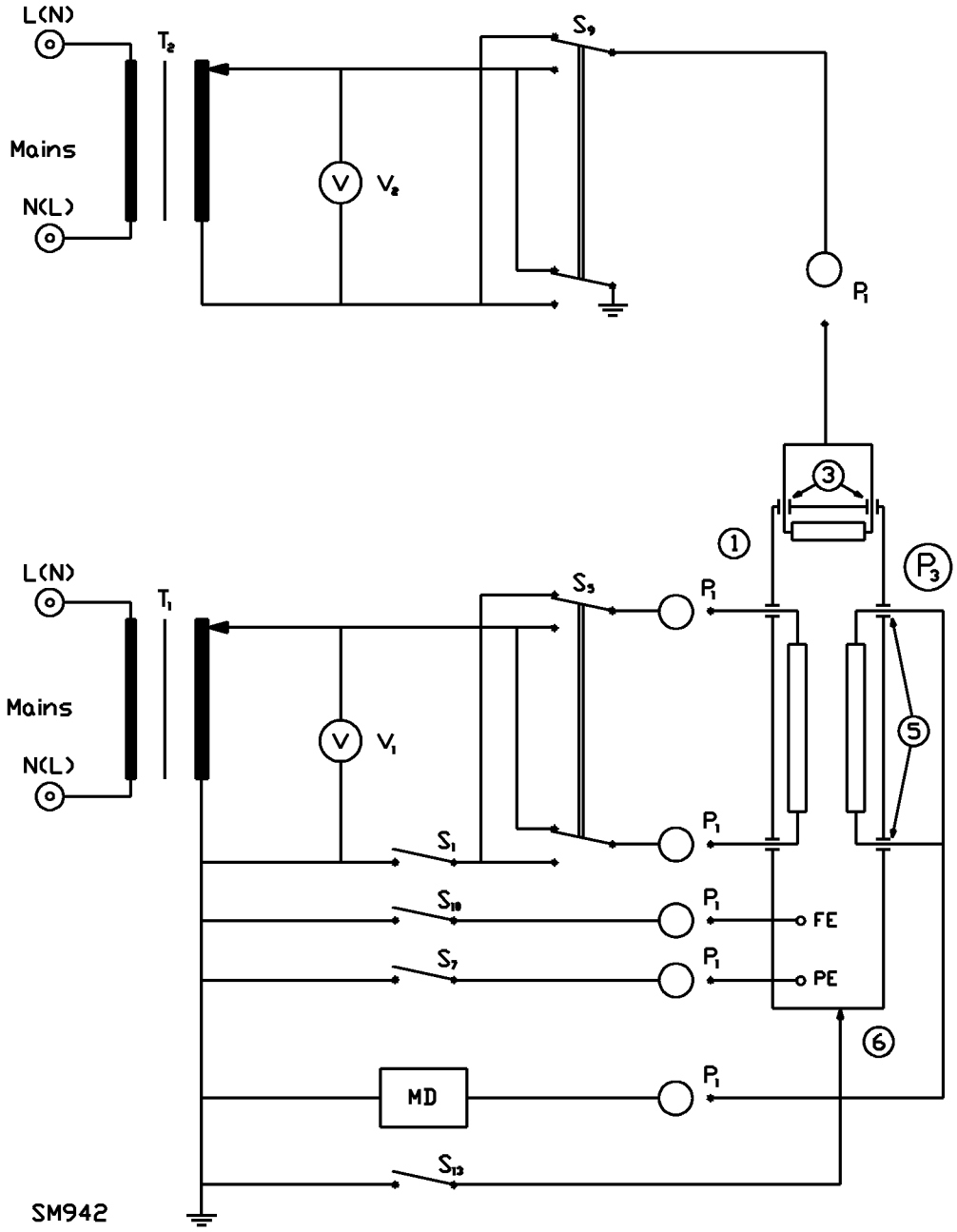
Figure 21 – Measuring circuit for the PATIENT LEAKAGE CURRENT via an F-TYPE APPLIED PART to earth caused by an external voltage on the APPLIED PART. For CLASS II EQUIPMENT the protective earth connection and S_7 are not used. Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h*)).



See legends after Figure 27

Measure (with S_7 closed, if CLASS I EQUIPMENT) with S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{13} (SINGLE FAULT CONDITION).

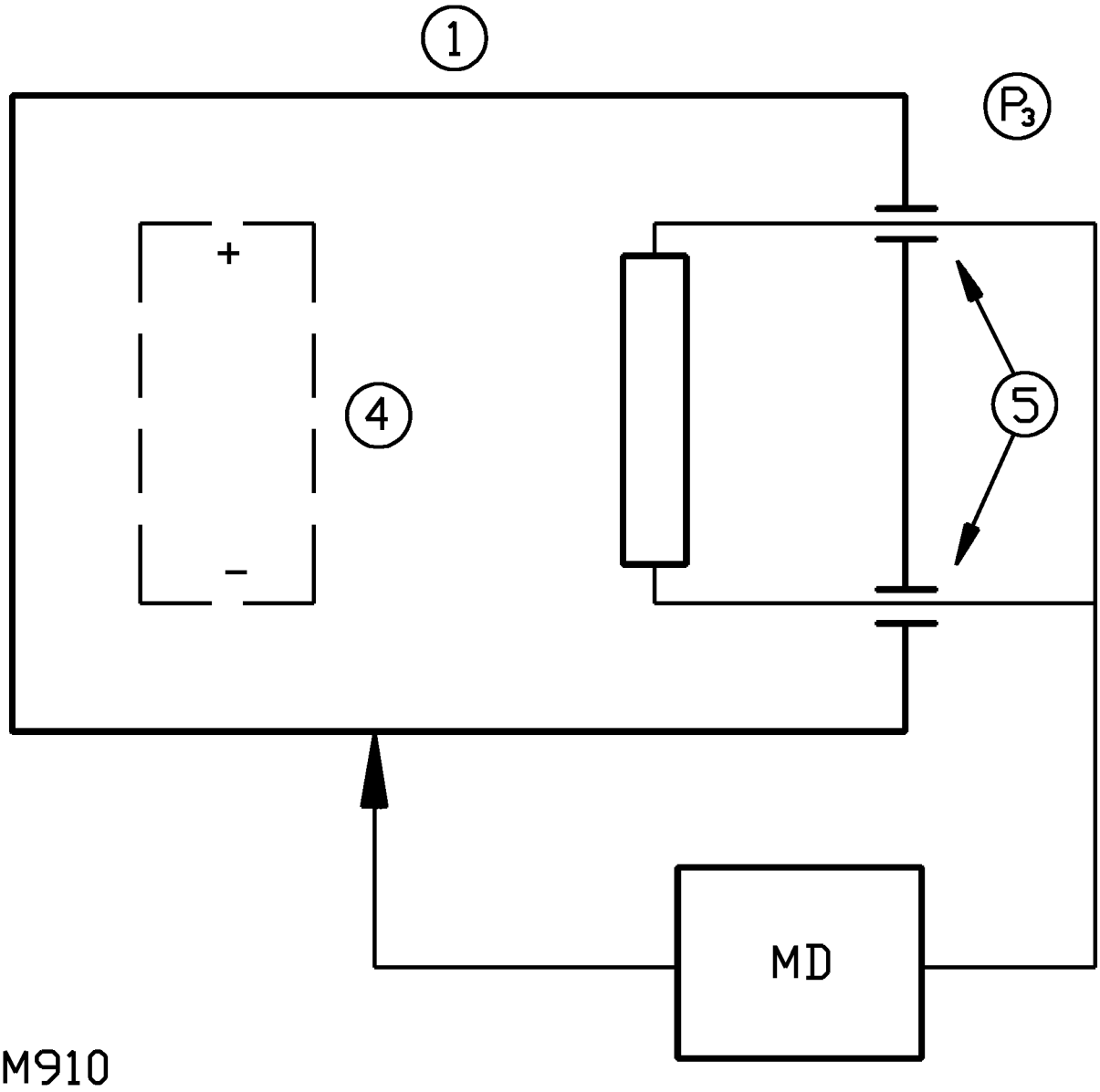
Figure 22 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth caused by an external voltage on a SIGNAL INPUT or a SIGNAL OUTPUT PART. For CLASS II EQUIPMENT the protective earth connection and S_7 are not used. Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h*)).



See legends after Figure 27

Measure (with S_7 closed, if Class I) with S_1 closed under all possible combinations of positions of S_5 and S_9, S_{10} and S_{13} (SINGLE FAULT CONDITION).

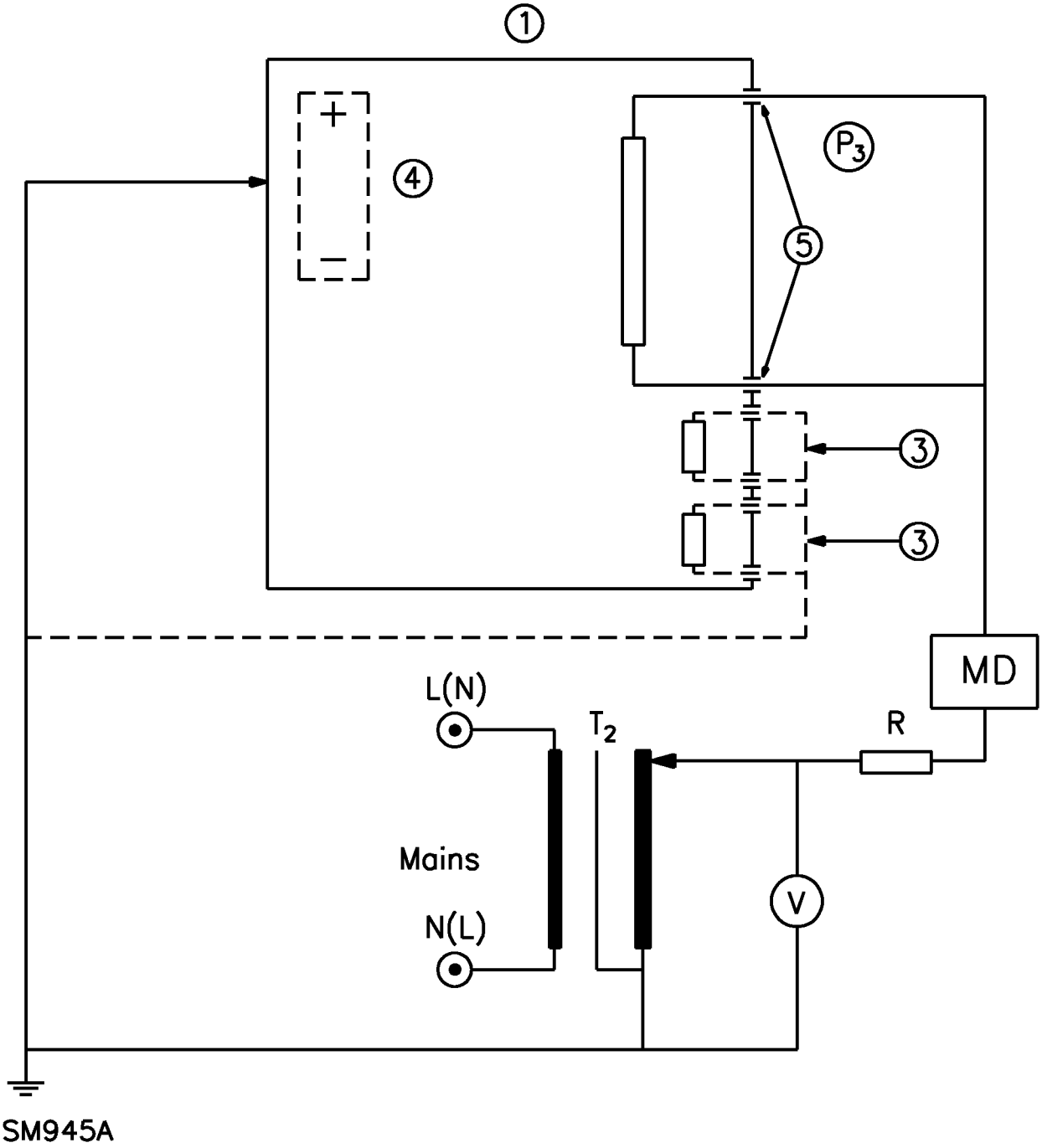
Figure 23 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to the ENCLOSURE of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*h*)).



See legends after Figure 27

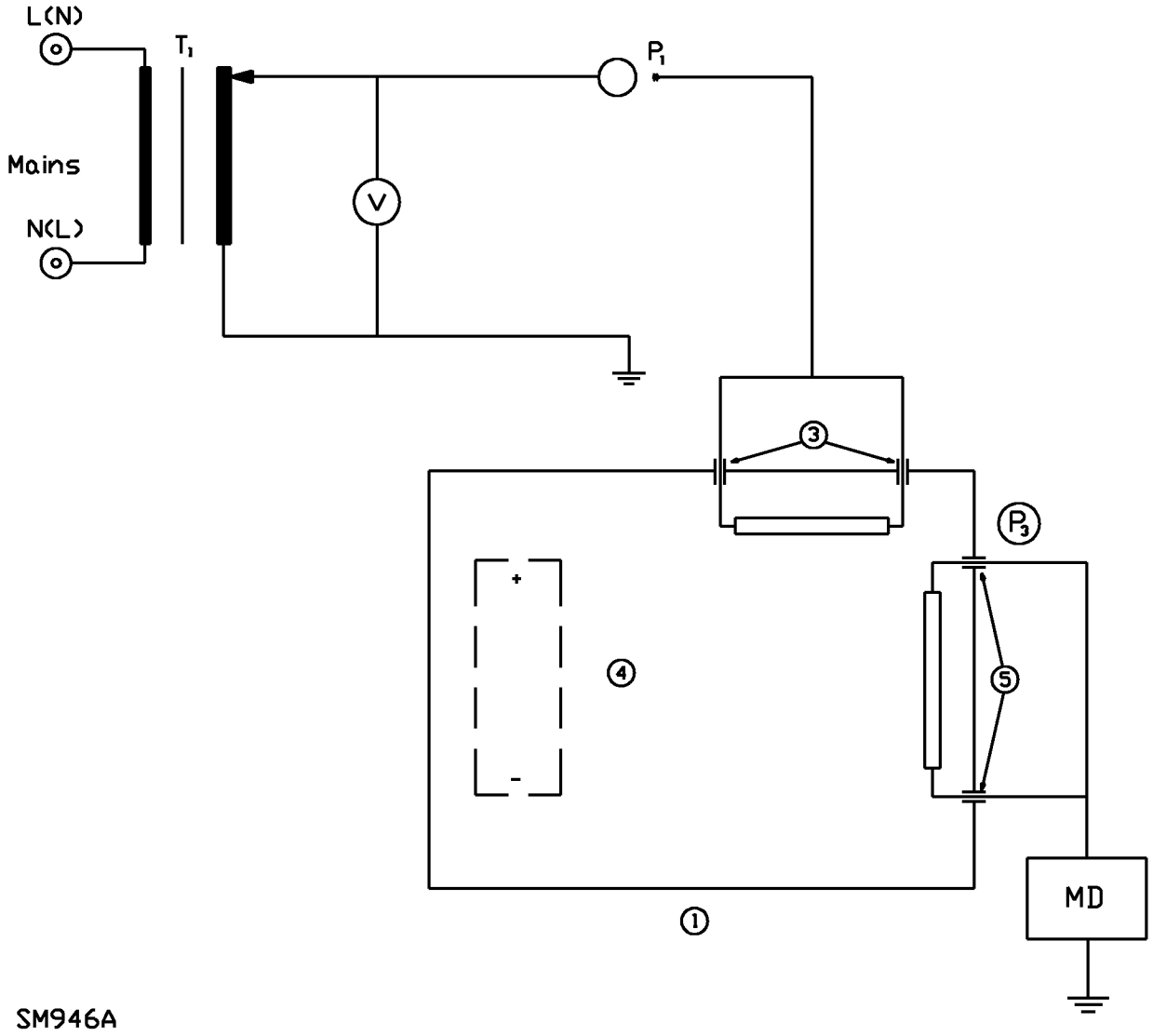
Measure between the APPLIED PART and the ENCLOSURE (NORMAL CONDITION). Perform, if applicable, the test of Sub-clause 17a).

Figure 24 – Measuring circuit for the PATIENT LEAKAGE CURRENT via an F-TYPE APPLIED PART to the ENCLOSURE of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*h*)).



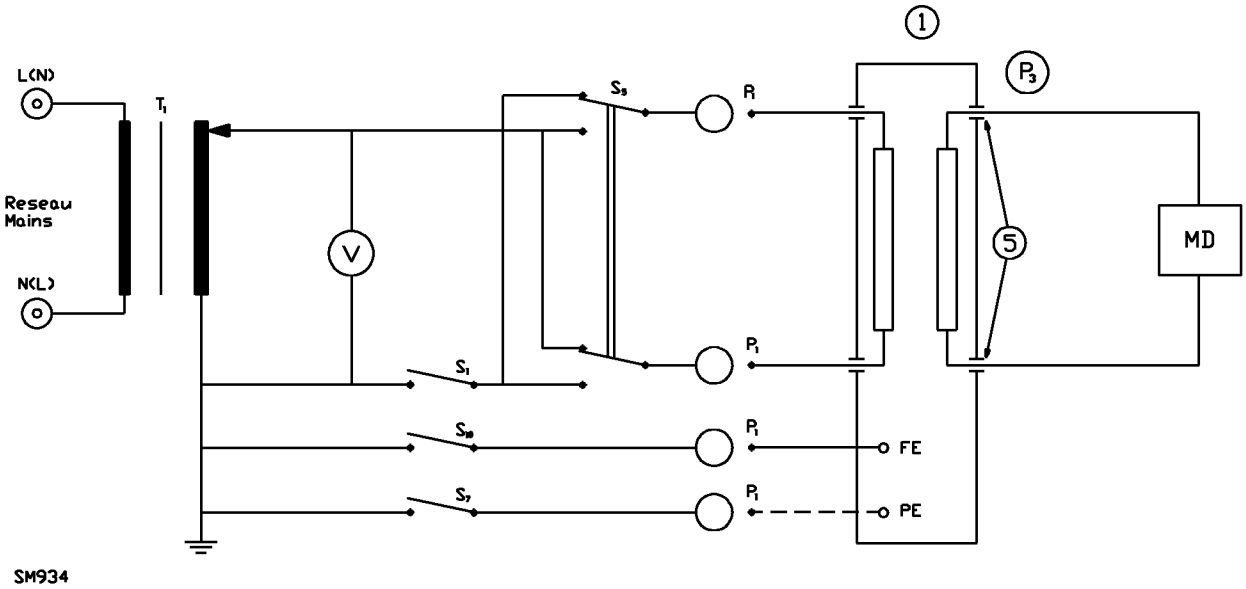
See legends after Figure 27

Figure 25 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED EQUIPMENT, caused by an external voltage on a SIGNAL INPUT or SIGNAL OUTPUT PART (see Sub-clause 19.4*h*)).



See legends after Figure 27

Figure 26 – Measuring circuit for the PATIENT AUXILIARY CURRENT. For CLASS II EQUIPMENT, the protective earth connection and S_7 are not used. Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*j*)).



See legends after Figure 27

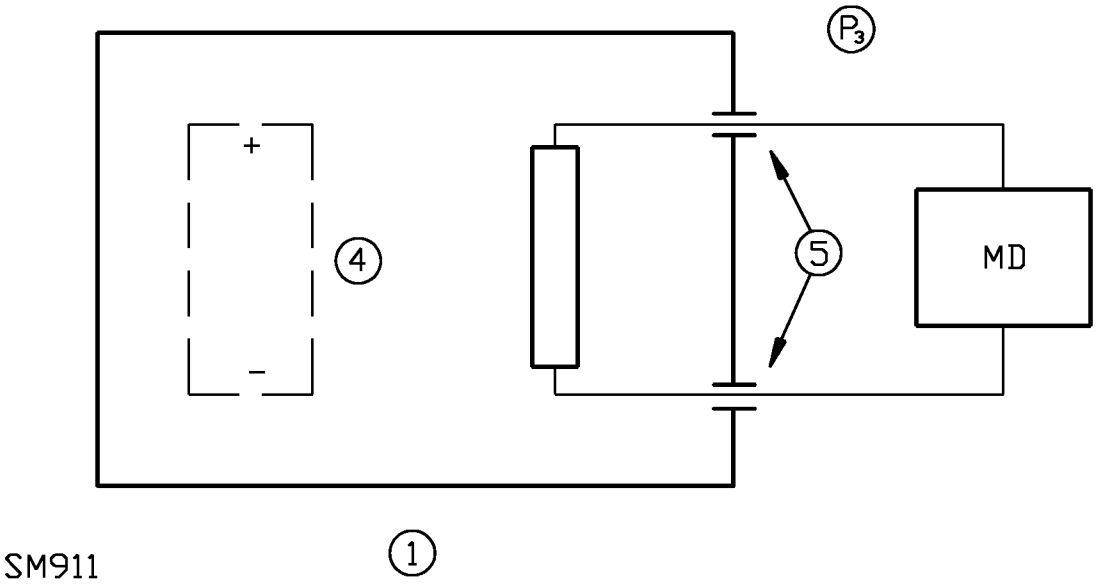
Measure (with S_7 closed if Class I) under all possible combinations of positions of S_1, S_5 and S_{10}.

S_1 open is SINGLE-FAULT CONDITION.

Class I only:

Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5 and S_{10}.

Figure 27 – Measuring circuit for the PATIENT AUXILIARY CURRENT of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*j*).

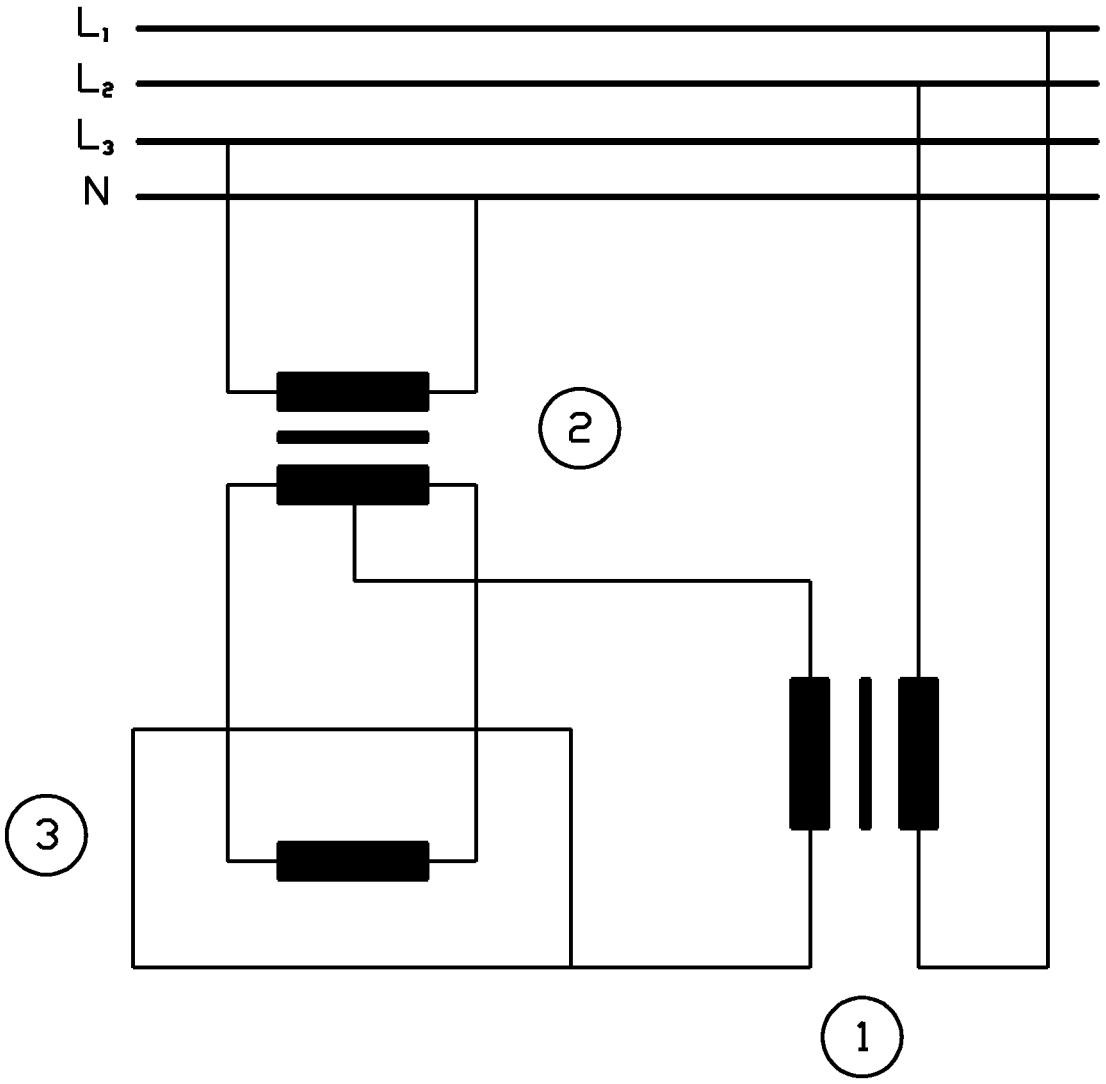


See legends

Legends of symbols for Figures 10 to 27

①	EQUIPMENT ENCLOSURE
②	Specified power supply
③	SIGNAL INPUT or SIGNAL OUTPUT PART short-circuited or loaded
④	INTERNAL ELECTRICAL POWER SOURCE
⑤	APPLIED PART
⑥	ACCESSIBLE METAL PART not being an APPLIED PART and not PROTECTIVELY EARTHED
T_1, T_2	Single-, double-, polyphase isolation transformers with sufficient power rating and adjustable output voltage
V (1,2,3)	Voltmeters indicating r.m.s. value, using, if relevant and possible, one meter with a commutator switch
S_1,S_2,S_3	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION)
S_5,S_9	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S_7,S_8	Single-pole switches, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR (SINGLE FAULT CONDITION)
S_{10},S_{11}	Switches for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply circuit.
S_{12}	Switch for connecting an F-TYPE APPLIED PART to the earthed point of the measuring supply circuit
S_{13}	Switch for connecting to earth an ACCESSIBLE METAL PART not being an APPLIED PART and not PROTECTIVELY EARTHED
P_1	Sockets, plugs or terminals for the supply connection of the EQUIPMENT
P_2	Sockets, plugs or terminals for the connection to a specified power supply
P_3	Sockets, plugs or terminals for the PATIENT CONNECTIONS
MD(1,2,3,4)	Measuring devices (see Figure 15)
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL
---	Optional connection.
R	Impedance for protection of USER of test apparatus.

Figure 28 – Example of a circuit for dielectric strength test at operating temperature for heating elements (see Sub-clause 20.4).



1 Test transformer

2 Isolating transformer

3 EQUIPMENT

SM947

Figure 29 – Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).

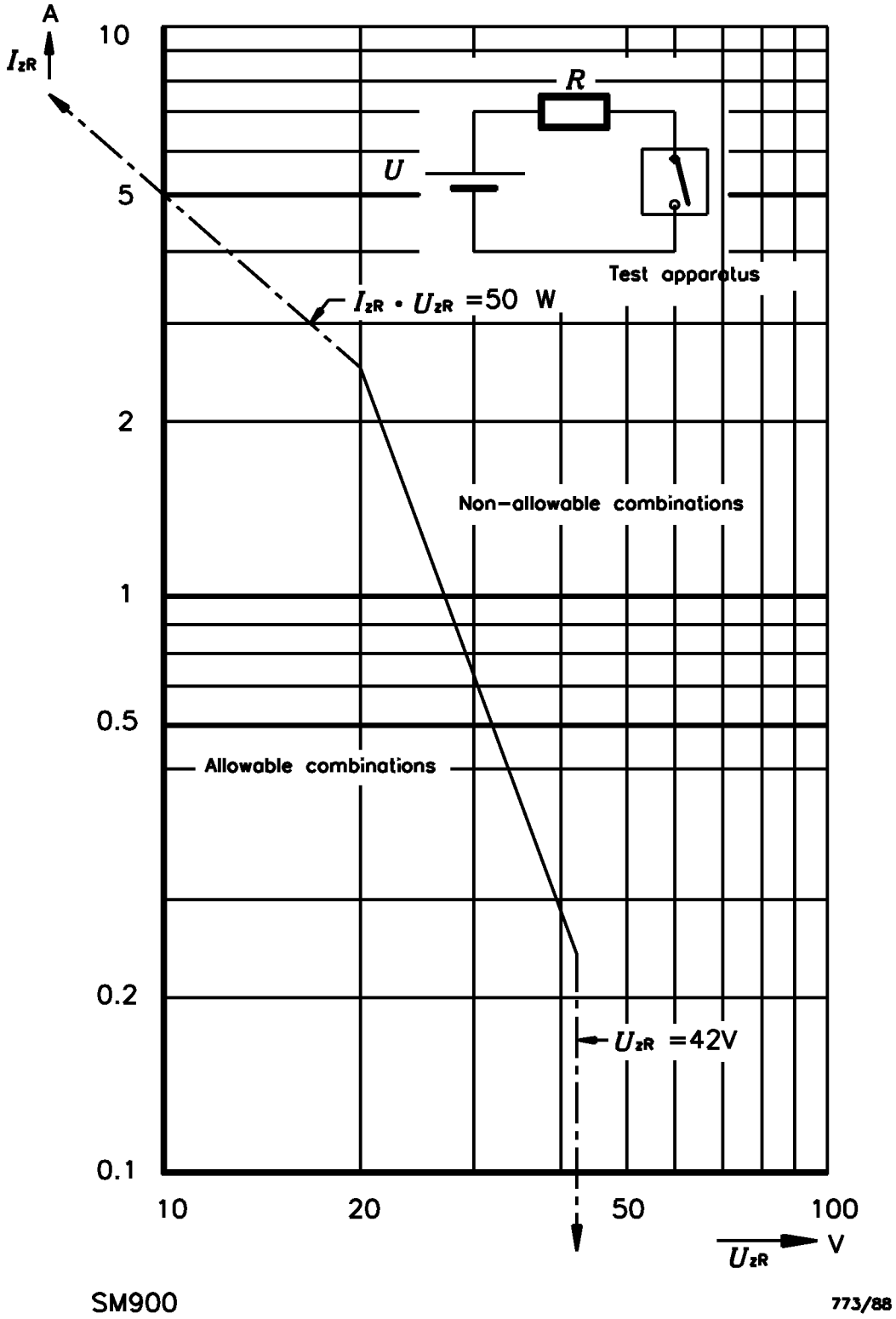
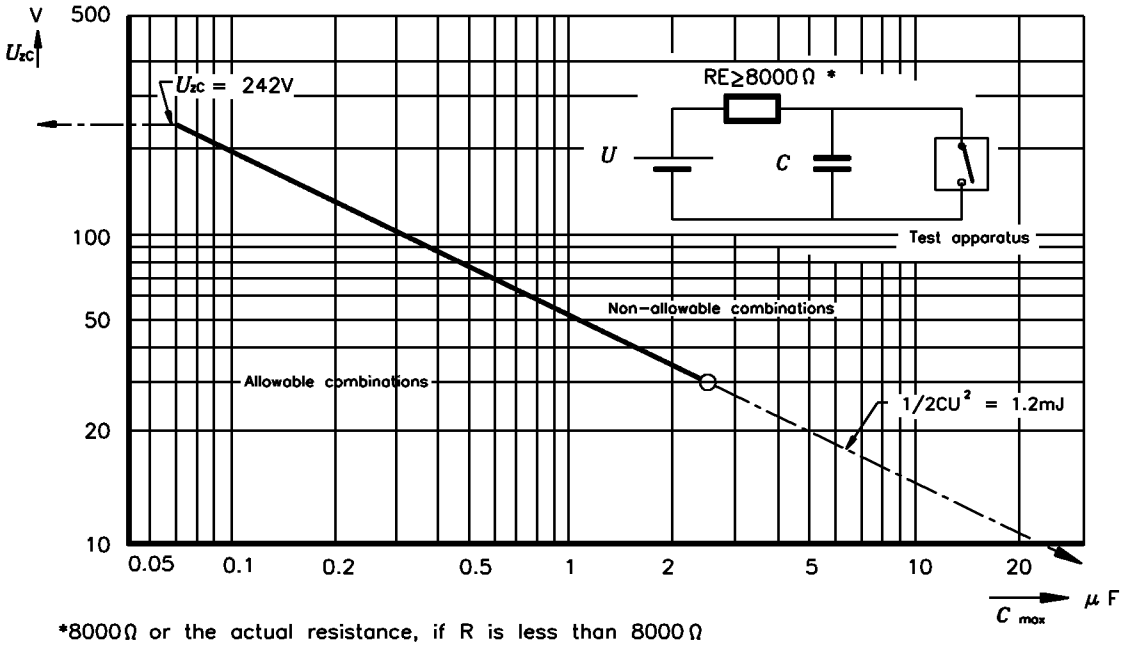


Figure 30 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).



*8000Ω or the actual resistance, if R is less than 8000Ω

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SM901

Figure 31 – Maximum allowable current I_{ZL} as a function of the inductance L_{max}, measured in an inductive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).

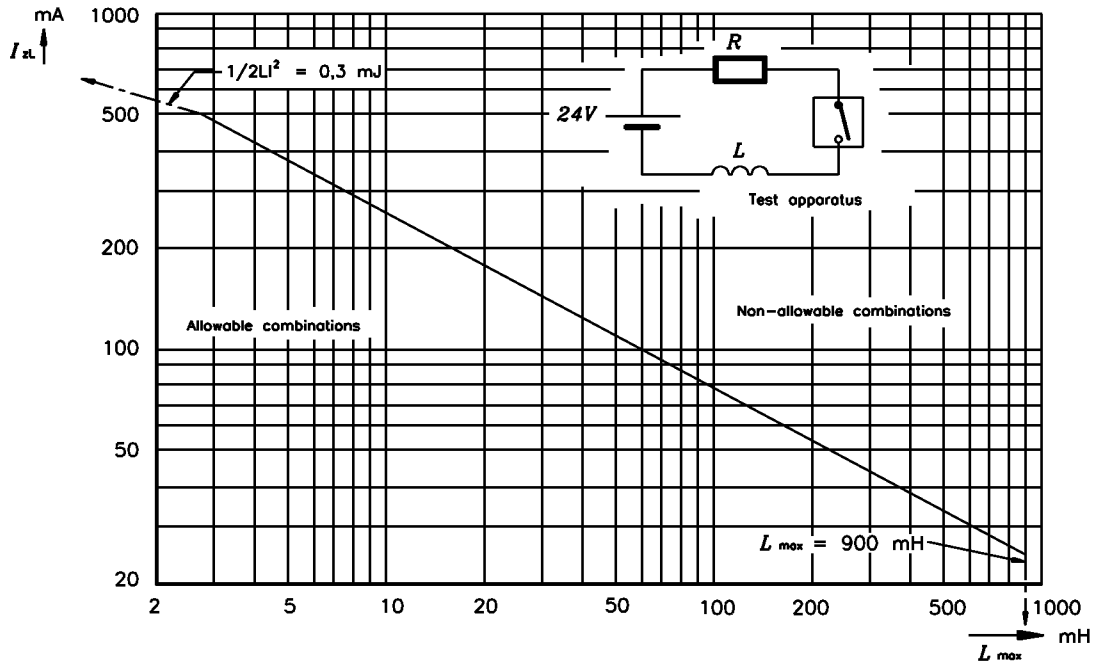

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Figure 32 – Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR}, measured in a purely resistive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).

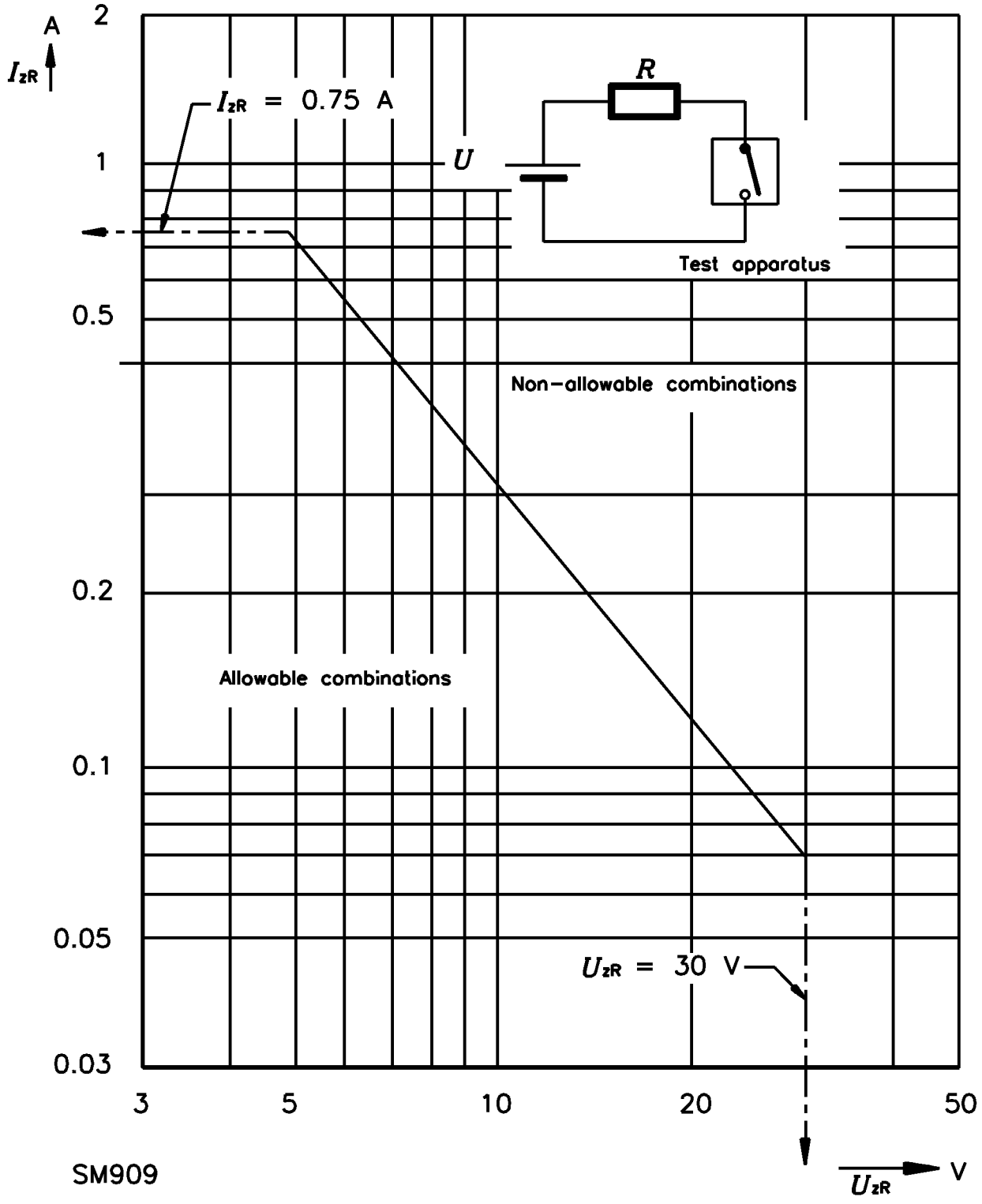
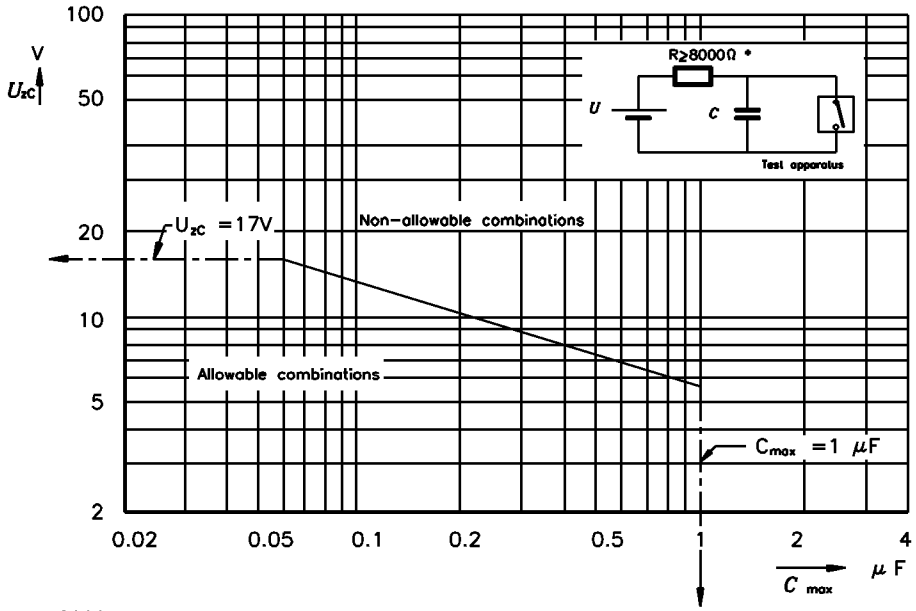


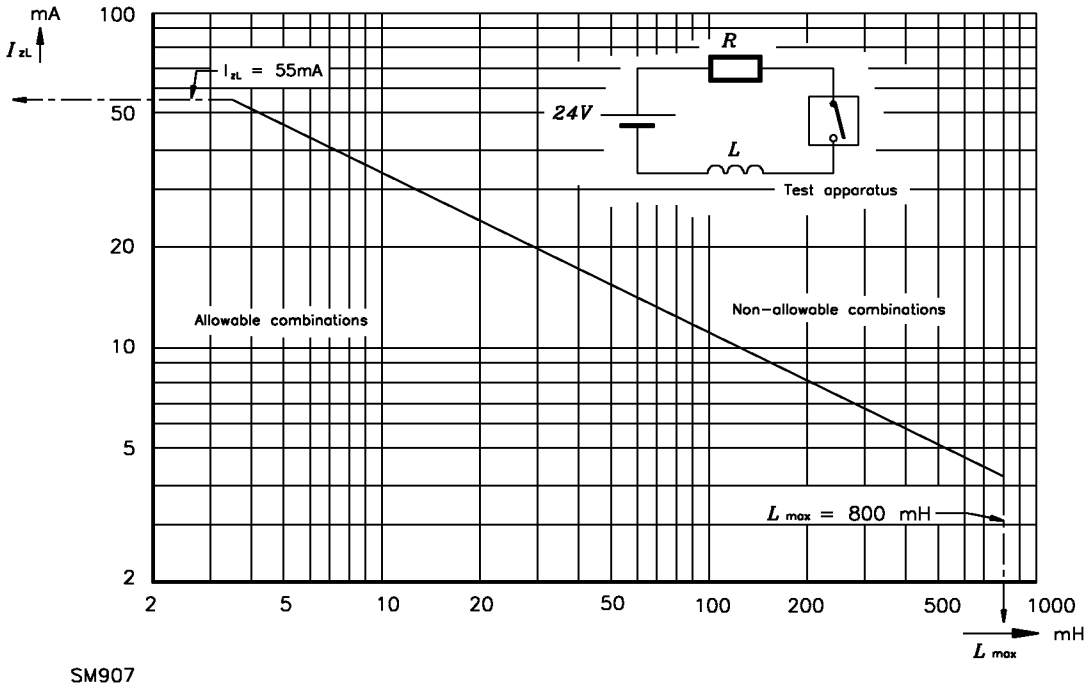
Figure 33 – Maximum allowable voltage U_{zC} as a function of the capacity C_{max}, measured in a capacitive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).



*8000Ω, or the actual resistance, if R is less than 8000Ω

SM908A

Figure 34 – Maximum allowable current I_{zL} as a function of the inductance L_{max}, measured in an inductive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).



SM907

Figure 35 – Not used.

Figure 36 – Not used.

Figure 37 – Not used.

Figure 38 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE (see Sub-clause 45.2).

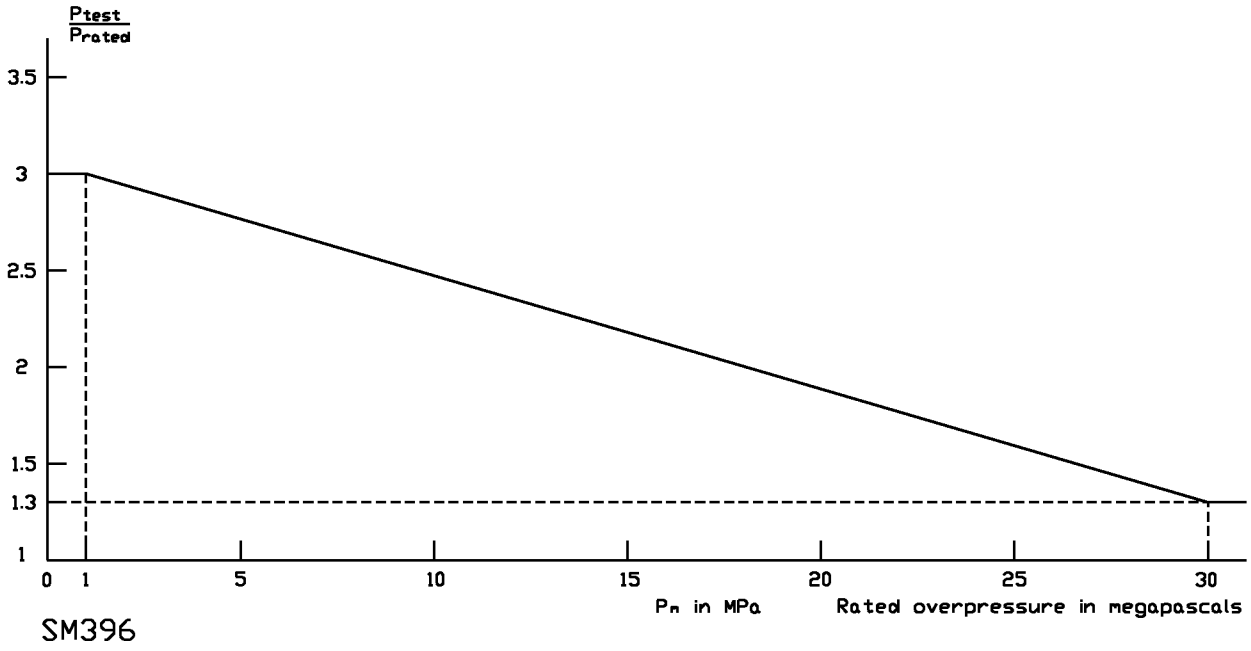
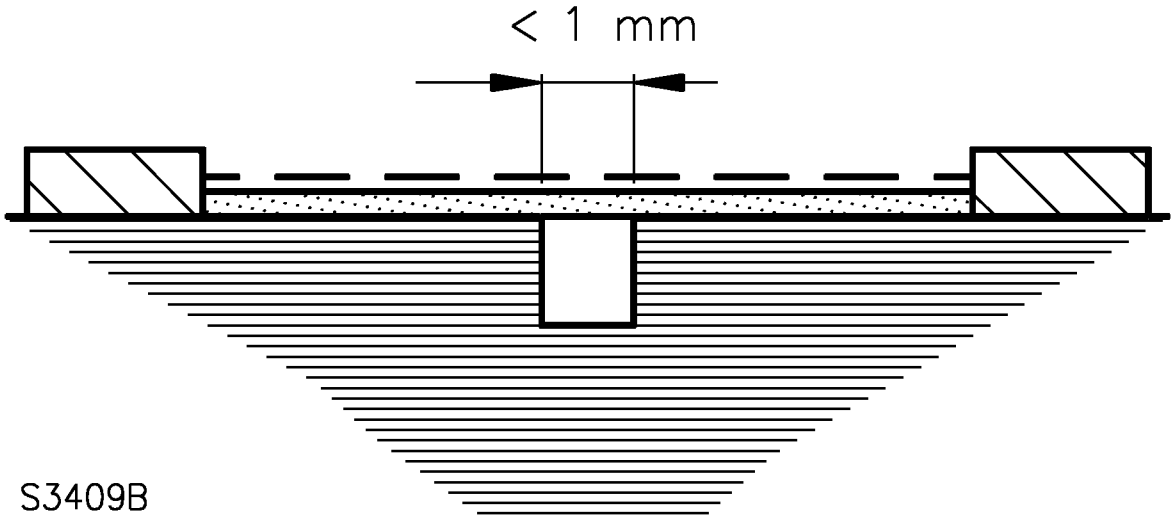


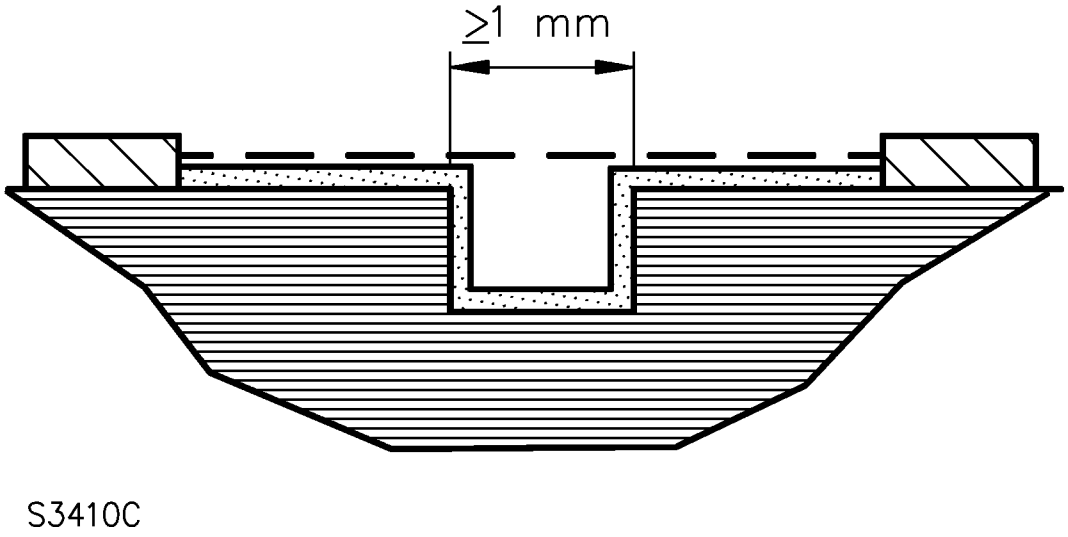
Figure 39 – Example 1 (see Sub-clause 57.10).



Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1 mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

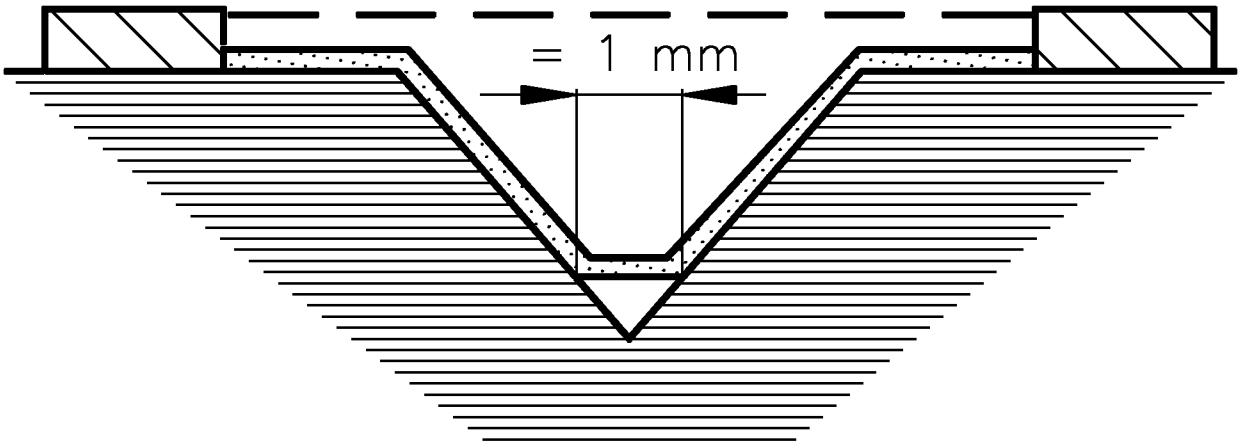
Figure 40 – Example 2 (see Sub-clause 57.10).



Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than 1 mm.

Rule: AIR CLEARANCE is the “line of sight” distance. Creepage path follows the contour of the groove.

Figure 41 – Example 3 (see Sub-clause 57.10).



S3411B

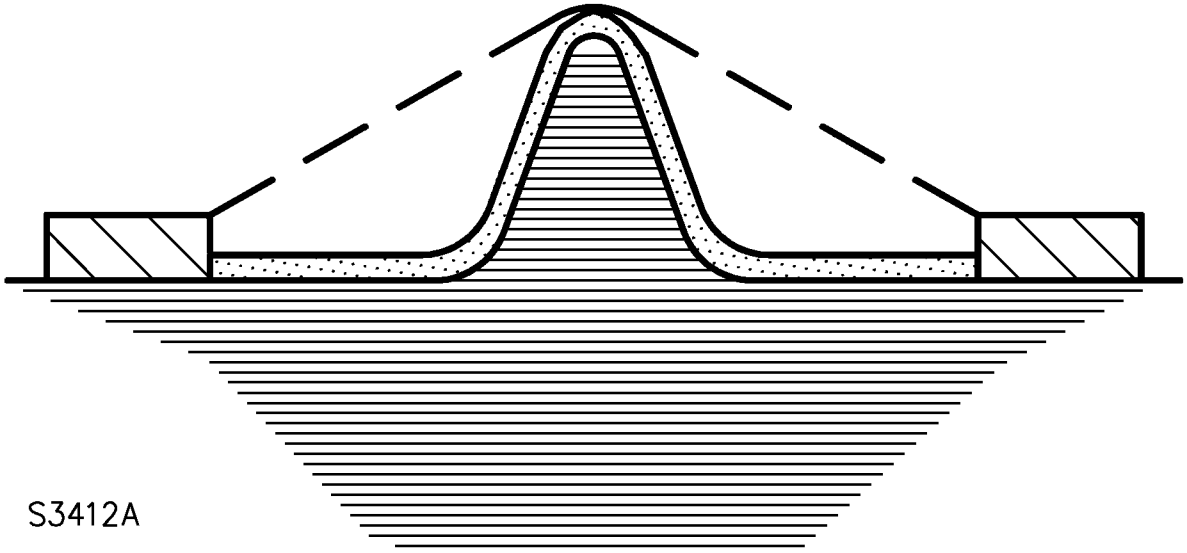
Condition: Path under consideration includes a V-shaped groove with a width greater than 1 mm.

Rule: AIR CLEARANCE is the “line of sight” distance. Creepage path follows the contour of the groove but “short-circuits” the bottom of the groove by a 1 mm link.

AIR CLEARANCE CREEPAGE DISTANCE

S3409C

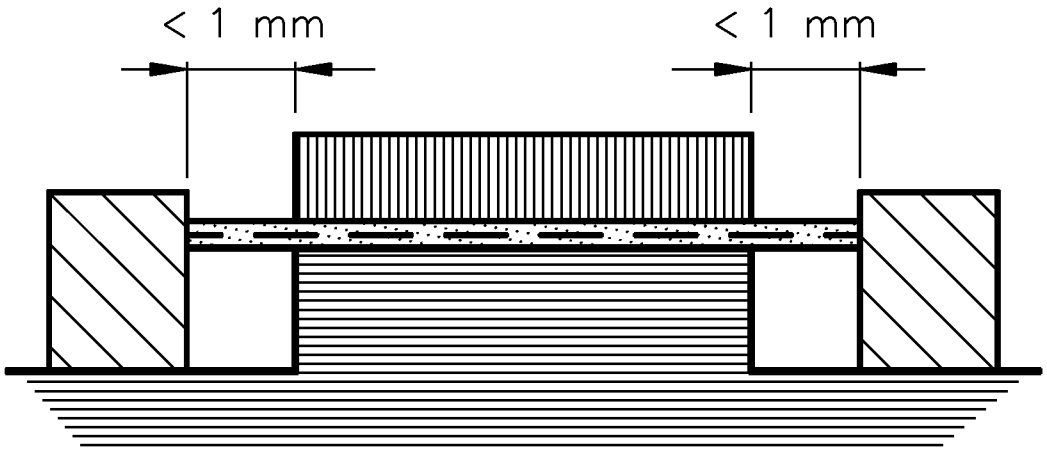
Figure 42 – Example 4 (see Sub-clause 57.10).



Condition: Path under consideration includes a rib.

Rule: AIR CLEARANCE is the shortest direct air path over the top of the rib. Creepage path follows the contour of the rib.

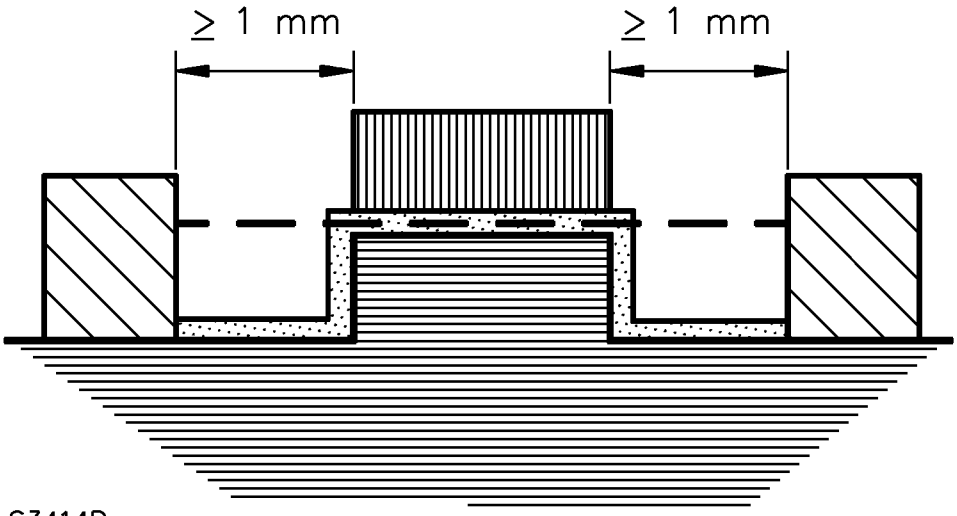
Figure 43 – Example 5 (see Sub-clause 57.10).



Condition: Path under consideration includes an uncemented joint with grooves less than 1 mm wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path is the “line of sight” distance shown.

Figure 44 – Example 6 (see Sub-clause 57.10).

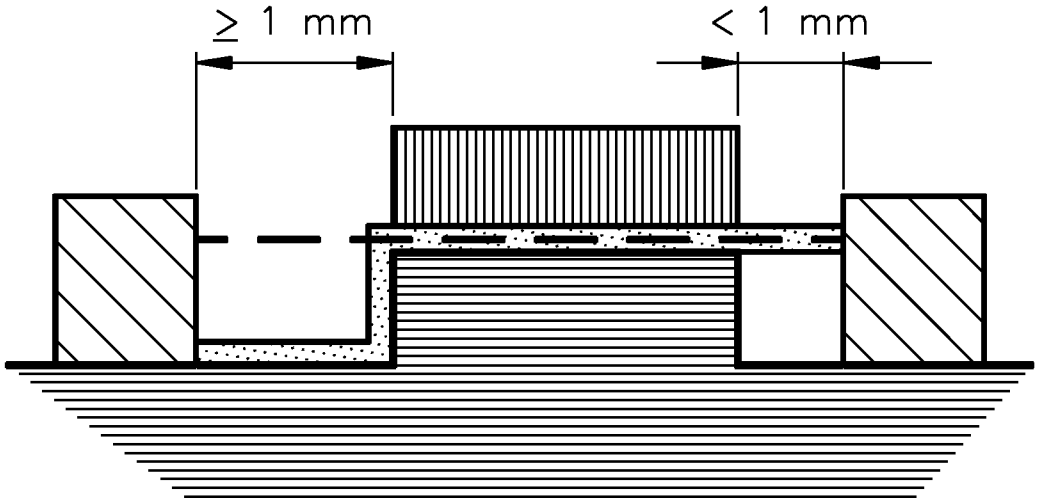


Condition: Path under consideration includes an uncemented joint with grooves equal to or more than 1 mm wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. Creepage path follows the contour of the grooves.

S3409C

Figure 45 – Example 7 (see Sub-clause 57.10).



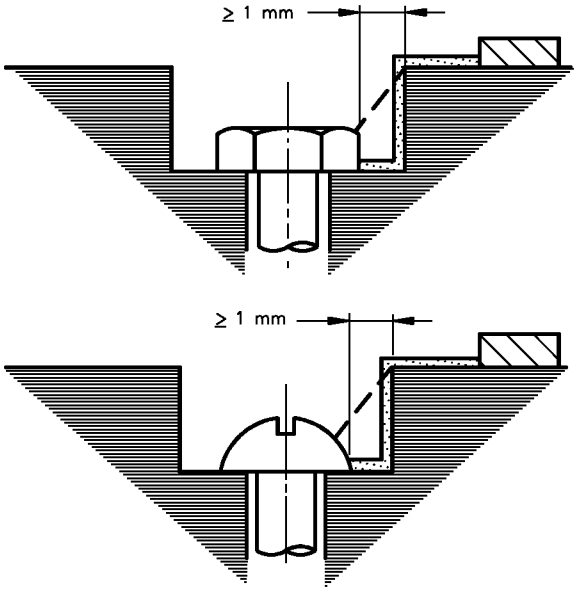
Condition: Path under consideration includes an uncemented joint with a groove on one side less than 1 mm wide and the groove on the other side equal to or more than 1 mm wide.

Rule: AIR CLEARANCES and CREEPAGE DISTANCES are as shown.

AIR CLEARANCE CREEPAGE DISTANCE

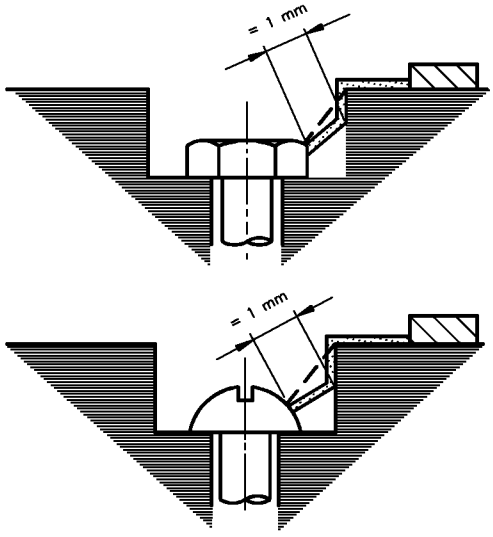
S3409C

Figure 46 – Example 8 (see Sub-clause 57.10).



Gap between head of screw and wall of recess wide enough to be taken into account.

Figure 47 – Example 9 (see Sub-clause 57.10).



Gap between head of screw and wall of recess too narrow to be taken into account.

Measurement of CREEPAGE DISTANCE is from screw to wall when the distance is equal to 1 mm.

Legends to Figures 39 to 47 (see Sub-clause 57.10)

1) The following methods for determination of CREEPAGE DISTANCES and AIR CLEARANCES shall be used in interpreting the requirements of this Standard.

The methods do not differentiate between gaps and grooves nor between types of insulation.

The following assumptions are made:

a) A transverse groove may have parallel, converging or diverging sides.

b) Any corner with included angle less than 80° may be assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 41).

c) Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 40).

d) CREEPAGE DISTANCES and AIR CLEARANCES measured between parts moving relative to each other are considered in their least favourable position.

e) Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.

f) Any air gap less than 1 mm wide is ignored in computing the total AIR CLEARANCE (see Figures 39 to 47).

2) LIVE parts which are varnished, enamelled or oxidized only are considered to be bare LIVE parts. Coverings of any insulating material, however, may be considered as insulation, if the covering is equivalent to a foil of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.

3) If CREEPAGE DISTANCES or AIR CLEARANCES are interrupted by a floating conductive part, the sum of the sections shall be not less than the minimum specified value given in Table XVI. Distances less than 1 mm are not taken into consideration. If the reference voltage is above 1 000 V, attention should be paid to the voltage division by the capacitances.

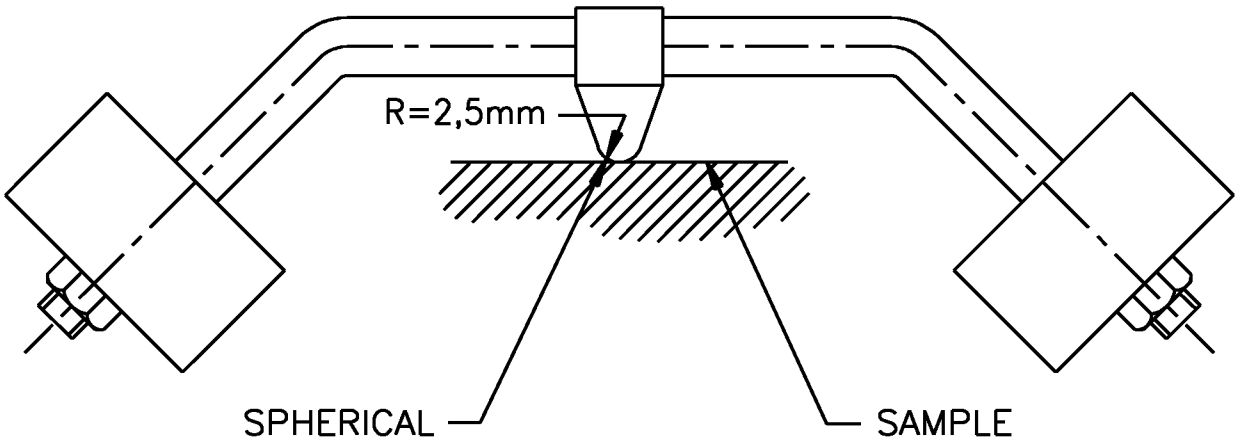
4) If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 40). In all other cases the groove is neglected.

5) In the case of barriers placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCE may be measured over the barrier only if the latter is so fixed that dust and moisture cannot penetrate into the joint or recess.

6) Narrow gaps, running into 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 may deposit there.

7) In figures 43 to 45 uncemented joints are mentioned for conditions of examples 5 to 7. For a description of cemented joints see subclause 57.9.4 f), second dash, in this Standard.

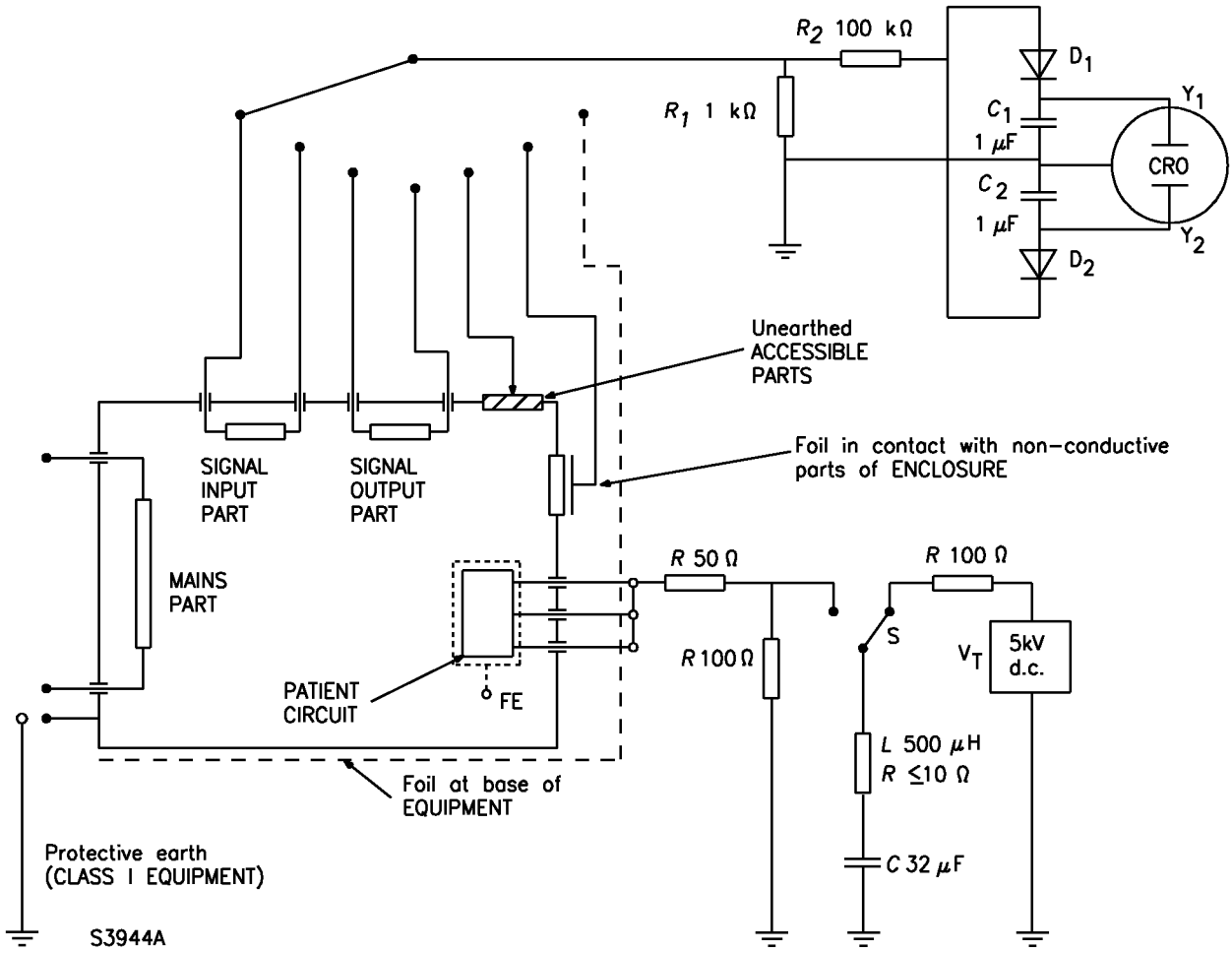
Figure 48 – Ball-PRESSURE test apparatus (see Sub-clause 59.2*b*)).



S1598B

Figure 49 – Not used.

Figure 50 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see subclause 17 *h))



See legends after Figure 27.

V_T Test voltage

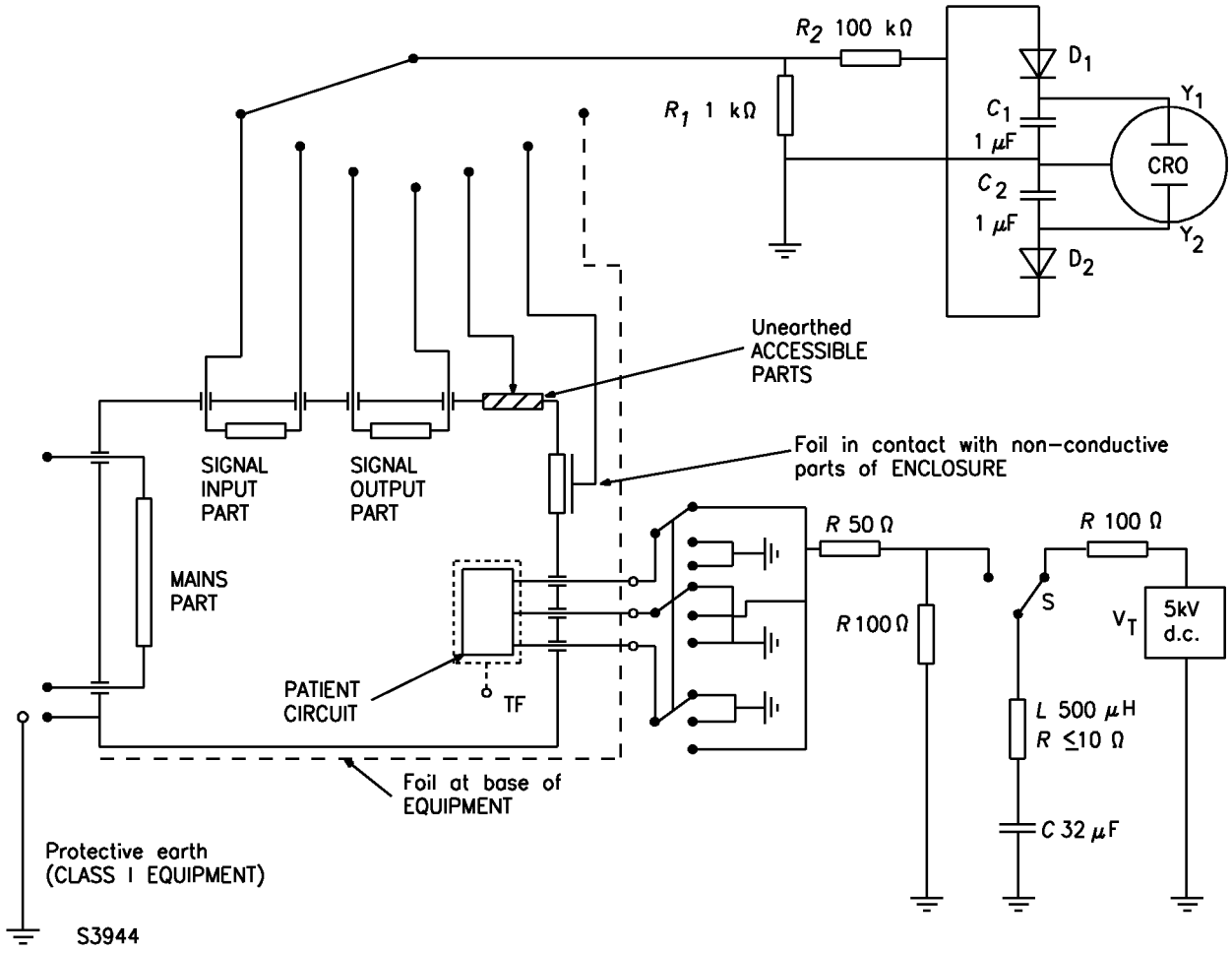
S Switch for applying the test voltage

R_1,R_2 Toleranced at 2%, not less than 2 kV; other components toleranced at 5%

CRO Cathode-ray oscilloscope (Z_{in} ≈ 1 MΩ)

D_1,D_2 Small signal silicon diodes

Figure 51 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see subclause 17 *h))



See legends after Figure 27.

V_T Test voltage

S Switch for applying the test voltage

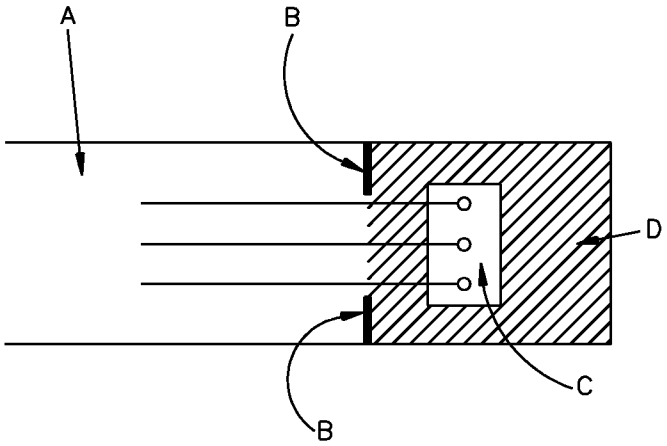
R_1,R_2 Toleranced at 2%, not less than 2 kV; other components toleranced at 5%

CRO Cathode-ray oscilloscope (Z_{in} ≈ 1 MΩ)

D_1,D_2 Small signal silicon diodes

Figure 52DV D2 *Addition:*

Figure 52DV – Example for 57.5DV



A – Field Wiring Compartment
B – Barrier
C – Terminal Block Not Intended for Field Wiring
D – Factory Wire Compartment

S2274

APPENDIX A
GENERAL GUIDANCE AND RATIONALE*

A1 General Guidance

This general safety Standard for MEDICAL ELECTRICAL EQUIPMENT is necessary because of the particular relationship of such EQUIPMENT to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) The inability of PATIENT or OPERATOR to detect the presence of certain potential hazards, such as ionizing or high-frequency radiation.

b) Absence of normal reactions of the PATIENT who may be ill, unconscious, anaesthetized, immobilized, etc.

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.

d) Support or replacement of vital body functions may depend on the reliability of EQUIPMENT.

e) The simultaneous connection to the PATIENT of more than one piece of EQUIPMENT.

f) Combination of high-power EQUIPMENT and sensitive low-signal EQUIPMENT often in ad hoc combinations.

g) The application of electrical circuits directly to the human body, either through contacts to the skin and/or through the insertion of probes into internal organs.

h) Environmental conditions, particularly in operating theatres, may present a combination of humidity, moisture and/or fire or explosion hazards caused by air, oxygen or nitrous oxide combined with anaesthetic media and cleaning agents.

*In the first edition Appendix A was entitled "Survey of medical electrical equipment." It has been deleted and replaced by the present appendix.

A1.1 Safety of MEDICAL ELECTRICAL EQUIPMENT, as described in IEC Publication 513, is part of the total safety situation, comprising safety of EQUIPMENT, safety of the installation in medically used rooms of medical establishments and safety of application.

Safety of EQUIPMENT is required for NORMAL USE and NORMAL CONDITION and for SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting EQUIPMENT and where interruption of an examination or treatment is considered as a SAFETY HAZARD for the PATIENT.

Adequate construction and lay-out which serve to prevent human errors are regarded as safety aspects.

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

Generally it is presumed that EQUIPMENT is operated under the jurisdiction of qualified or licensed persons, that the OPERATOR has the skill required for a particular medical application and that he acts according to the instructions for use.

The total safety of EQUIPMENT may consist of:

– Protective precautions incorporated in the EQUIPMENT (unconditional safety).

– Additional protective precautions, such as the use of shields or protective clothing (conditional safety).

– Restriction in the instructions for use concerning transport, mounting and/or positioning, connection, putting in service, operation and the position of the OPERATOR and his assistants in relation to the EQUIPMENT during use (descriptive safety).

Generally, safety precautions are presumed to be applied in the order as described here. They may be attained by sound engineering (which includes knowledge of methods of production and environmental conditions during manufacture, transport, storage and use), by application of redundancy and/or by protective devices of a mechanical or electrical nature.

Reference to other publications is only made if such publications are of a general nature, that is, not restricted to particular EQUIPMENT types (see References in Appendix L). In other cases requirements and tests have been adopted unmodified or slightly modified, without quoting the source.

A1.2 *Guidance to the second edition*

In this second edition a number of clauses and sub-clauses from the first edition have been deleted as, e.g., when no test requirements are available or when it is indicated ″under consideration″.

In order to indicate the relevant subject the title is kept, so that Particular Standards may refer to this sub-clause.

The paragraphs concerning the content of Particular Standards have been moved from Clause 1 to this Appendix (A2 Sub-clause 1.3).

Specifications of environmental conditions formerly in Sub-clause 1.4 now appear as a requirement for EQUIPMENT in Clause 10, where it is stated that compliance with these requirements for operation is considered to have been checked by application of the test of this Standard.

The new specification of the scope (Sub-clause 1.1) refers to a new definition of MEDICAL ELECTRICAL EQUIPMENT which is considered to be more appropriate and more practical (see Sub-clause 2.2.15).

A new defined concept PROTECTIVELY EARTHED has been introduced.

The term SAFETY HAZARD and its definition will simplify referencing in the standard itself (see Sub-clause 2.12.18).

The standard now distinguishes between an OPERATOR of EQUIPMENT and a USER, who may be considered responsible for its proper application and maintenance (see Sub-clauses 2.12.17 and 2.12.13).

The sequence of Sub-clauses of Clause 14 was rationalized. Paragraphs which had been derived from IEC Publication 536 (1976) and which were of descriptive nature have been deleted.

The requirements for the separation between an APPLIED PART and LIVE parts were also applied to the separation between ACCESSIBLE PARTS and LIVE parts (see Clause 17). The PATIENT currents allowed where CREEPAGE DISTANCE and AIR CLEARANCES are less than the values in Sub-clause 57.10 were changed from the values for SINGLE FAULT CONDITION to those for NORMAL CONDITION.

The requirement in Sub-clause 18*e)* for a facility for connection of a POTENTIAL EQUALIZATION CONDUCTOR was withdrawn and replaced with requirements for the construction of such a connection if provided.

All references to an additional PROTECTIVE EARTH CONDUCTOR were deleted, because the protective function of such a conductor was no longer recognized.

The sequence of sub-clauses of Clause 18 was rationalized.

An appendix was added illustrating the connection of the APPLIED PART for measurement of the PATIENT LEAKAGE CURRENT and of the PATIENT AUXILIARY CURRENT (see Appendix K and Sub-clause 19.1*e)*).

The allowable ENCLOSURE LEAKAGE CURRENT for EQUIPMENT with a TYPE CF APPLIED PART in NORMAL CONDITION was changed from 0,01 mA to 0,1 mA.

EQUIPMENT with a high EARTH LEAKAGE CURRENT due to compliance with requirements for radio-interference suppression was recognized.

Sub-clauses 19.4*a)* and 20.4*a)* were changed.

A true r.m.s. meter was recognized as a suitable instrument for LEAKAGE CURRENT measurements.

Clause 20 was rearranged in a number of ways:

– The requirements for the insulation between the MAINS PART and other parts were extended to include all LIVE parts, but restricted to cases where a SAFETY HAZARD would develop.

– For each particular insulation a statement was added to clarify that such insulation would be BASIC, SUPPLEMENTARY, DOUBLE or REINFORCED INSULATION.

– As a result all references to the Class of EQUIPMENT (I, II, INTERNALLY POWERED) could be deleted and Tables V, VI and VII replaced by one new much simplified Table V. Test voltages for reference voltages of more than 10 000 V were referred to Particular Standards.

– The insulation between an F-TYPE APPLIED PART and the ENCLOSURE of the EQUIPMENT was reviewed to distinguish the case where such an APPLIED PART would contain voltages which would make the PATIENT LIVE when the insulation would become defective (see new categories B-d and B-e).

– Sub-clauses 20.1, 20.2, 20.3 and 20.4 were rearranged to include exclusively all statements pertaining to their titles.

– The new version of Clause 20 has led to an important simplification of Sub-clause 57.10 in Section Ten (AIR CLEARANCES and CREEPAGE DISTANCES).

A1.3 *Protection against electric shock hazards*

Protection against electric shocks caused by currents not resulting from the specified physical phenomena of EQUIPMENT may be obtained by a combination of the following measures:

– prevention of contact between the body of the PATIENT, the OPERATOR, or a third person and parts which are LIVE or may become LIVE in the case of an insulation failure, by means of enclosing, guarding or mounting in inaccessible locations;

– restriction of voltages on or currents from parts which may be touched intentionally or unintentionally by the PATIENT, the OPERATOR or a third person. These voltages or currents may be present during NORMAL USE or may appear in SINGLE FAULT CONDITION.

Generally, this protection is obtained by a combination of:

– limitation of voltage and/or energy, or protective earthing (see Clauses 15 and 18);

– enclosing and/or guarding of LIVE parts (see Clause 16);

– insulation of adequate quality and construction (see Clause 17).

The value of electric current flowing in the human or animal body which may 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.

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.

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPES B, BF and CF APPLIED PARTS). TYPES B and BF 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.

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.

Nevertheless, engineers are provided with data enabling them to design EQUIPMENT; so, for the time being, the requirements represent what is considered reasonably safe.

The requirements for LEAKAGE CURRENT were formulated taking into account:

a) that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;

b) that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, and

c) 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.

The measurement of LEAKAGE CURRENTS has been described in a way which enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the USER (to be described in the Application Code).

The dielectric strength requirements are included to check the quality of the insulation material used at different places in the EQUIPMENT.

A1.4 *Protection against mechanical hazards*

Requirements in Section Four are divided into one part describing SAFETY HAZARDS caused by damage or deterioration of EQUIPMENT (mechanical strength) and several parts describing hazards of a mechanical nature caused by EQUIPMENT (injury 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 EQUIPMENT parts).

EQUIPMENT may 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.

Effects of mechanical overloads, material failure or wear can be avoided by:

– means which interrupt or render non-hazardous the operation or the energy-supply (for example, fuses, PRESSURE valves) as soon as overloading occurs;

– means which guard against or catch flying or falling parts (caused by material failures, wear or overload) which may constitute a SAFETY HAZARD.

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of safety catches.

EQUIPMENT parts which are intended to be held in the hand or positioned on a bed must be sufficiently robust to withstand a fall. They may be subject to vibration and shocks, not only when transported but also when used in vehicles.

A1.5 *Protection against hazards from unwanted or excessive radiation*

Radiation from MEDICAL ELECTRICAL EQUIPMENT may occur in all forms known in physics. Safety requirements are concerned with unwanted radiation. Protective measures are necessary for EQUIPMENT and for the environment and methods for determining levels of radiation must be standardized.

Limits for EQUIPMENT may have to be exceeded for the intended application, where the medical supervisor takes the responsibility. For ionizing radiation IEC requirements generally comply with ICRP Recommendations. Their purpose is to provide data which are immediately usable by designer and USER.

Their evaluation is possible only by adequate study of operating methods and duration of operation of EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations which might hamper proper diagnosis or treatment.

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

A1.6 *Protection against hazards of ignition of flammable anaesthetic mixtures*

A1.6.1 *Applicability*

Where EQUIPMENT is used in areas in which flammable anaesthetics and/or flammable agents for disinfection and/or skin cleaning are applied, an explosion risk may exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.

Ignition of such a mixture may be caused by sparks or by contact with parts having a high surface temperature.

Sparks may be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

In HIGH VOLTAGE parts sparks may be caused by corona. Static discharges may cause sparks.

The probability of 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.

The hazard caused by an ignition depends on the location and on the relative quantity of the mixture.

A1.6.2 *Industrial EQUIPMENT and components*

The constructional requirements of IEC Publication 79 are generally not appropriate for MEDICAL ELECTRICAL EQUIPMENT for several reasons:

a) they lead to constructions of a size, weight or design which are not applicable for medical reasons and/or which may not be sterilizable;

b) some constructions allow an explosion inside an ENCLOSURE, but prevent propagation outside it. Such a construction which may be inherently safe would be unacceptable in an operating theatre where continuity of operation of EQUIPMENT is essential;

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;

d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.

However some of the constructions described in IEC Publication 79 are acceptable for CATEGORY AP EQUIPMENT (see Sub-clause 40.1).

A1.6.3 *Requirements for MEDICAL ELECTRICAL EQUIPMENT*

The location of flammable anaesthetic mixtures is described:

– as much as necessary for the construction of EQUIPMENT in Clause 37 of this Standard, as minimum for specified conditions of exhaust and absorption;

– as much as necessary for the allocation of EQUIPMENT and the construction of the electrical installation in IEC Publication 364.

That standard additionally provides information on flammable concentrations of a number of flammable agents, their usual application concentrations, ignition temperatures, lowest ignition energy and flash-points. Requirements for ventilation and exhaust of areas, maintenance of a minimum relative humidity and permission to use certain EQUIPMENT types in certain areas may be subject to local (hospital) or national and possibly legal regulations.

The requirements, limits and tests of this section 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 Appendix F. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

Where temperatures or circuit parameters of 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.

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

For EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, requirements, limits and tests are far more stringent.

Requirements apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in Sub-clause 3.6. 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.

A1.7 *Protection against excessive temperatures and other SAFETY HAZARDS*

– Temperatures (see Clause 42)

Temperature limits are required to prevent hazards for almost all types of electrical EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where EQUIPMENT is touched or manipulated, or injuries where PATIENTS may contact EQUIPMENT parts.

EQUIPMENT parts may be inserted into body cavities, usually temporarily but sometimes permanently.

For PATIENT contact, special temperature limits have been set.

– Preventing fire hazard (see clause 43)

Except for CATEGORY AP and CATEGORY APG EQUIPMENT prevention of the fire hazard of MEDICAL ELECTRICAL EQUIPMENT may be subject to requirements in Particular Standards.

The normal limits for operating temperatures and requirements for overload protection are applicable.

– PRESSURE vessels (see clause 45)

Attention is drawn to the requirements dealing with PRESSURE vessels and parts subject to PRESSURE, where no local regulations are available.

– Interruption of the power supply (see clause 49)

Interruption of the power supply may cause a SAFETY HAZARD.

A1.8 *Accuracy of operating data and protection against incorrect output*

IEC Publication 601-1 is the guideline for all Particular Standards and must therefore contain some requirements of a more general character in order to serve this purpose. So it is necessary to have some generally formulated requirements in Section Eight.

It is also, for the time being, and for several reasons, impossible to provide standards, even urgently needed, for a number of kinds of MEDICAL ELECTRICAL EQUIPMENT.

Standardization bodies, including those outside IEC, have taken over the system of this IEC Publication in order to have an unique system of standards. In such cases it is most important to give a guideline in this section as a help towards "functional" PATIENT safety.

A1.9 *Abnormal operation and fault conditions; environmental tests*

EQUIPMENT or parts of EQUIPMENT may cause, due to abnormal operation, excessive temperatures or other SAFETY HAZARDS. Therefore these abnormal operations or fault conditions must be investigated.

A1.10 *APPLIED PARTS and ENCLOSURES – General*

Parts which are intended to 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.

NOTE – Other ACCESSIBLE PARTS of the ENCLOSURES of MEDICAL ELECTRICAL EQUIPMENT are subject to tests which are more demanding than those for ENCLOSURES of other kinds of EQUIPMENT, because the PATIENT may touch them, or the OPERATOR may touch them and the PATIENT simultaneously.

In order to determine which requirements apply, it is necessary to distinguish between APPLIED PARTS and parts which are simply considered as the ENCLOSURE. However there can be difficulties in doing this, especially with parts which can be expected to contact the PATIENT on some occasions but do not have to do so for the EQUIPMENT to perform its function.

The distinction between ENCLOSURES and APPLIED PARTS is made according to two criteria. Firstly, if contact is essential for the NORMAL USE of the EQUIPMENT, the part is subject to the requirements for APPLIED PARTS.

If contact is incidental to the functioning of the EQUIPMENT, the part is categorized according to whether contact results from deliberate action by the PATIENT or by the OPERATOR. Where contact is incidental and results from action by the PATIENT, the PATIENT is in most respects no more at risk than any other person, so the requirements for ENCLOSURES are sufficient.

In order to assess which parts are APPLIED PARTS, PATIENT CONNECTIONS and PATIENT CIRCUITS, the following process is employed in the order shown:

a) Determine whether the EQUIPMENT has an APPLIED PART and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).

b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S) or PATIENT CIRCUIT(S).

c) If there is an APPLIED PART, there may be one or more PATIENT CONNECTION(S). Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not isolated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.

d) The PATIENT CIRCUIT then consists of these PATIENT CONNECTION(S) and any other conductive parts from which they are inadequately insulated/segregated.

NOTE – Relevant separation requirements are those which relate to APPLIED PARTS and are necessary to comply with the dielectric strength tests in clause 20, and the CREEPAGE DISTANCE and AIR CLEARANCE requirements in subclause 57.10.

A2 Rationale to particular clauses and sub-clauses

Clause

1 Particular Standards can in further sub-clauses specify the particular subject and it should be quite clear as to what is being referred to in the General Standard and in the Particular Standard.

Only such laboratory EQUIPMENT is included in the scope of this Standard which is related to the PATIENT in such a way that the PATIENT'S safety can be influenced.

Laboratory EQUIPMENT within the scope of IEC SC 66E is not covered by this Standard.

Combinations of EQUIPMENT developed by the USER may not conform to this Standard even if they are composed of EQUIPMENT that, taken separately, satisfy the requirements of this Standard.

Sub-clause

1.3 A Particular Standard may state:

– clauses of the General Standard which apply without amendment;

– clauses or sub-clauses (or parts of them) of the General Standard which do not apply;

– clauses or sub-clauses (or parts of them) of the General Standard which are replaced by a clause or a sub-clause in a Particular Standard;

– any additional clauses or sub-clauses.

A Particular Standard may contain:

a) requirements which result in an increased degree of safety;

b) requirements which may be less stringent than the requirements in this General Standard, if the latter cannot be maintained because of, for example, the power output of EQUIPMENT;

c) requirements concerning performance, reliability, interfaces, etc.;

d) accuracy of working data;

e) extension and limitation of environmental conditions.

Subclause

2.1.5 This General Standard includes a definition for APPLIED PART which, in most cases, clearly establishes which parts of the EQUIPMENT need to be treated as APPLIED PARTS and comply with more stringent requirements than those for ENCLOSURES.

Excluded are those parts which are only likely to be contacted following an unnecessary action by the PATIENT. Thus:

– An infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT.

– The only part of an X-ray table which is an APPLIED PART is the top on which the PATIENT lies.

– Likewise, in an MRI scanner, the only APPLIED PARTS are the table supporting the PATIENT and any other parts which must be brought into direct contact with the PATIENT.

This definition may not always clearly establish whether an individual part of a particular item of EQUIPMENT is an APPLIED PART. Such cases need to be considered on the basis of the above rationale, or by reference to the Particular Standards which should specifically identify the APPLIED PART(S) in particular types of EQUIPMENT.

Subclause

2.1.15 Where APPLIED PARTS have PATIENT CONNECTIONS, these should be adequately separated from specified LIVE parts within the EQUIPMENT and, in the case of TYPE BF and TYPE CF APPLIED PARTS, from earth. Testing of the dielectric strength of the insulation involved, and assessment of CREEPAGE DISTANCE and AIR CLEARANCE are used to verify compliance with these criteria.

The definition of the PATIENT CIRCUIT is intended to identify all the parts of the EQUIPMENT which can readily provide current to, or receive it from, the PATIENT CONNECTION(S).

For an F-TYPE APPLIED PART the PATIENT CIRCUIT extends as seen from the PATIENT into the EQUIPMENT to the point(s) where the prescribed insulation and/or protection impedance is completed.

For a TYPE B APPLIED PART, the PATIENT CIRCUIT may be connected to protective earth.

Subclause

2.1.23 One of the potential hazards associated with the application of an APPLIED PART is the fact that LEAKAGE CURRENT may flow through the PATIENT via the APPLIED PART. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.

NOTE – The current which flows through the PATIENT, between various parts of the APPLIED PART, is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT which flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current may flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT may flow into an earthed PATIENT.

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.

PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART which come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps which do not comply with the relevant dielectric strength tests or AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS.

Examples include the following:

– 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.

– 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.

Where an APPLIED PART has a surface of insulating material, subclause 19.4 *h) 9)* specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

Subclause

2.1.24 TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.25 TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This degree of protection is achieved by isolation from earthed parts and other ACCESSIBLE PARTS of the EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event of the PATIENT contacting other LIVE EQUIPMENT.

However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.26 TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This degree of protection is achieved by increased isolation from earthed parts and other ACCESSIBLE PARTS of the EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.27 A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators designed in accordance with IEC 601-2-4. Sometimes defibrillators of other construction are used in hospitals, e.g. defibrillators with higher voltages and pulses. Such defibrillators may also damage DEFIBRILLATION-PROOF APPLIED PARTS.

Sub-clause

2.3.2 This definition does not necessarily include insulation used exclusively for functional purposes.

Sub-clause

2.3.4 BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately.

Sub-clause

2.3.7 The term "insulation system" does not imply that the insulation must be one homogeneous piece. It may comprise several layers which cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

Sub-clause

2.4.3 This definition is based on IEC Publications 364-4-41 and 536.

Sub-clause

2.5.4 This is distinct from what was formerly referred to as "PATIENT functional current" which is intended to produce a physiological effect, for example, current necessary for nerve and muscle stimulation, cardiac pacing, defibrillation, high-frequency surgical procedures.

Subclause

2.6.4 In MEDICAL ELECTRICAL EQUIPMENT functional earth connections may be made by means of a FUNCTIONAL EARTH TERMINAL which is accessible to the OPERATOR. Alternatively this Standard also allows a functional earth connection for CLASS II EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts concerned have to be insulated from ACCESSIBLE PARTS (see subclause 18 *l)*).

Sub-clause

2.7.6 Cord sets are covered by IEC Publication 320.

Sub-clause

2.11.2 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.

In some countries, the figure may be reduced from time to time.

Sub-clause

2.12.2 The MODEL OR TYPE REFERENCE is intended to establish its relationship to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of EQUIPMENT.

Sub-clause

3.6 As stated in Sub-clause 3.1 EQUIPMENT is required to remain safe in SINGLE FAULT CONDITION. Thus one fault of a single protective means is allowed.

The probability of simultaneous occurrence of two single faults is considered small enough to be negligible.

This condition can only be relied upon if either:

a) the probability of a single fault is small, because of sufficient design reserve, or the presence of a double protection prevents the development of a first single fault, or

b) a single fault causes operation of a SAFETY DEVICE (e.g. a fuse, OVER-CURRENT RELEASE, safety catch, etc.) which prevents occurrence of a SAFETY HAZARD, or

c) a single fault is discovered by an unmistakable and clearly discernible signal which becomes obvious to the OPERATOR, or

d) a single fault is discovered and remedied by periodic inspection and maintenance which is prescribed in the instructions for use.

Non-exclusive examples of the categories *a)* to *d)* are:

a) REINFORCED or DOUBLE INSULATION;

b) CLASS I EQUIPMENT in case of a fault in BASIC INSULATION;

c) Abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;

d) Deterioration of a flexible protective earth connection which is moved in NORMAL USE.

Sub-clause

3.6 c)

The appearance of an external voltage on an F-TYPE APPLIED PART (which may be conductively connected to a SIGNAL INPUT PART or to a SIGNAL OUTPUT PART) would have to be caused by a double failure of protective means in other EQUIPMENT, simultaneously connected to the PATIENT and complying with this Standard, or by a single failure of protective means in EQUIPMENT not complying with this Standard. As such this condition is very unlikely in good medical practice.

However, since the main safety feature of EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth must 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 PATIENT'S environment would appear on the APPLIED PART, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.

In this hypothetical case the PATIENT is supposed not to be connected to the APPLIED PART.

Clause

4 In EQUIPMENT there may be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a SAFETY HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of EQUIPMENT.

Sub-clause

4.1 In order to ensure that every individually produced item of EQUIPMENT conforms to this Standard, the manufacturer and/or installer should carry out such measures during manufacture and/or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.

Such measures may take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests may not be identical with type tests, but may be adapted to manufacturing conditions and possibly invoking less risk for the quality of the insulation or other characteristics important for safety.

Production tests would, of course, be restricted to setting (possibly derived from type tests) which would provoke the worst case situation.

Depending upon the nature of EQUIPMENT, production methods and/or tests may concern critical insulation of the MAINS PART, of the APPLIED PART and the insulation and/or the separation between these parts.

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

Where applicable, the continuity of protective earthing may be a major test parameter.

Sub-clause

4.3 Whether a sample is representative is decided by the test laboratory and the manufacturer.

Sub-clause

4.8 The aim is to verify that EQUIPMENT is operating properly.

Sub-clause

4.10

a) The humidity preconditioning treatment and subsequent tests of MEDICAL ELECTRICAL EQUIPMENT are often performed in laboratories suitable for treatment and tests for household and similar electrical appliances.

To avoid unnecessary investments and costs for such laboratories, preconditioning treatments and tests should be aligned as far as is feasible.

b) According to IEC 529, the ENCLOSURE of EQUIPMENT RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could cause a SAFETY HAZARD.

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.

Parts sensitive to humidity, normally used in controlled environments and which do not influence safety, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc.

c) To prevent condensation when EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet must be equal to or slightly lower than the temperature of the 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.

d) DRIP-PROOF EQUIPMENT and SPLASH-PROOF EQUIPMENT may be used in an environment where the humidity is higher than the humidity of the environment in which ordinary EQUIPMENT is used.

Therefore such EQUIPMENT is kept in the humidity cabinet for 7 days (see Sub-clause 4.10, 7th paragraph).

Clause

5 EQUIPMENT may have a multiple classification.

Sub-clause

5.1 The 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 MEDICAL ELECTRICAL EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons this Standard does not recognize Class III EQUIPMENT in this second edition.

Sub-clause

6.1 f)

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may possible not denote the exact construction, including the applied components and materials. If this is required, the MODEL OR TYPE REFERENCE may have to be supplemented by a SERIAL NUMBER. The SERIAL NUMBER may also be used for other purposes.

Indication of a manufacturing series only may not be sufficient if local requirements require individual identification.

Subclause

6.1 n)

For fuses in accordance with IEC 127, the marking of the type and rating should be in accordance thereto. Examples of marking: T 315L or T 315mAL, F 1,25H or F 1,25AH.

Sub-clause

6.1 z)

The rubbing test is performed with distilled water, methylated spirit and isopropyl alcohol.

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms:

C_3H_8O (MW60.1) – Propanol. Isopropyl alcohol. A clear colourless liquid with a characteristic odour, mixable with water and with alcohol. It has a relative density of 0,785 at 20 °C, boiling point 82,5 °C at 1013 hPa.

Subclause

6.2 e)

For fuses in accordance with IEC 127, the marking of the type and rating should be in accordance thereto. Examples of marking: T 315L or T 315mAL, F 1,25H or F 1,25AH.

Subclause

6.4 No special colour is requested.

Sub-clause

6.7 For colours of indicator lights see also IEC Publication 73.

Sub-clause

6.8.1 The subject 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 worldwide.

Subclause

6.8.2 a)

– It is important to ensure that an EQUIPMENT is not used inadvertently in an application for which it is not intended.

– Examples of interference would include:

Power supply transients, magnetic interference, mechanical interaction, vibration, thermal radiation, optical radiation.

Sub-clause

6.8.2 b)

Responsibility of the manufacturer

The instructions for use may contain a statement saying that the manufacturer, assembler, installer or importer considers himself responsible for the effects on safety, reliability and performance of the EQUIPMENT only if:

– assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by him,

– the electrical installation of the relevant room complies with the appropriate requirements, and

– the EQUIPMENT is used in accordance with the instructions for use.

Subclause

6.8.3 a)

Accuracy and precision are not possible to define in this General Standard. These concepts have to be addressed in Particular Standards.

Sub-clause

10.2.1 These environmental conditions are based on the conditions in buildings without air-conditioning in climates where the ambient temperature occasionally reaches +40°C.

The EQUIPMENT covered by this Standard may not be suitable for use in PRESSURE chambers.

The EQUIPMENT should be safe according to this standard when operated under the conditions of subclause 10.2 but it need only be fully operable under conditions specified by the manufacturer in the ACCOMPANYING DOCUMENTS (see also definition of NORMAL USE).

Sub-clause

10.2.2 Because of the wide range of MEDICAL ELECTRICAL EQUIPMENT covered in this Standard, it is not possible to specify the permissible effects on performance of each particular type of EQUIPMENT due to MAINS VOLTAGE and frequency fluctuations.

In this Standard such effects are covered in a number of safety tests.

According to Fortescue's theorem any unbalanced polyphase system can be resolved in three balanced systems of phases:

– a system of so-called positive sequence components of equal magnitude and phase angle, but having the opposite phase sequence as the original system;

– a system of so-called negative sequence components of equal magnitude and phase angle, but having the same phase sequence as the original system;

– a system of so-called zero sequence components of equal magnitude, no mutual phase angle (in phase) and no phase sequence (stationary vectors). Systems without a neutral conductor cannot have zero sequence current components.

The zero sequence current can be determined as the sum of the three phase currents divided by three.

Thus the neutral current is three times the zero sequence current.

Literature:

- Elements of Power Systems Analysis
  W.D. Stevenson, jr.
  McGraw Hill (page 272)
- IEEE Vol 37 Part II (1918)
  page 1329
- Modern Power Systems
  Neuenswonder
  page 183, Measurement of Zero Sequence.

Sub-clause

10.2.2 a)

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, unless stated otherwise;

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;

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.

Sub-clause

14.1 b)

EQUIPMENT, specified for an external d.c. power source (e.g. for use in an ambulance), has to satisfy all requirements for CLASS I or CLASS II EQUIPMENT.

Subclause

14.5 b)

If INTERNALLY POWERED EQUIPMENT has a means of connection to a separate battery charger or power supply unit which in turn has a means of connection to the SUPPLY MAINS, the battery charger or power supply unit is considered as part of the EQUIPMENT and the requirements apply.

These requirements do not apply to EQUIPMENT (including any separate power supply unit or battery charger) which is incapable of being connected to a SUPPLY MAINS and to a PATIENT simultaneously.

Subclause

14.6 EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more TYPE CF APPLIED PARTS may have one or more additional TYPE B or TYPE BF APPLIED PARTS which may be applied simultaneously (see also subclause 6.1 *l)*).

Similarly EQUIPMENT may have a mixture of TYPE B and TYPE BF APPLIED PARTS.

Clause

16 ENCLOSURES and PROTECTIVE COVERS are intended to provide protection for human beings against contact with parts that are LIVE or may become LIVE after a single failure of protective insulation. They may, at the same time, provide protection against other hazards (mechanical, thermal, chemical, etc.).

"Accidental contact" means that parts are touched in NORMAL USE by a human being, without the aid of a TOOL and without appreciable force.

Except in special cases, such as PATIENT supports and waterbeds, contact with EQUIPMENT is supposed to be made with:

– one hand, simulated by a metal foil of 10 cm × 20 cm (or less if the total EQUIPMENT is smaller);

– one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;

– a pencil or pen, held in a hand, simulated by a guided test pin;

– a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;

– a screwdriver for adjustment of a preset control by the OPERATOR, simulated by an inserted metal rod;

– an edge or slit that can be pulled outward allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.

Other devices are not permitted unless they are necessary for the compliance check.

Sub-clause

16 a) 5)

This sub-clause is also intended to cover those cases where EQUIPMENT is remotely controlled by means of a hand-held control box, usually connected to the mainframe of the EQUIPMENT by means of a multiconductor flexible cable.

Usually control circuits are operated at extra-low voltage or even at SAFETY EXTRA-LOW VOLTAGE. Control currents and cross-sections of conductors are usually small.

Protective earthing of the ENCLOSURE of the control box would not be very effective (high resistance).

DOUBLE INSULATION would consume a lot of space and weight and control switches and push buttons of miniature size would not be available with REINFORCED INSULATION.

Where it is unlikely in NORMAL USE that the control box and a PATIENT are touched simultaneously, the control box may be made with BASIC INSULATION only, with a metal ENCLOSURE or an ENCLOSURE made of insulating material.

The insulation may be designed for extra-low voltage.

Sub-clause

16 c)

The compliance test for the protective earthing of ACCESSIBLE METAL PARTS of EQUIPMENT (sub-clause 18 *f*)) is conducted with a current between 10 A and 25 A provided by a source with a sufficient low voltage (not exceeding 6 V). The current is maintained for at least 5 s. The reasons for these requirements are that the connection can only perform its protective function if it is able to carry the fault current resulting from a failure in BASIC INSULATION.

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.

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" may not be discovered by resistance measurement alone.

Where conductive parts of actuating mechanism of electrical controls are PROTECTIVELY EARTHED the required maximum resistance is 0,2 Ω, the minimum test current is 1 A, the maximum source voltage is 50 V and there is no minimum time other than the time needed for reading the test instruments.

This relaxation is justified because:

a) Where actuating mechanisms are fragile and not able to carry a test current of 10 A to 25 A, they are usually part of a secondary circuit and the fault current through the connection will be limited.

b) In connection with this, maximum resistance may be raised because it forms a smaller fraction of the total fault circuit impedance. The source voltage and testing time are less critical, a burn-out of the protective connection is unlikely.

Sub-clause

16 d)

The use of the Symbol 14, Table DI, "Attention, consult ACCOMPANYING DOCUMENTS" of Appendix D is not sufficient. A warning notice on the outside of the EQUIPMENT may be sufficient.

Sub-clause

16 e)

The combination of isolated supply and the restricted voltage is regarded as an additional protective measure against electric shock hazard.

Clause

17 Air may form part or all of the BASIC INSULATION and/or SUPPLEMENTARY INSULATION.

Subclause

17 h)

One or the other of the defibrillation paddles may, by virtue of its clinical application, be connected to earth or at least referenced to earth.

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the EQUIPMENT and another, or between such parts collectively and earth. Therefore ACCESSIBLE PARTS should either be adequately isolated from PATIENT CIRCUITS or, if the insulation of the APPLIED PART is protected by voltage-limiting devices, be PROTECTIVELY EARTHED.

Also, although safety is not likely to be endangered, even in the case of incorrect use, in the absence of a Particular Standard it should generally be expected that APPLIED PART marked as DEFIBRILLATION-PROOF can be subjected to defibrillation voltages without any adverse effect on subsequent use of the EQUIPMENT in health care.

The tests ensure:

a) that any ACCESSIBLE PARTS of EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not become LIVE due to flashover of defibrillation voltage; and

b) that the EQUIPMENT will continue to function after exposure to defibrillation voltage.

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the 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 which do not comply with the requirements of clause 18 is more probable, and is therefore required for these tests.

The severity of electric shock which a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 µC) which can be felt and which may be unpleasant, but which is not dangerous.

SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS are included, as signal lines to remote EQUIPMENT could otherwise carry energies which might be hazardous.

The test circuits of figures 50 and 51 of this Standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R_1).

The value of the inductance L in the test circuits of figures 50 and 51 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means.

Rationale 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.

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity which is far from uniform.

If the electrode of another item of MEDICAL ELECTRICAL 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.

Unfortunately it is not possible to say *how much* less as the electrode in question may be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant Particular Standard, it must therefore be required that such an electrode and the EQUIPMENT to which it is connected will be able to withstand the full defibrillation voltage, and this must be the no-load voltage as one of the defibrillator paddles may not be making good contact with the PATIENT.

This amendment to the General Standard therefore specifies 5 kV as the appropriate value in the absence of a relevant Particular Standard.

Subclause

18 a)

Generally, ACCESSIBLE METAL PARTS of CLASS I EQUIPMENT shall be connected permanently and with sufficiently low impedance to the PROTECTIVE EARTH TERMINAL.

However, CLASS I EQUIPMENT may contain ACCESSIBLE PARTS which are so separated from the MAINS PART that, in NORMAL CONDITION and SINGLE FAULT CONDITION of the insulation of the MAINS PART or of the protective earthing, the LEAKAGE CURRENT from these ACCESSIBLE PARTS to earth does not exceed the value of Table IV (see Clause 19).

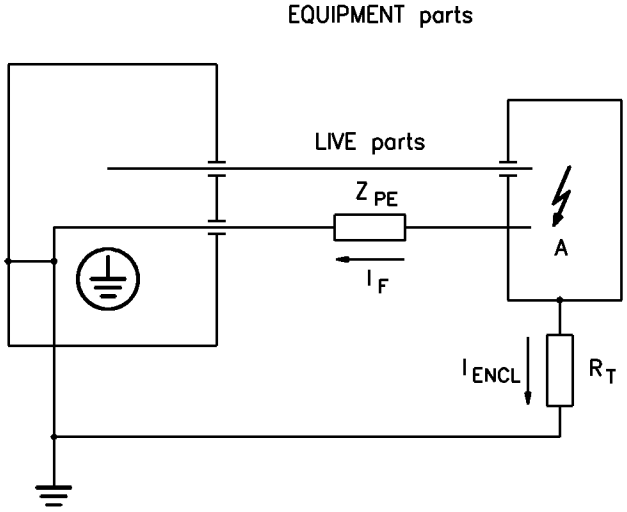
In this case, these ACCESSIBLE PARTS need not be connected to a PROTECTIVE EARTH TERMINAL but they may be connected to, for example, a FUNCTIONAL EARTH TERMINAL, or they may be left floating.

The separation of ACCESSIBLE METAL PARTS from the MAINS PART may be obtained by DOUBLE INSULATION, by metallic screening or by a PROTECTIVELY EARTHED ACCESSIBLE METAL PART or a PROTECTIVELY EARTHED secondary circuit, separating the ACCESSIBLE METAL PARTS completely from the MAINS PART.

Metal parts behind a decorative cover, which does not comply with the mechanical strength test, are regarded as ACCESSIBLE METAL PARTS.

Subclause

18 g)



Legend

A = Short circuiting between two parts.
Z_{PE} = Impedance of protective earth connection in ohms (exceeding 0.1Ω).
I_F = Maximum continuous prospective fault current in amperes in the protective earthing connection caused by a single failure of the insulation to earth.
I_{ENCL} = Allowable value of the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION.
R_T = Test resistance (1kΩ).

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The fault current may 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.

In such cases the cross-section of the protective earthing connection may be determined primarily by mechanical considerations.

Sub-clause

19.1 d)

The ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT from PROTECTIVELY EARTHED parts is negligible in NORMAL CONDITION.

Sub-clause

19.2 a)

The breakdown of BASIC INSULATION in CLASS I EQUIPMENT is not generally regarded as a SINGLE FAULT CONDITION as the LEAKAGE CURRENTS in this case cannot be kept within allowable limits (Table IV) during the time before a fuse, or OVER-CURRENT RELEASE operates. Exceptionally, LEAKAGE CURRENTS are measured during short-circuiting BASIC INSULATION in cases where there are doubts concerning the effectiveness of protective earth connections inside the EQUIPMENT (see Sub-clauses 17*a)* and 17*g)*).

Sub-clause

19.3 and Table IV

Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz.

– 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 may have no effect when applied to another part of the heart.

– The risk is highest and approximately equal for frequencies in the 10 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.[1)] The values in Table IV cover the range from d.c. to 1 kHz. SUPPLY MAINS frequencies of 50 and 60 Hz are in the range of highest risk.

– 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 IV have been set at such a value that:

a) the majority of EQUIPMENT types can comply, and

[1)]See references.

b) they can be applied to most EQUIPMENT types (existing or future) for which no Particular Standards exist.

EARTH LEAKAGE CURRENT

– The allowable values for EARTH LEAKAGE CURRENT are not critical and have been chosen to avoid any significant increase in the currents flowing through the protective earthing system of the installation.

– In Note 2) to Table IV is stated under which conditions higher EARTH LEAKAGE CURRENTS are allowed if internal conductive parts are not accessible.

– In Note 3) to Table IV is stated that EQUIPMENT with a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR may have higher allowable EARTH LEAKAGE CURRENTS as the accidental interruption of the PROTECTIVE EARTH CONDUCTOR is very unlikely.

ENCLOSURE LEAKAGE CURRENT

The limits are based on the following considerations:

a) The ENCLOSURE LEAKAGE CURRENT of EQUIPMENT with TYPE CF APPLIED PARTS in NORMAL CONDITION was raised to the same level as for EQUIPMENT with TYPES B and BF APPLIED PARTS because such EQUIPMENT may be used simultaneously on a PATIENT.

b) The current density created at the heart by current entering the chest is 50 $\mu A/mm^2$ per ampere.[8)] The current density at the heart for 500 µA (maximum allowable value in SINGLE FAULT CONDITION) entering the chest is 0,025 $\mu A/mm^2$, well below the level of concern.

c) The probability of the ENCLOSURE LEAKAGE CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

ENCLOSURE LEAKAGE 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 probability of a direct contact between an intracardiac device and an EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 procedures. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 procedures. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 µA 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.

[8)]See references.

The probability of the ENCLOSURE LEAKAGE CURRENT rising to the maximum allowable level of 500 µA (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. 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.

The probability of ENCLOSURE LEAKAGE CURRENT at the maximum allowable level of 500 µA (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 procedures.

d) The probability of the ENCLOSURE LEAKAGE CURRENT being perceptible to the PATIENT.

The probability of 500 µA being perceptible is 0,01 for men and 0,014 for women when using grip electrodes with intact skin.[1,2)] There is a higher perceptibility for current passing through mucous membranes or skin punctures.[2)] Since distribution is normal[1)], there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 µA passing through a mucous membrane.[2)]

ENCLOSURE LEAKAGE CURRENT for EQUIPMENT with TYPE B, BF and CF APPLIED PARTS is made equal because all types of EQUIPMENT may be used simultaneously on a PATIENT.

PATIENT LEAKAGE CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS in NORMAL CONDITION is 10 µA which has a probability of 0,002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation.[4)] A limit of 10 µA is readily achievable and does not significantly increase the risk of ventricular fibrillation during intracardiac procedures.

The 50 µA maximum allowed in SINGLE FAULT CONDITION for TYPE CF APPLIED PARTS is based on a value of current which 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.

For catheters 1,25 – 2 mm diameter likely to contact the myocardium, the probability of 50 µA causing ventricular fibrillation is near 0,01 (see Figure A1 and its explanation). Small cross-section area (0,22 mm^2 and 0,93 mm^2) catheters used in angiography have higher probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION is 0,001 (0,1 for probability of SINGLE FAULT CONDITION, 0,01 probability of 50 µA causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

The 50 µA 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.

For TYPE B and TYPE BF APPLIED PARTS where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 µA, the same rationale applies as that for ENCLOSURE LEAKAGE CURRENT since this current will not flow directly to the heart.

The probability of MAINS VOLTAGE appearing on the PATIENT is considered to be extremely low. For this to happen the following faults must have occurred:

a) failure of PROTECTIVE EARTHING of CLASS I EQUIPMENT (probability of 0,1);

[1,2,4)]See references.

b) a fault in BASIC INSULATION. The probability, based on experience, is less than 0,01.

This gives an overall probability of 0,001 of MAINS VOLTAGE appearing on the PATIENT.

For TYPE CF APPLIED PARTS the PATIENT LEAKAGE CURRENT will be limited to 50 µA, no worse than the previously discussed SINGLE FAULT CONDITION.

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 µA/mm^2. This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low.

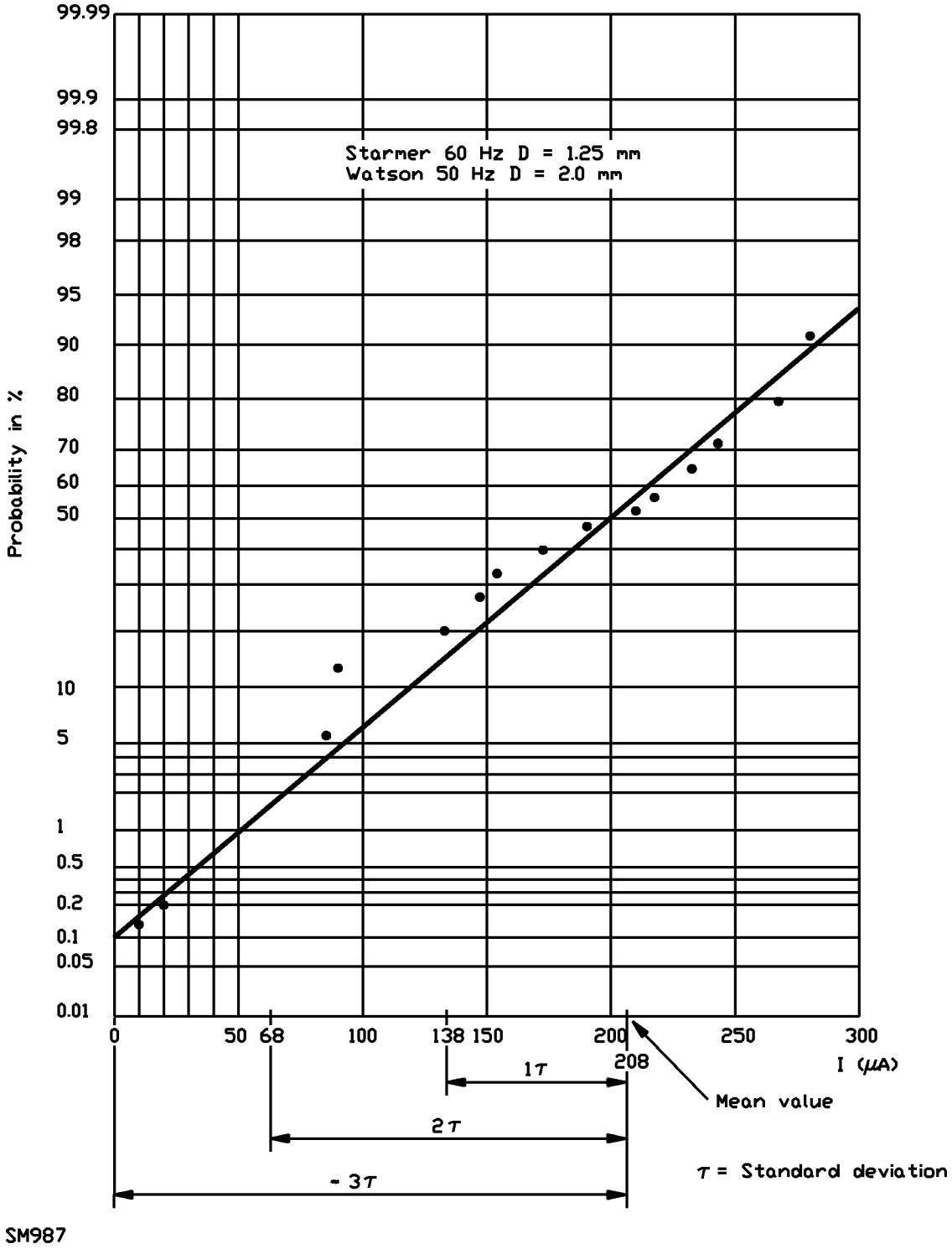
A PATIENT LEAKAGE CURRENT of 5 mA is allowed in a SINGLE FAULT CONDITION, in which an external voltage is applied to a TYPE BF APPLIED PART, because the risk of harmful physiological effects is small and the appearance of MAINS VOLTAGE on the PATIENT is very unlikely.

As the existence of an earth connection to a PATIENT is a NORMAL CONDITION, not only PATIENT AUXILIARY CURRENT but also PATIENT LEAKAGE CURRENT may flow for a prolonged period. In this situation also a low value of direct current is necessary to avoid tissue necrosis.

PATIENT AUXILIARY CURRENT

The allowable values for PATIENT AUXILIARY CURRENT are for EQUIPMENT such as impedance plethysmographs, these apply to currents having a frequency not less than 0,1 Hz. Lower values are given for d.c. to prevent tissue necrosis with long-term application.

Figure A1 – Probability of ventricular fibrillation



Note – Refer to original papers by Starmer and Watson for interpretation of data.

Explanation of Figure A1

Articles by Starmer[6)] and Watson[7)] 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 A1). From this extrapolation, it is seen that:

a) any value of current, however small, has some probability of causing ventricular fibrillation, and

b) the commonly used values have low probabilities, ranging from approximately 0,002 to 0,01.

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.

References

1) Charles F. Dalziel; Re-evaluation of lethal electric currents, IEEE Transactions on Industry and General Applications, Vol. 1 GA-4, No. 5, September/October 1968.

2) Kohn C. Keesey, Frank S. Letcher; Human thresholds of electric shock at power transmission frequencies; Arch. Environ. Health, Vol. 21, October 1970.

3) O. Z. Roy; 60 Hz Ventricular fibrillation and rhythm thresholds and the non-pacing intracardiac cathether; Medical and Biological Engineering, March 1975.

4) E. B. Rafferty, H. L. Green, M. H. Yacoub; Cardiovascular Research; Vol. 9, No. 2, pp. 263 – 265, March 1975.

5) H. L. Green; Electrical Safety Symposium Report; Department of Health and Social Security; United Kingdom, October 1975.

6) C. Frank Starmer, Robert E. Whalen; Current density and electrically induced ventricular fibrillation; Medical Instrumentation; Vol. 7, No. 1, January – February 1973.

7) A. B. Watson, J. S. Wright; Electrical thresholds for ventricular fibrillation in man; Medical Journal of Australia; June 16, 1973.

8) A. M. Dolan, B. M. Horacek, P. M. Rautaharaju; Medical Instrumentation (abstract), January 12, 1953, 1978.

Sub-clause

19.4 a)

Although it is recognized that absorption of humidity by insulation would have a far greater effect on the resistance of the insulation than on the capacitance of it, the results of a resistance measurement would be influenced heavily by the choice of the moment when the measurement was made. Such results could thus become irreproducible.

To improve reproducibility even further it was proposed to retain the LEAKAGE CURRENT test and to start it 1 h after the end of the humidity preconditioning treatment. It was considered that if a deterioration of insulation resistance would become a safety risk, it would also be noticeable in an increased LEAKAGE CURRENT and in the results of the dielectric strength test.

Sub-clause

19.4 b)

The switches S_1 or $S_1 + S_2$ or $S_1 + S_2 + S_3$ in Figures 10, 11, 12 and 13 may be omitted and the interruptions of the relevant leads may be obtained by other means.

Instead of the single or polyphase isolating transformers with adjustable output voltage(s), as shown in Figures 10, 11, 12, 13 and 14, a combination of an isolating transformer with fixed output voltage and an auto-transformer with adjustable output voltage may be used.

Sub-clause

19.4 Table IV

The current flowing from the APPLIED PART, due to an external voltage on the APPLIED PART to earth in BF TYPE EQUIPMENT of 5 mA is allowed because the risk of harmful physiological effects is small and the appearance of 220 V on the PATIENT is very unlikely.

Sub-clause

19.4 d)

Although it is not unlikely that 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 first statement is therefore to be considered as a convention.

The likelihood that PATIENT cables have an important capacitance to earth is usually important and of considerable influence on test results. A position providing reproducible results is therefore prescribed.

Sub-clause

19.4 e) 4)

The measuring device represents a measuring method which takes into account the physiological effect of a current through the human body, including the heart.

Sub-clause

19.4 h)

Care should be taken that the capacitance of the measuring device and its connecting leads to earth and to the body of the EQUIPMENT is kept as low as possible.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a fixed output voltage and an auto-transformer with an adjustable output voltage may be used.

Subclause

20.1 Item A-f

Contrary to the definition *2.3.2 *"BASIC INSULATION:* Insulation applied to LIVE parts to provide basic protection against electric shock", the insulation A-f does not provide such protection, but if testing is necessary the same test voltage values as for BASIC INSULATION apply.

Sub-clause

20.3 Components in EQUIPMENT which are subjected to a dielectric strength test according to Clause 20, like fuseholder, push-buttons, switches etc. will be subjected to the relevant test voltages. If these components cannot fulfil these requirements, due to the specification of the relevant component, additional measures may be taken in the EQUIPMENT (e.g. by additional insulation material) (see also Sub-clauses 4.4 and 56.1).

The dielectric strength test voltages specified in table V are appropriate for insulation which is normally subjected to a continuous reference voltage *U* and to transient overvoltages.

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a reference voltage *U* equal to the defibrillation peak voltage would be far too high for insulation which in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than 10 ms and without additional overvoltage.

The special test described in subclause 17 **h)* is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.

Sub-clause

20.4 a)

Since the dielectric strength test as described in Sub-clause 20.4*a)* is applied immediately after the humidity preconditioning treatment, with the EQUIPMENT still in the humidity cabinet, adequate precautions for the protection of laboratory personnel may be necessary.

Sub-clause

20.4 b)

The test voltage may be provided by a transformer, a d.c. power source or by using the transformer(s) of the EQUIPMENT. In the last case, to prevent overheating, the test voltage may have a frequency which is higher than the RATED frequency of the EQUIPMENT.

The procedure and duration of the test for reference voltages equal to or higher than 1 000 V a.c. or 1 500 V d.c. or peak values may be specified further by Particular Standards.

Sub-clause

20.4 g)

This may 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.

Sub-clause

20.4 j)

Components designed to limit the voltage which may be destroyed by power dissipation during the dielectric strength test may be removed when the test is made.

Sub-clause

21.5 The tests for HAND-HELD EQUIPMENT or EQUIPMENT parts is different from the test for PORTABLE and MOBILE EQUIPMENT because of the difference in practical application.

Sub-clause

21.6 Contrary to what is often assumed, MEDICAL ELECTRICAL EQUIPMENT may be used in a hostile environment. In case of emergency, EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators and subjected to bumps and vibration. Such conditions may in fact typify NORMAL USE for some EQUIPMENT.

Clause

22 The degree of protection required for ENCLOSURES or guards protecting moving parts depends upon the general design and intended use of the EQUIPMENT. Factors to be taken into consideration in judging the acceptability of exposed moving parts may be the degree of exposure, the shape of the moving parts, the likelihood of accidental contact, the speed of movement and the likelihood of fingers, arms or clothing being 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).

These factors may be considered with respect to both NORMAL USE and also during setting of any adjustments, or the replacement of any ACCESSORY or attachment, possibly including the installation instructions, because guards may be provided at installation and may not be part of a single item of STATIONARY EQUIPMENT.

Features of guards that may be considered include:

– removability with the use of TOOLS only;

– removability for servicing and replacement;

– strength and rigidity;

– completeness;

– 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.

See also rationale to Sub-clause 6.8.2*b)*.

Clause

26 In factories and workshops, excessive noise may cause fatigue or even damage to hearing. Limits to prevent hearing damage are described in ISO Standards.

In medically used rooms, much lower limits are needed for the comfort of PATIENT and medical personnel. The actual effect of EQUIPMENT noise is strongly influenced by the acoustical properties of the room, the insulation between rooms and interaction of EQUIPMENT parts.

Sub-clause

28.5 Calculation of forces (dynamic loads) caused by acceleration or deceleration of suspended masses is often difficult because the acceleration or deceleration may be greatly influenced by the flexibility of several parts whose combined effect is difficult to predict. This applies in particular to hand-driven movements with end-stops. For motor-driven movements, the effects of fault conditions in the motor-control circuitry may have to be considered.

Requirements concerning alternating stresses (including dimensions of guiding means and wheels) are under consideration.

Clause

36 High frequency radiation above 0,15 MHz is normally directly harmful only if produced at substantial energy levels, for example, by diathermy and surgical EQUIPMENT. However, this radiation may, even when produced at fairly low energy levels, influence the function of sensitive electronic devices and cause interference in radio and television reception.

Constructional requirements can hardly be given, but limits and measuring methods have been described in CISPR publications.

The sensitivity of EQUIPMENT to external interference (electromagnetic field, perturbations of the supply voltage) is under consideration.

Sub-clause

40.3 The graphs of Figures 29, 30 and 31 are given to assist in the design of circuits which fulfil the requirements for allowable limits stated for CATEGORY AP EQUIPMENT without performing the ignition test.

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.

Sub-clause

40.4 The amount of air or inert gas escaping from the EQUIPMENT by leakage is assumed to be limited so that hygienic conditions in the medically used room are not disturbed appreciably.

For the purposes of Sub-clauses 40.4 and 40.5 the term "enclosure" may represent either the ENCLOSURE as defined in Sub-clause 2.1.6 or a distinct compartment or housing.

Sub-clause

40.5 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.

Sub-clause

41.2 This requirement prevents the introduction of voltages higher than those permitted by Sub-clause 41.3. Such voltages can exist on earth wiring.

Sub-clause

41.3 The graphs of Figures 32, 33 and 34 are given to assist in the design of circuits which fulfil the requirements for allowable limits stated for CATEGORY APG EQUIPMENT, without performing the ignition test.

Sub-clauses

42.1 and 42.2

Tables XA and XB originate from IEC Publication 60335-1. In Table XA temperature limits are listed for ACCESSIBLE PARTS, components with T-marking and classified winding insulations. In Table XB materials and components are listed, the temperature of which may influence the life of EQUIPMENT.

Subclause

43.2 While not a flammable mixture, the presence of an oxygen enriched atmosphere increases the flammability of many substances.

EQUIPMENT intended to operate within oxygen enriched atmospheres should be designed to minimize the likelihood of ignition of flammable materials.

Where appropriate, Particular Standards should specify the corresponding requirements.

Sub-clause

44.4 Leakage is considered as a SINGLE FAULT CONDITION

Subclause

44.8 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.

Where appropriate, Particular Standards should specify the corresponding requirements.

Clause

45 The requirements of this clause do not represent the most stringent combination of national regulations or standards.

In some countries such regulations or standards apply.

Sub-clause

45.2 It is assumed that if the PRESSURE × volume is equal to or smaller than 200 kPa × l or the PRESSURE is equal to or smaller than 50 kPa, a hydraulic test is not necessary.

The SAFETY FACTORS implied by Figure 38 are higher than those generally applied in testing 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.

The deletion of national references in the amended text avoids subordinating the requirements of the Standard to those of local regulations. The EQUIPMENT will sometimes have to satisfy both, or the more demanding, assuming that there are no local regulations which conflict with the Standard.

Sub-clause

45.3 The way the maximum PRESSURE in use is determined depends on circumstances.

Clause

46 In the first edition the content of this clause dealt only with the interchangeability of connections, and it has now been moved to Sub-clause 56.3.

Clause

49 For EQUIPMENT, in which the safety of the PATIENT depends on the continuity of the power supply, Particular Standards should include requirements regarding power failure alarms or other precautions.

Sub-clause

49.2 Attention is paid to the effect of a power interruption concerning unwanted movements, removal of compression forces and removal of PATIENTS from a hazardous position.

Subclause

51.1 If the control range of EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output which is regarded as non-hazardous, means should be provided which prevent such a setting or which indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock or by an additional special or audible signal) that the selected setting is in excess of a safety limit.

Where appropriate, Particular Standards should specify safe output levels.

Subclause

51.2 Any EQUIPMENT delivering energy or substances to a PATIENT should indicate the possible hazardous output, preferably as a pre-indication, e.g. energy, rate or volume.

Where appropriate, Particular Standards should specify the corresponding requirements.

Subclause

51.5 EQUIPMENT delivering energy or substances to the PATIENT should be provided with an alarm to alert the OPERATOR to any significant departure from the commanded level of delivery.

Where appropriate, Particular Standards should specify the corresponding requirements.

Sub-clause

52.4.1

– The delivery of unintended hazardous quantities of energy or substances to a PATIENT or into the environment may be described by Particular Standards.

Hazardous quantities of poisonous or ignitable gas depend on the type of gas, concentration, place of emission etc.

At a power dissipation of 15 W or less, no fire hazard exists.

– The occurrence of malfunctions and failure to operate (breakdown), causing a direct SAFETY HAZARD for a PATIENT (for example non-recognizable failures in life-supporting EQUIPMENT, non-recognizable measuring errors and substitution of PATIENT data) may be described in Particular Standards.

Sub-clause

52.5.7 The effect of functioning centrifugal switches may be taken into account. A locked rotor condition is specified because some capacitor motors may or may not start, causing variable results.

Sub-clause

52.5.8 Table XII, last line

Temperature limits of motor windings in EQUIPMENT are determined after the first hour as an arithmetic average because experience of test houses has shown that EQUIPMENT for INTERMITTENT OPERATION reaches variable values which may temporarily differ from the maximum values.

Therefore a lower temperature limits is required.

Clause

54 In Section Ten, where compliance is specified to be checked by inspection, it may be done by analysis of the relevant documents presented by the manufacturer.

Sub-clause

54.1 Controls, instruments, indicating lamps, etc., which are associated with a specific function of the EQUIPMENT, should be grouped together (see Section Eight).

Sub-clause

54.2 Parts liable to be replaced or adjusted should be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.

Sub-clause

54.3 The setting of controls which, if unintentionally changed, may affect safety should be so designed or guarded that unintentional changing of the setting or adjustments is unlikely.

Mains switches and other vital controls in life-supporting EQUIPMENT and other critical EQUIPMENT should be so designed or guarded that unintentional switching or changing of the setting is unlikely. Such EQUIPMENT should be identified by Particular Standards.

Controls, instruments, indicators and the like which are associated with a particular function of the EQUIPMENT should have their functions clearly marked in accordance with Sub-clause 6.1 and are located so as to minimize the possibility of inadvertent or incorrect adjustment. Where incorrect adjustment of controls can constitute a hazard, appropriate steps should be taken to prevent this possibility, e.g. by an interlocking device or an additional safety control.

Sub-clause

55.1 At least all LIVE parts, with the exception of POWER SUPPLY CORDS and other necessary interconnecting cords, should be enclosed in material which will not support combustion.

This does not preclude the use of an outer cover of other material covering an inner cover complying with the above recommendation.

For flammability tests see IEC Publication 695.

Sub-clause

55.2 Mechanical strength is described in Section Four.

Sub-clause

56.1 b)

Normally compliance with this requirement is checked for components in the MAINS PART and APPLIED PART.

Subclause

56.3 c)

There are two sets of circumstances to guard against:

– firstly, for TYPE BF and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead which may become detached from the EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth may have an adverse effect on the operation of the EQUIPMENT;

– secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to any LIVE parts or hazardous voltages.

"Possibly hazardous voltages" can refer either to LIVE parts of MEDICAL ELECTRICAL EQUIPMENT or to voltages appearing on other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.

The strength of the insulating material used for the connector is checked by pressing the test finger against the connector.

This requirement is also to prevent insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD.

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the PATIENT connector inadvertently into the mains socket.

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 which 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.

"Any connector" should be understood to include multiple contact connectors, several connectors and connectors in series.

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.

Sub-clause

56.4 Such capacitors cannot provide DOUBLE INSULATION or REINFORCED INSULATION.

Subclause

56.7 c)

If a SAFETY HAZARD might develop as a result of exhaustion of the battery, means should be provided to forewarn of this condition.

Where appropriate, Particular Standards should specify the corresponding requirement.

Subclause

57.2 b)

APPLIANCE COUPLERS with locking devices may be needed where inadvertent disconnection could lead to a hazard.

Sub-clause

57.2 e)

This requirement reduces the likelihood of other EQUIPMENT being connected which might lead to excessive LEAKAGE CURRENT.

EMERGENCY TROLLEYS are exempted to allow rapid exchange of EQUIPMENT in emergencies.

Subclause

57.2 g)

This requirement aims to avoid the possibility of misuse of POWER SUPPLY CORDS (see also subclause 18 *l)*).

Sub-clause

57.5 a)

Terminals of components other than terminal blocks may be used as terminals intended for external conductors.

This practice should be generally discouraged, but allowed in special cases where the terminal arrangement is adequate (accessible and clearly marked) and complying with this Standard. This situation may occur for example in motor starters.

Sub-clause

57.5 d)

The term "special preparation of the conductor" covers soldering of the strands, use of cord lugs, attachment of eyelets, etc., but not the reshaping of the conductor before its introduction into the terminal or the twisting of a stranded conductor to consolidate the end.

Sub-clause

57.7 Interference suppressors may be connected on the SUPPLY MAINS side of an EQUIPMENT mains switch or on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE.

Sub-clause

57.9 The scopes of IEC Publications 742 and 601-1 are different. Many types of transformers used in MEDICAL ELECTRICAL EQUIPMENT are not covered by IEC Publication 742.

For reasons of PATIENT safety additional requirements must be applied to the construction of such transformers, e.g. restriction of LEAKAGE CURRENTS flowing to PATIENT CIRCUITS.

The contents of Appendix J of the first edition now appear in Sub-clause 57.9.

Future work has to be done in order to establish e.g. appropriate CREEPAGE DISTANCES and AIR CLEARANCES inside transformers, taking into consideration the values for safety isolating transformers given in IEC Publication 742.

Requirements for switch-mode power supplies are under consideration.

Sub-clause

57.10 Values of CREEPAGE DISTANCES and AIR CLEARANCES are influenced by the following factors:

a) the reference voltage as defined in Sub-clause 20.3

b) The material of the insulation is assumed to have a low resistivity against tracking. A tracking test according to IEC Publication 112 may indicate lower values for spacings, but the practical value of such a test is being kept under consideration, until a study of the applicability of IEC Publication 664 is completed.

c) Spacings for SUPPLEMENTARY INSULATION are equal to those for BASIC INSULATION even if the dielectric strength test voltages according to Sub-clause 20.3 are different. Spacings for DOUBLE INSULATION and REINFORCED INSULATION are twice the values for BASIC INSULATION.

d) For insulation between the ENCLOSURE and an F-TYPE APPLIED PART special rules apply:

1) In the case of an F-TYPE APPLIED PART having no LIVE parts even when the APPLIED PART is earthed, the insulation between the APPLIED PART and the ENCLOSURE will only be stressed to the MAINS VOLTAGE in the case of a single fault in other EQUIPMENT connected to the PATIENT.

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.

2) In the case of an F-TYPE APPLIED PART containing parts with voltage difference, the connection of a part of the APPLIED PART to earth via an earthed PATIENT (NORMAL CONDITION) may result in LIVE parts within the APPLIED PART.

The insulation between such LIVE parts and the ENCLOSURE may be subject, under worst case conditions (when a part of the APPLIED PART is earthed via the PATIENT), to the whole of the voltage within the APPLIED PART.

Since this voltage appears in NORMAL CONDITION, even though infrequently, the relevant insulation must 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 XVI are considered adequate.

3) The value to be applied is the highest of the values found according to Items *d)*1) and *d)*2) above.

DEFIBRILLATION-PROOF APPLIED PARTS

From IEC 664, table II, 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, with a reasonable safety margin.

The validity of this margin, which has been retained to ensure that the EQUIPMENT pass the defibrillator test, and not only remain safe afterwards but also function normally, comes from three factors:

– The values in IEC 664 already have an inherent safety margin;

– in practice the applied voltage even on the PATIENT'S thorax will be much less than the assumed open-circuit voltage of 5 kV, as the defibrillator will be on load, and it has an appreciable internal impedance and a series inductor which adds to this impedance;

– IEC 664 allows for heavily contaminated surfaces, whereas in MEDICAL ELECTRICAL EQUIPMENT internal surfaces are clean.

Sub-clause

59.1 e)

Conductors may 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 realised by sufficient rating of the conductor insulation and by arranging for sufficient AIR CLEARANCES and CREEPAGE DISTANCES, complying with the requirements of Sub-clause 57.10, between conductive parts in connecting devices.

Sub-clause

59.2 b)

Tests concerning flammability of materials will be found in IEC Publication 707.

APPENDIX B
TESTING DURING MANUFACTURE AND/OR INSTALLATION

Not used. See the rationale to Sub-clause 4.1.

APPENDIX C
SEQUENCE OF TESTING

C1 *General*

Tests should, if applicable, be carried out in the sequence indicated below, unless otherwise stated by Particular Standards. The sequence of the tests marked by an * is mandatory. See also Sub-clause 4.11.

However, this does not preclude the possibility of conducting a test which preliminary inspection suggests might cause failure.

*The sequence of these tests is mandatory.

C1DV DE *Modification of C1 by adding the following:*

Asterisks shall not be used to mark which tests have a mandatory sequence. The tests for C23 – C29 shall be performed in sequential order.

C2 *General requirements*

See Sub-clause 3.1 and Clause 4.

C3 *Markings*

See Sub-clauses 6.1 to 6.8.

C4 *Power input*

See Clause 7.

C5 *Classification*

See Clause 14.

C6 *Limitation of voltage and/or energy*

See Clause 15.

C7 *ENCLOSURES and PROTECTIVE COVERS*

See Clause 16.

C8 *Separation*

See Clause 17.

C9 *Protective earthing, functional earthing and potential equalization*

See Clauses 18 and 58.

C10 *Mechanical strength*

See Clause 21.

C11 *Moving parts*

See Clause 22.

C12 *Surfaces, corners and edges*

See Clause 23.

C13 *Stability and transportability*

See Clause 24.

C14 *Expelled parts*

See Clause 25.

C15 *Suspended masses*

See Clause 28.

C16 *Radiation hazards*

See Section Five.

C17 *Electromagnetic compatibility*

See CISPR recommendations and the rationale for Clause 36.

C18 *PRESSURE vessels and parts subject to PRESSURE*

See Clause 45.

C19 *Human errors*

See Clause 46.

C20 *Temperatures – Fire prevention*

See Clauses 42 and 43.

C21 *Interruption of the power supply*

See Clause 49.

C22 *Accuracy of operating data and protection against incorrect output*

See Clauses 50 and 51.

C23 *Abnormal operation, fault conditions, environmental tests*

See Clauses 52 and 53.

C24 *Continuous* LEAKAGE CURRENTS *and* PATIENT AUXILIARY CURRENTS *at operating temperature*

See Sub-clause 19.4.

C25 *Dielectric strength at operating temperature*

See Sub-clause 20.4.

C26 *Humidity preconditioning treatment*

See Sub-clause 4.10.

C27 *Dielectric strength test (*COLD CONDITION*)*

See Sub-clause 20.4.

C28 LEAKAGE CURRENT *after humidity preconditioning treatment*

See Sub-clause 19.4.

C29 *Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection*

See Clause 44, exception Sub-clause 44.7.

See Clause C34.

C30 ENCLOSURES *and covers*

See Clause 55.

C31 *Components and general assembly*

See Clause 56.

C32 MAINS PARTS*, components and layout*

See Clause 57.

C33 *Not used, covered by Clause C9.*

C34 *Construction and layout*

See Clause 59 and Sub-clause 44.7.

C35 CATEGORY AP *and* CATEGORY APG EQUIPMENT

See Clauses 37 to 41 inclusive.

C36 *Verification of markings*

See Sub-clause 6.1, last paragraph.

APPENDIX D
SYMBOLS ON MARKING
(See Clause 6)

Introduction

Symbols are frequently used on 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.

If, for the purpose of this Standard, symbols are necessary, the following symbols should be used. See IEC Publications 417 and 878.

For symbol requirements not met by these lists refer in the first instance to published IEC or ISO symbols, noting that, where necessary, two or more symbols may 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.

Table DI

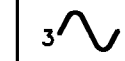
No.	Symbol	IEC Publication	Description
1		417–5032	Alternating current
2		335–1	Three–phase alternating current
3		335–1	Three–phase alternating current with neutral conductor
4		417–5031	Direct current
5		417–5033	Direct current and alternating current
6		417–5019	Protective earth (ground)
7		417–5017	Earth (ground)
8	N	445	Connection point for the neutral conductor on PERMANENTLY INSTALLED EQUIPMENT
9		417–5021	Equipotentiality
10		417–5172	CLASS II EQUIPMENT
14		348	Attention, consult ACCOMPANYING DOCUMENTS
15		417–5008	Off (power: disconnection from the mains)
16		417–5007	On (power: connection to the mains)
17		417–5265	"Off" (only for a part of EQUIPMENT)
18		417–5264	"On" (only for a part of EQUIPMENT)

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Table DII

No.	Symbol	IEC Publication	Description
1		417-... 878-02-02	TYPE B APPLIED PART
2		417-5333 878-02-03	TYPE BF APPLIED PART
3		417-5335 878-02-05	TYPE CF APPLIED PART
4		878-02-07	CATEGORY AP EQUIPMENT
5		878-02-08	CATEGORY APG EQUIPMENT
6		878-03-01	Dangerous voltage
7		–	Not used
8		878-03-04	Non-ionizing radiation
9		417-... 878-...	DEFIBRILLATION-PROOF TYPE B APPLIED PART
10		417-5334 878-02-04	DEFIBRILLATION-PROOF TYPE BF APPLIED PART
11		417-5336 878-02-06	DEFIBRILLATION-PROOF TYPE CF APPLIED PART

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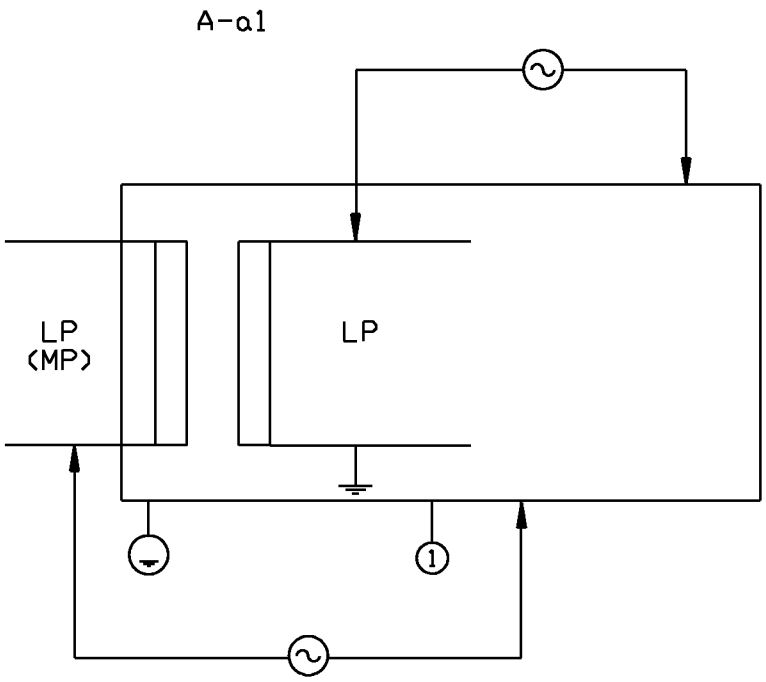
NOTE 1 – Symbol No. 1 will be later introduced in IEC 417 and descriptions of the three symbols No. 1, 2 and 3 will be modified in IEC 878.

NOTE 2 – Symbol No. 9 will be later introduced in IEC 417 and IEC 878 and descriptions of the two symbols No. 10 and 11 will be modified in IEC 878.

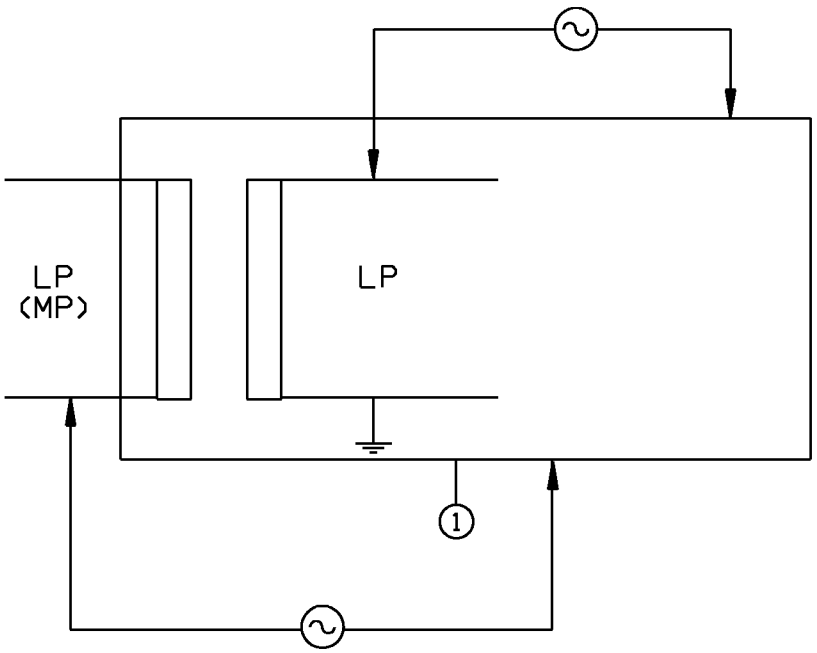
APPENDIX E
SURVEY OF INSULATION PATHS AND TEST CIRCUITS
(See Clause 20)



SM916A

1 Accessible Metal Part

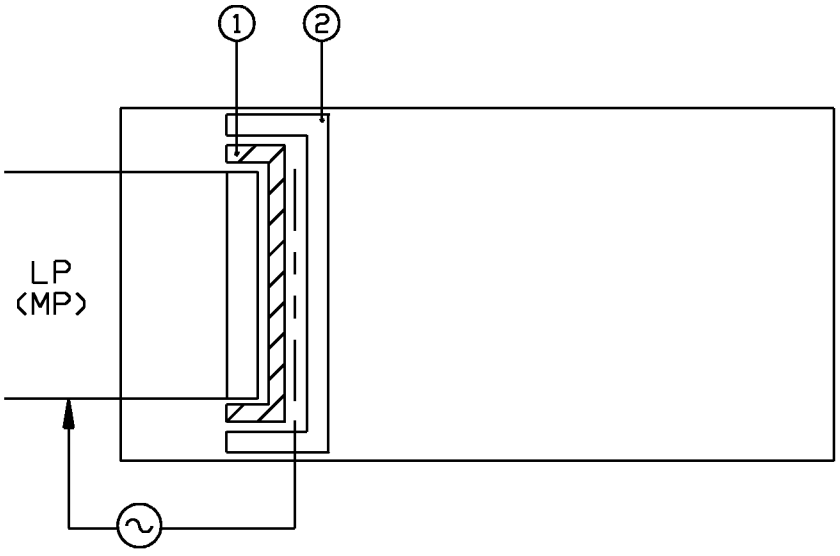
A-a2



SM917

① Enclosure

A-b

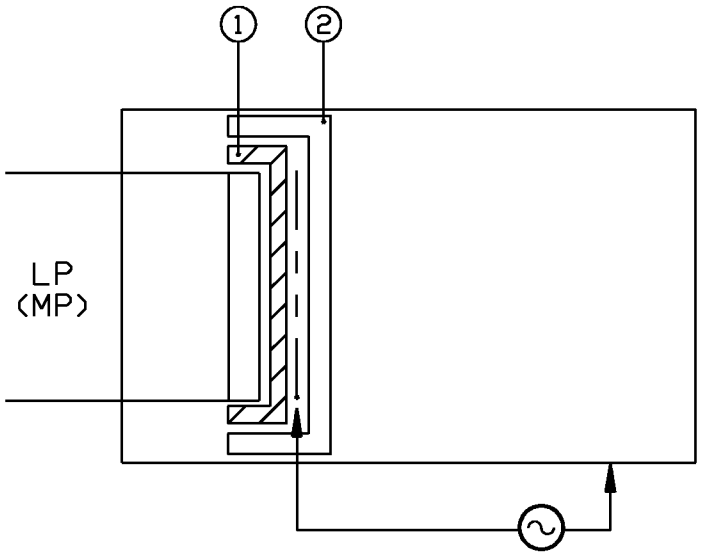


① Basic Insulation

② Supplementary Insulation

SM918

A-c

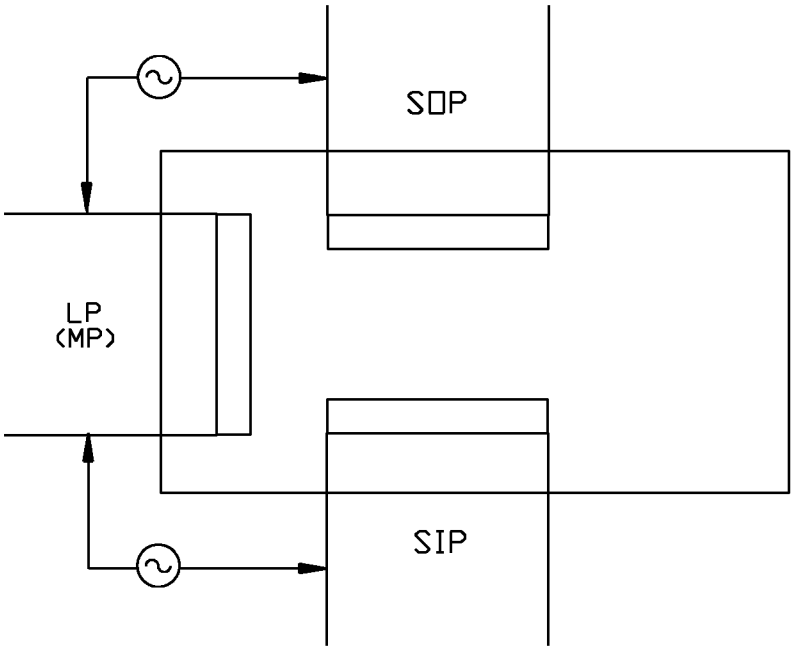


① Basic Insulation

② Supplementary Insulation

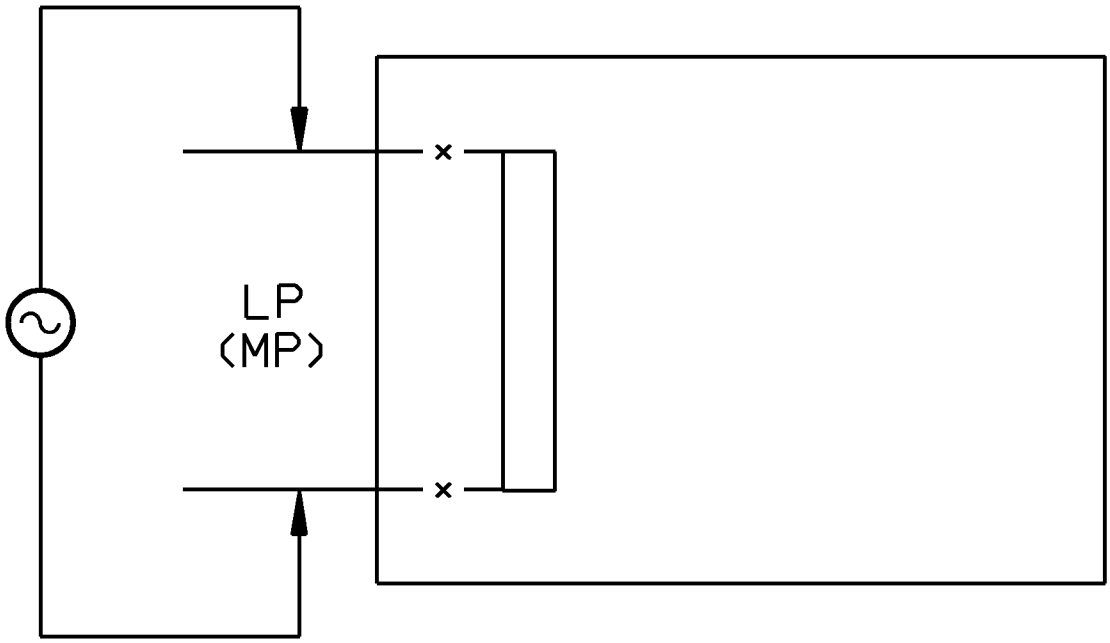
SM920

A-e



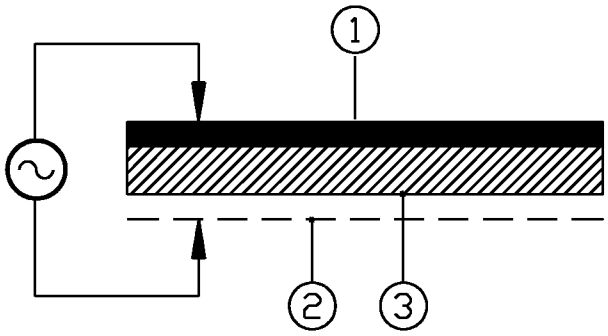
SM921

A-f



SM922

A-g



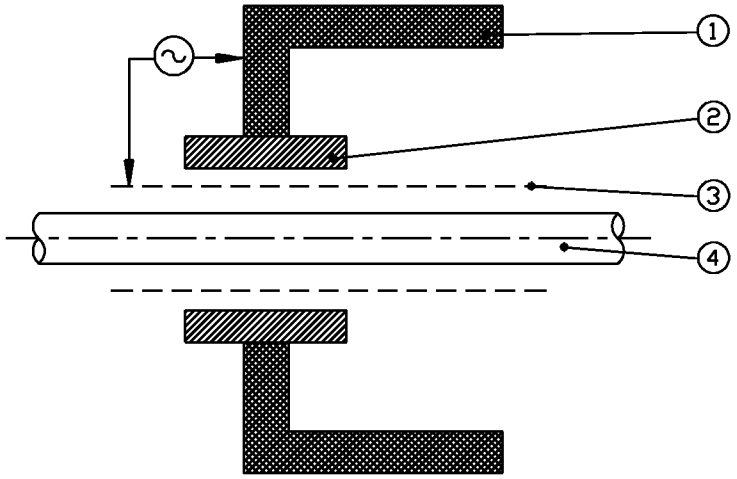
1 Metal ENCLOSURE

2 Metal foil

3 Insulation lining

SM923

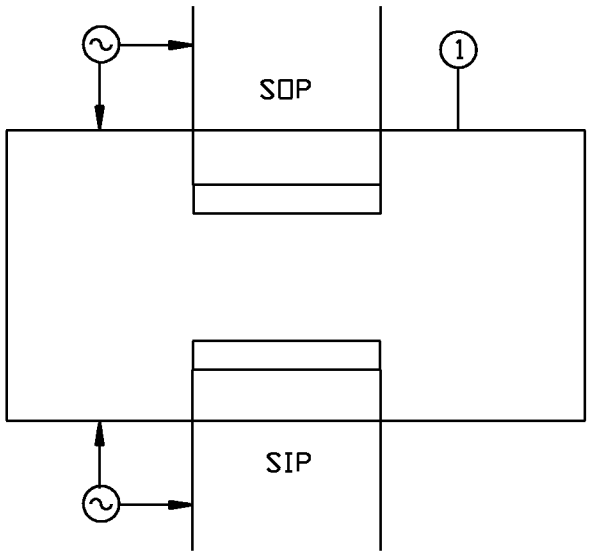
A-j



① ACCESSIBLE PART
② Bushing
③ Metal foil
④ POWER SUPPLY CORD or metal rod

SM925

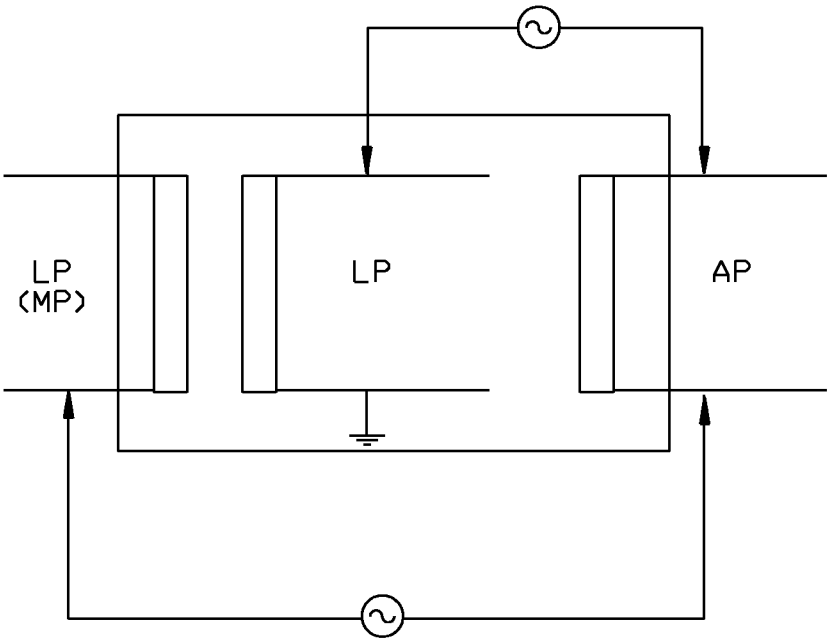
A-k



① ACCESSIBLE PART, not PROTECTIVELY EARTHED

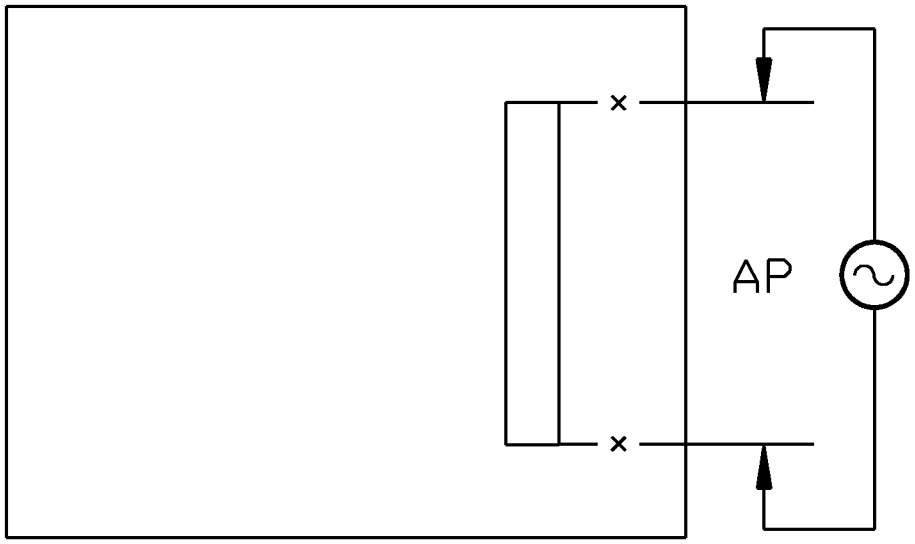
SM926

B-a



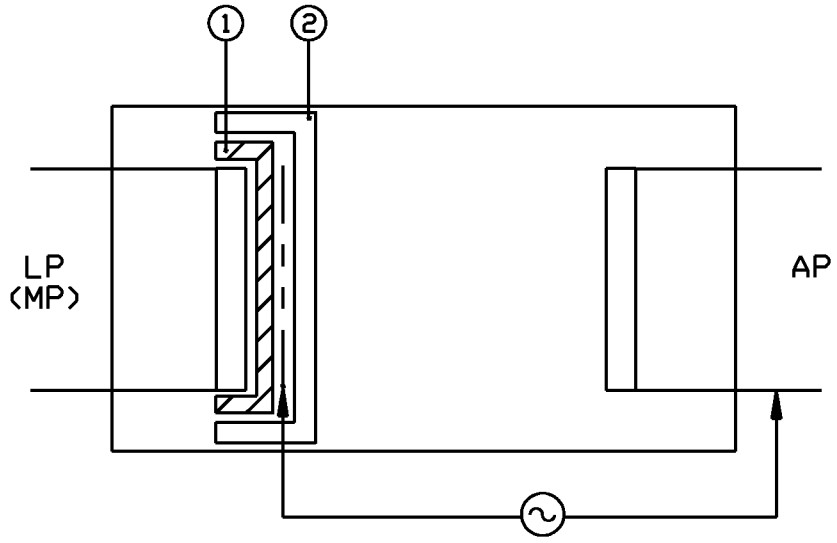
SM927

B-b



SM928

B-c

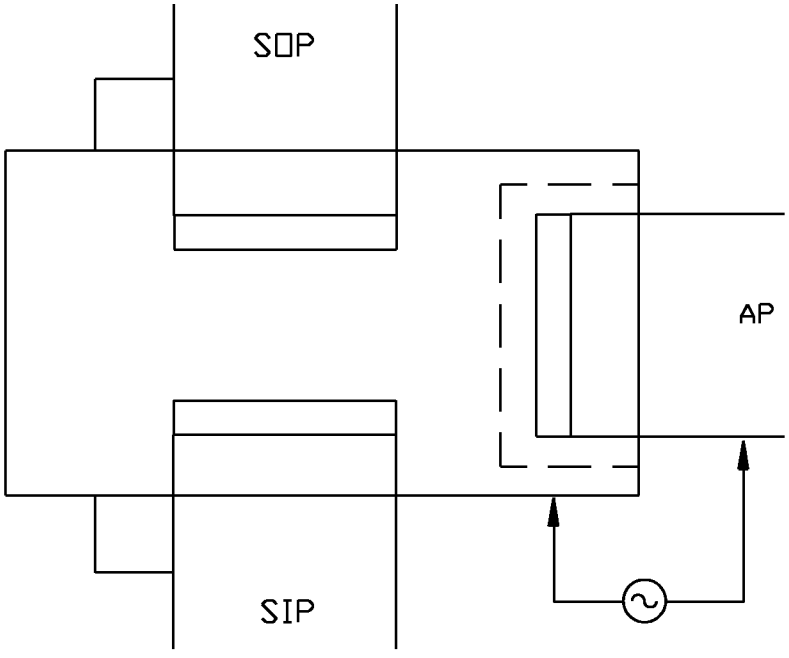


1 Basic Insulation

2 Supplementary Insulation

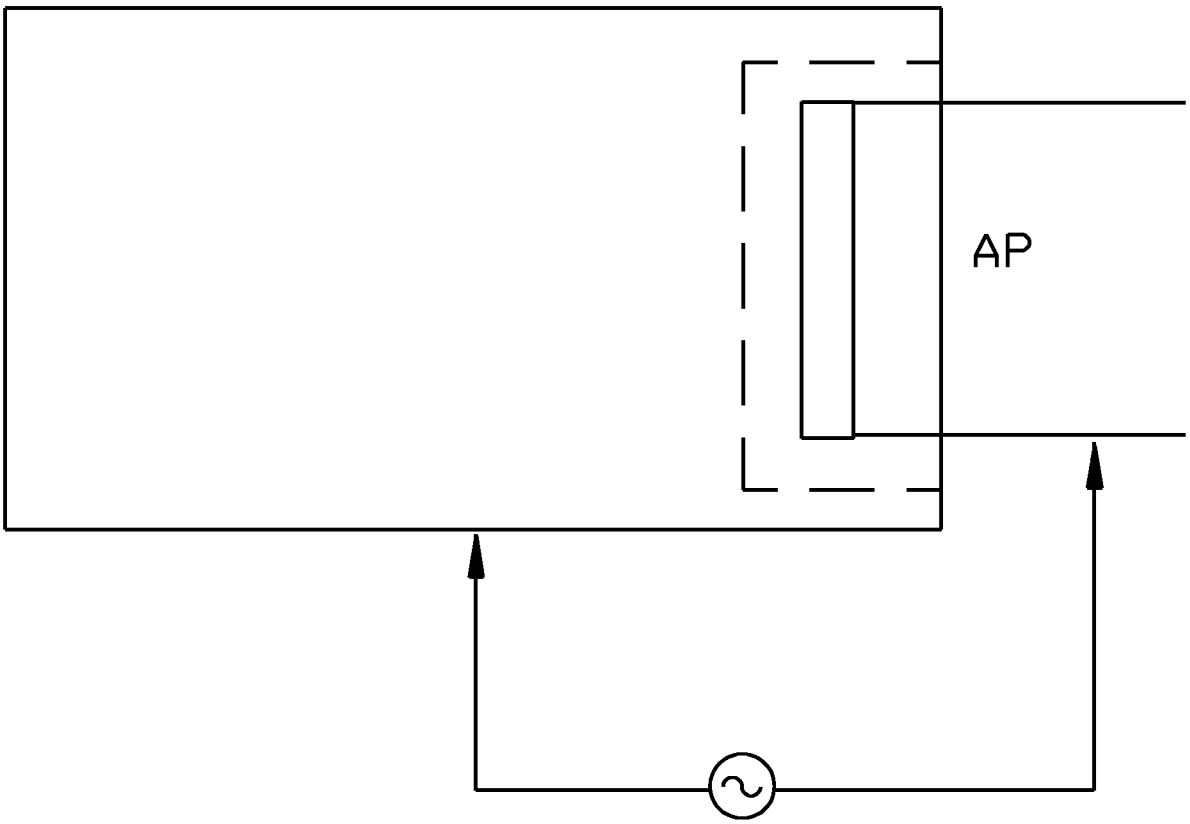
SM929

B-d



SM930

B-e



SM931

Legend

MP = MAINS PART

SOP = SIGNAL OUTPUT PART

SIP = SIGNAL INPUT PART

AP = APPLIED PART

LP = LIVE part

X = Interruption of circuit for measuring purposes

APPENDIX F
TEST APPARATUS FOR FLAMMABLE MIXTURES
(See Appendix A, Sub-clause A1.6.3)

The test apparatus comprises an ignition space with a volume of at least 250 cm^3, which contains the prescribed atmosphere or mixture and a contact arrangement (see figure below) providing sparks by opening and closing.

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 which 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 rev/min. The shaft connected to the cadmium disk turns in opposite direction to the shaft connected to the disk with wires.

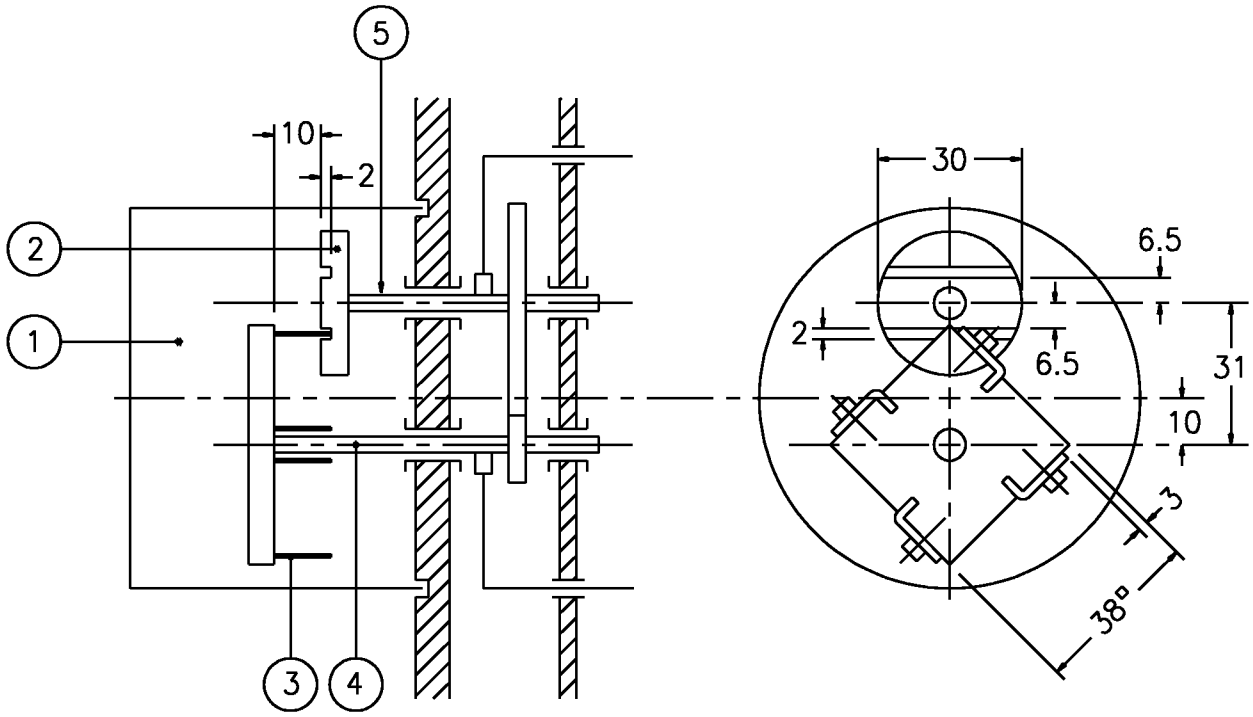
The ratio of the rotation speed of the shaft connected to the wires and the other shaft is 50:12.

Both shafts are isolated from each other and from the frame.

The ignition space must be able to support an internal overpressure of 1,5 MPa.

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.

Test apparatus



Legend:

① Ignition space
② Cadmium disk
③ Tungsten wire
④ Shaft of wire disk
⑤ Shaft of disk with grooves

Dimensions in millimetres

SM906A

Test apparatus

APPENDIX G
IMPACT-TEST APPARATUS

The test apparatus (see figure below) consists of three main parts: the body, the striking element and the spring-loaded release cone.

The body comprises the housing, the striking element guide, the release mechanism and all parts rigidly fixed thereto.

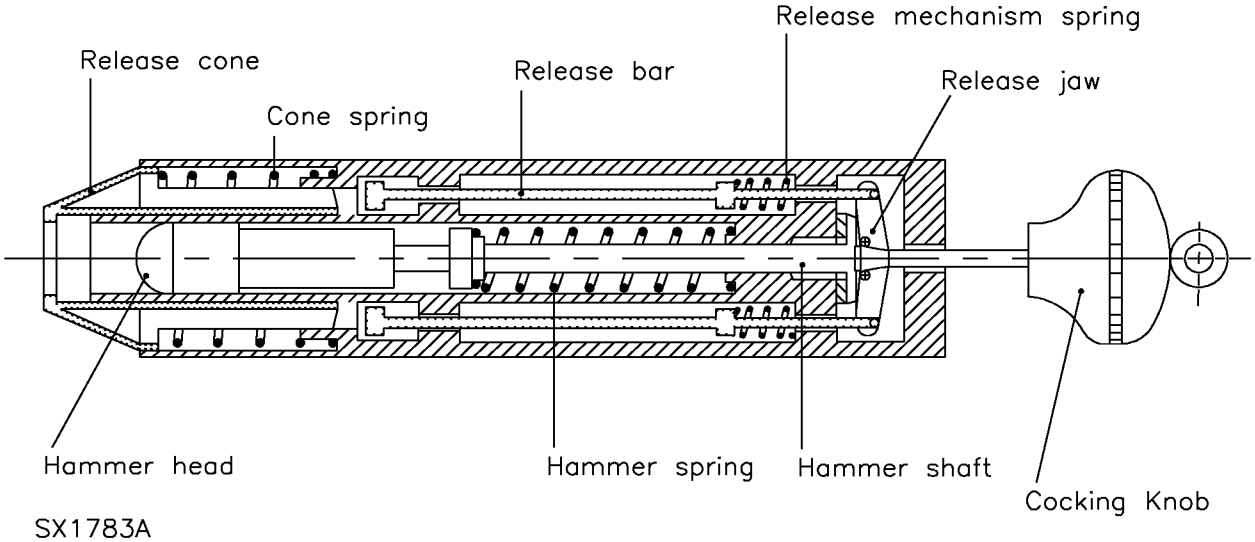
The mass of this assembly is 1 250 g.

The striking element comprises the hammer head, the hammer shaft and the cocking knob. The mass of this assembly is 250 g. The hammer head has a hemispherical face of polyamide having a Rockwell hardness of R100, with a radius of 10 mm; it is so fixed to the hammer shaft that the distance from its tip to the plane of the front of the cone when the striking element is on the point of release is 20 mm.

The cone has a mass of 60 g and the cone spring is such that it exerts a force of 20 N when the release jaws are on the point of releasing the striking element.

The hammer spring is adjusted so that the product of the compression, in millimetres, and the force exerted, in newtons, equals 1 000, the compression being approximately 20 mm. With this adjustment, the impact energy is 0,5 J ± 0,05 J.

Impact-test apparatus (see Clause 21)



APPENDIX H
SCREWED TERMINAL CONNECTIONS

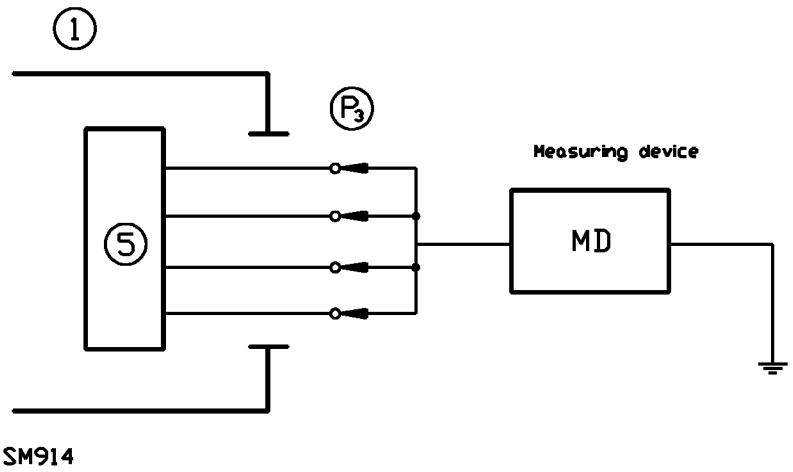
Not used.

APPENDIX J
MAINS SUPPLY TRANSFORMERS

Text transferred to Sub-clause 57.9.

APPENDIX K*

Example for the CONNECTION of the APPLIED PART for measurement of the PATIENT AUXILIARY CURRENT (see legends after Figure 27)

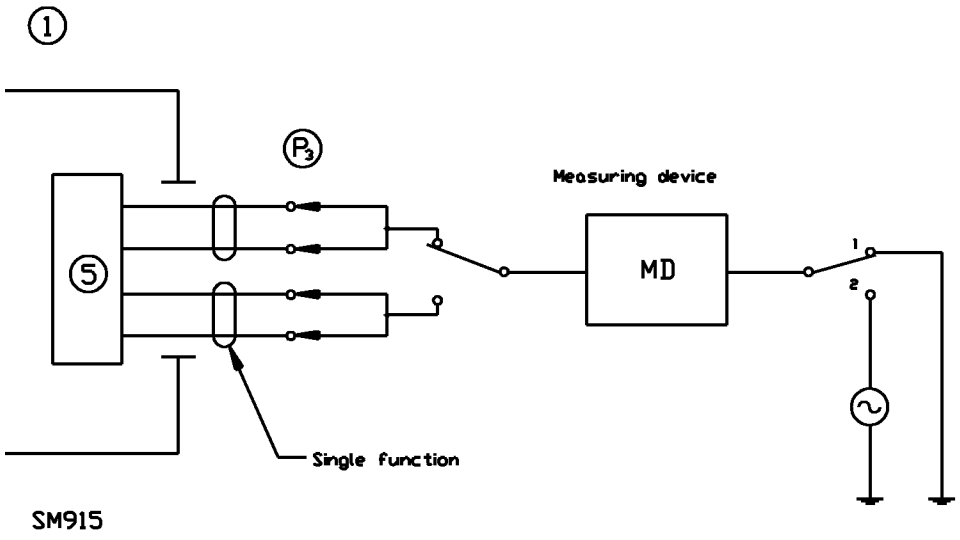


EQUIPMENT with TYPE B APPLIED PART

From all PATIENT CONNECTIONS connected together.

See legends after Figure 27.

*In the first edition this appendix was entitled “Medical isolating transformers”. It has been deleted and replaced by the present appendix.



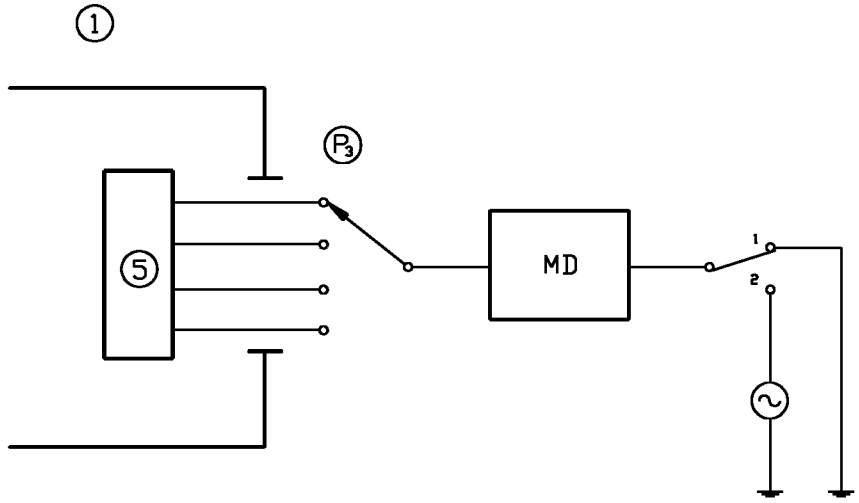
SM915

EQUIPMENT with TYPE BF APPLIED PART

From and to all PATIENT CONNECTIONS of a single function connected together.

See legends after Figure 27.

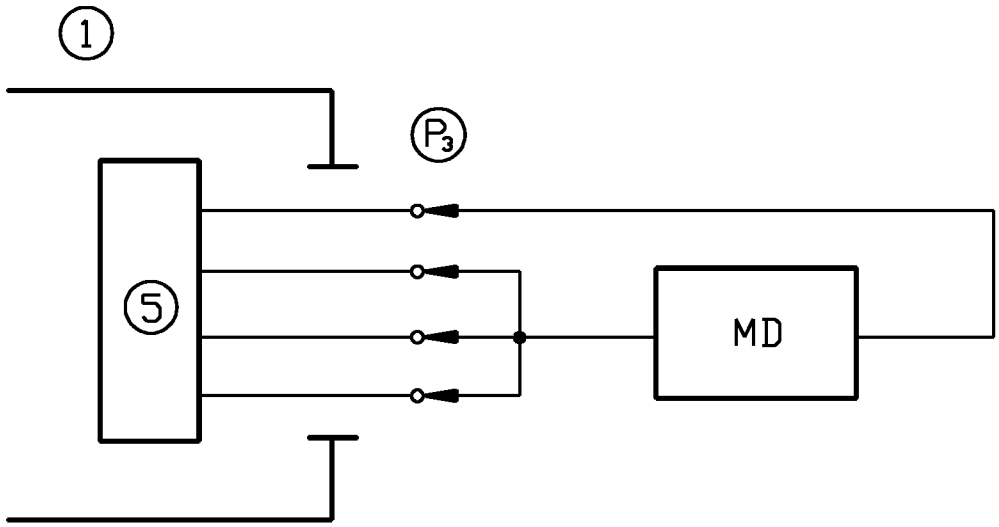
Examples for the CONNECTION of the APPLIED PART for measurement of the PATIENT AUXILIARY CURRENT (See legends after Figure 27)



SM912

EQUIPMENT with TYPE CF APPLIED PART

From and to every PATIENT CONNECTION.



SM913

EQUIPMENT with TYPES B, BF and CF APPLIED PARTS

Between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS connected together.

APPENDIX L
REFERENCES – PUBLICATIONS MENTIONED IN THIS STANDARD

IEC Standards	*Date*	*Title*
Publication 65	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use. Fifth edition 1985, incorporating Amendment No. 1 (1978). Amendment No. 2 (1981).
Publication 68-2-2	1974	Basic environmental testing procedures. Part 2-2: Test B, Dry heat.
Publication 73	1984	Colours of indicator lights and push-buttons.
Publication 79	–	Electrical apparatus for explosive gas atmospheres.
Publication 79-2	1983	Electrical apparatus for explosive gas atmospheres. Part 2: Electrical apparatus – type of protection “p”.
Publication 79-5	1967	Electrical apparatus for explosive gas atmospheres. Part 5: Sand-filled apparatus.
Publication 79-6	1968	Electrical apparatus for explosive gas atmospheres. Part 6: Oil-immersed apparatus.
Publication 85	1984	Thermal evaluation and classification of electrical insulation.
Publication 112	1979	Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions.
Publication 127	1974	Cartridge fuse-links for miniature fuses.
Publication 227	–	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Amendment No. 1 (1985).
Publication 241	1968	Fuses for domestic and similar purposes.
Publication 245	–	Rubber insulated cables of rated voltages up to and including 450/750 V.
Publication 245-4	1980	Rubber insulating cables of rated voltages up to and including 450/750 V. Part 4: Cords and flexible cords.
Publication 252	1975	A.C. motor capacitors.
Publication 309	–	Plugs, socket-outlets and couplers for industrial purposes.
Publication 320	1981	Appliance couplers for household and similar general purposes.
Publication 328	1972	Switches for appliances.
Publication 60335-1	1976	Safety of household and similar electrical appliances. Part 1: General requirements.
Publication 336	1982	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use.
Publication 348	1978	Safety requirements for electronic measuring apparatus.
Publication 364-4-41	1982	Electrical installation of buildings. Part 4: Protection for safety. Chapter 41: Protection against electric shock.
IEC 384-14	1993	Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains
Publication 417	–	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.
Publication 445	1973	Identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation.
Publication 447	1974	Standard directions of movement for actuators which control the operation of electrical apparatus.
IEC 513	1994	Fundamental aspects of safety standards for medical electrical equipment

Table Continued on Next Page

Table Continued

IEC 529	1989	Degrees of protection provided by enclosures (IP Code)
Publication 536	1976	Classification of electrical and electronic equipment with regard to protection against electric shock.
Publication 601-1	1977	Safety of medical electrical equipment. Part 1: General requirements.
		First edition 1977.
		Amendment No. 1 (1984)
IEC 601-1-1	1992	Medical electrical equipment – Part 1: General requirements for safety.
		1. Collateral Standard: Safety requirements for medical electrical systems
IEC 601-1-2	1993	Medical electrical equipment – Part 1: General requirements for safety.
		2. Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 601-1-3	1994	Medical electrical equipment – Part 1: General requirements for safety.
		3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 601-1-4*		Medical electrical equipment – Part 1: General requirements for safety.
		4. Collateral standard: Safety requirements for programmable electronic medical systems
Publication 664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment.
Publication 695	–	Fire hazard testing.
Publication 707	1981	Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source.
Publication 742	1983	Isolating transformers and safety isolating transformers: Requirements.
Publication 878	1988	Graphical symbols for electrical equipment in medical practice.
ISO Publications		
ISO 32	1977	Gas cylinders for medical use – Marking for identification of content.
ISO 407	1983	Small medical gas cylinders – Yoke-type valve connections.
ISO 471	1983	Rubber – Standard temperatures, humidities and times for the conditioning and testing of test pieces.
ISO 780	1985	Packaging – Pictorial marking for handling of goods.
ISO 1000	1981	SI units and recommendations for the use of their multiples and of certain other units
ISO 1853	1975	Conducting and antistatic rubbers – Measurement of resistivity.
ISO 2878	1987	Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance.
ISO 2882	1979	Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits.
ISO 8185	1988	Humidifiers for medical use – Safety requirements.
ISO 10993-1	1992	Biological evaluation of medical devices – Part 1: Guidance on selection of tests.

* Currently under consideration by TC 62.

Annex DVA
(informative)
Standards for Components

DVA D2 ***Addition of a new annex DVA as follows:***

Standards under which components of the products covered by this standard are evaluated include the following:

Title of Standard – UL Standard Designation

Attachment Plugs and Receptacles, Electrical **–**
UL 498

Cathode-Ray Tubes, Implosion-Protected, for Television-Type Appliances **–**
UL 1418

Circuit Breakers, Molded-Case, and Circuit-Breaker Enclosures **–**
UL 489

Conduit, Electrical Flexible Metal **–**
UL 1

Conduit, Electrical, Liquid-Tight Flexible Steel **–**
UL 360

Controls, Limit **–**
UL 353

Cord Sets and Power-Supply Cords **–**
UL 817

Determination of Sharpness of Edges on Equipment **–**
UL 1439

Flexible Cord and Fixture Wire **–**
UL 62

Fuseholders **–**
UL 512

Ground-Fault Circuit Interrupters **–**
UL 943

Lampholders, Edison-Base **–**
UL 496

Lithium Batteries **–**
UL 1642

Motors, Impedance-Protected –
UL 519

Optical Isolators –
UL 1577

Outlet Boxes and Fittings, Electrical –
UL 514

Outlet Boxes, Flush-Device Boxes and Covers, Nonmetallic –
UL 514C

Printed-Wiring Boards, Electrical –
UL 796

Protectors for Electric Motors, Thermal –
UL 547

Protectors, Supplementary, for Use in Electrical Equipment –
UL 1077

Switches, Clock-Operated –
UL 917

Switches, Snap, General-Use –
UL 20

Switches, Special-Use –
UL 1054

Tape, Insulating –
UL 510

Terminals, Quick-Connect –
UL 310

Thermal Cutoffs for Use in Electrical Appliances and Components –
UL 1020

Tubing, Extruded Insulating –
UL 224

Wire and Cables, Thermoplastic-Insulated –
UL 83

Wire Connectors and Soldering Lugs for Use With Copper Conductors –
UL 486A

Wire Connectors for Use With Aluminum Conductors –
UL 486B

Annex DVB
(informative)
Manufacturing and Production Tests

DVB D2 *Addition of a new annex DVB as follows:*

DVB.1 Production-line dielectric voltage-withstand test

DVB.1.1 Each appliance shall withstand without an indication of unacceptable performance, as a routine production-line test, the application of a 40 – 70 Hz potential or a d.c. potential of 1,414 times the stated a.c. value between:

a) The primary wiring, including connected components, and accessible dead metal parts that are likely to become energized, and

b) Primary and accessible low voltage (42,4 volt peak or less) metal parts, including terminals, and, where applicable,

c) Primary circuits and PATIENT-connected circuits.

DVB.1.2 The production-line test shall be in accordance with either condition A or condition B of Table DVB.1.

DVB.1.3 The appliance may be in a heated or unheated condition for the test.

Table DVB.1 D2 *Addition:*

Table DVB.1 – Production line test conditions

Appliance rating and form	Condition A		Condition B	
	Potential volts	Time seconds	Potential volts	Time seconds
105 – 130 Volts with or without a motor RATED 1/2 horsepower or less and not applied to or contacted by persons in NORMAL USE.	1 000	60	1 200	1
105 – 130 Volts and applied to or contacted by persons in the intended use or with a motor RATED more than 1/2 horsepower	1 000 + 2 V[a]	60	1 200 + 2,4 V[a]	1
210 – 600 Volts	1 000 + 2 V[b]	60	1 200 + 2,4 V[b]	1
PATIENT connected circuits (Regardless of voltage rating)[c]	2 500	60	3 000	1
[a] Maximum marked voltage but not less than 120 volts.				
[b] Maximum marked voltage but not less than 240 volts.				
[c] Applied between primary circuits and PATIENT CONNECTIONS only.				

DVB.1.4 The test shall be conducted when the appliance is complete (fully assembled). It is not intended that the appliance be unwired, modified or disassembled for the test.

DVB.1.4.1 Parts such as snap covers or friction-fit knobs that would interfere with performance of the test need not be in place.

DVB.1.4.2 The test may be performed before final assembly if the test represents that for the completed appliance.

DVB.1.5 When the appliance employs a solid-state component that is not relied upon to reduce the risk of an electric shock and that can be damaged by the dielectric potential, the test may be conducted before the component is electrically connected provided that a random sampling of each day's production is to be tested at the potential specified in Table DVB.1. The circuitry may be rearranged for the purpose of the test to minimize the likelihood of solid-state-component damage while retaining representative dielectric stress of the circuit.

DVB.1.6 The test EQUIPMENT, when adjusted for production-line testing, is to produce an output voltage that is not less than the factory test value specified, nor is the magnitude of the test voltage to be greater than 120 percent of the specified test potential when the tester is used in each of the following conditions:

a) If the test duration is 1 second, the output voltage is to be maintained within the specified range, 1) when only a voltmeter having an input impedance of at least 2 megaohms and a specimen of the product being tested are connected to the output terminals, and 2) when a relatively high resistance is connected in parallel with the voltmeter and the product being tested, and the value of the resistance is gradually reduced to the point where an indication of unacceptable performance just occurs.

b) If the test duration is 1 minute, the output voltage is to be maintained within the specified range, by manual or automatic means, throughout the 1 minute duration of the test or until there is an indication of unacceptable performance.

DVB.1.7 The specified control of the applied voltage, manual or automatic, shall be maintained under conditions of varying line voltage. Higher test potentials may be used if the higher dielectric stress is not likely to adversely affect the insulating system of the product.

DVB.1.8 In addition, the test EQUIPMENT is to have the following features and characteristics:

a) A means of indicating the test voltage that is being applied to the appliance under test. This may be accomplished by sensing the voltage at the test leads or by an equivalent means.

b) An output voltage that 1) has a sinusoidal waveform, 2) has a frequency that is within the range of 40 – 70 Hz, and 3) has a peak value of the waveform that is not to be less than 1,3 and not more than 1,5 times the root-mean-square value, or is a d.c. input.

c) A means of effectively indicating unacceptable performance. The indication is to be 1) auditory if it can be readily heard above the background noise level, 2) visual if it commands the attention of the OPERATOR, or 3) a device that automatically rejects an unacceptable product. If the indication of unacceptable performance is auditory or visual, the indication is to remain active and conspicuous until the test EQUIPMENT is reset manually.

d) When the test EQUIPMENT is adjusted to produce the test voltage and a resistance of 120 000 ohms is connected across the output, the test EQUIPMENT is to indicate an unacceptable performance within 0,5 second. A resistance of more than 120 000 ohms may be used to produce an indication of unacceptable performance, if the manufacturer elects to use a tester having higher sensitivity.

DVB.1.9 There is not to be any transient voltage applied to the appliance under test that results in the instantaneous voltage applied to the product exceeding 120 percent of the peak value of the test voltage that the manufacturer elects to use for this test. This requirement applies for the entire duration of the test, including the time that the voltage is first applied to the product and the time that the voltage is removed from the product.

DVB.1.10 During the test, a sufficient number of primary switching components shall be in the on position so that all primary circuitry will be stressed. Both sides of the primary circuit of the appliance are to be connected to one terminal of the test EQUIPMENT. The second EQUIPMENT terminal is to be connected to accessible dead metal.

DVB.2 Production-Line Grounding-Continuity Test

DVB.2.1 Each appliance that has provision for grounding by fixed wiring means or has a power-supply cord having a grounding conductor shall be tested, as a routine production-line test, to determine grounding continuity is provided between the point of connection of the EQUIPMENT grounding means (grounding blade of the attachment plug in the case of a portable appliance) and the accessible dead metal parts of the appliance that are likely to become energized.

DVB.2.1.1 This test need not be conducted on appliances intended for permanent connection by fixed wiring means if the construction does not employ bonding jumpers or grounding wiring to remote units.

DVB.2.2 Only a single test need be made if the accessible metal selected is conductively connected to all other accessible metal.

DVB.2.3 Any indicating device (an ohmmeter, a battery-and-buzzer combination or the like) may be used to determine compliance with the grounding continuity requirements in DVB.2.1 and DVB.2.1.1.

DVB.3 Single Suspension Test

DVB.3.1 In addition to the requirements in 28.4, a single suspension without a SAFETY DEVICE construction shall be subject to a production-line loading test.

DVB.3.2 Each production unit's single suspension shall be subjected to a loading test as described in 28.4DV.2 with a load of 1,0 multiplied by its SAFE WORKING LOAD.

Annex DVC
(informative)
Rationale for national differences

DVC D2 ***Addition of a new annex DVC as follows:***

The following represents the rationale for the national differences made to the basic IEC 60601-1 text.

1.1DV This is an explanation of UL's procedures for handling certain types and/or aspects of EQUIPMENT and for handling EQUIPMENT not envisioned (or existing) at the time the standard was written. Legal aspects are taken into consideration here as the U.S. legal system differs from most of the legal systems in other countries.

2.10.12DV This requirement is based on the National Electrical Code. Where the National Electrical Code is mentioned, no further explanation is given as these national differences are considered of critical importance in installation compatibility, building wire sizing, branch circuits overcurrent levels, etc. for U.S. located applications.

2.10.13DV This requirement is based on the National Electrical Code.

2.12.20DV By introducing this definition the types of EQUIPMENT subject to the 300 micro-ampere LEAKAGE CURRENT requirement can be reduced as only EQUIPMENT intended for use in the PATIENT care vicinity need comply with this requirement.

3.10DV A significant part of the standards development effort has been devoted to refining the component handling procedures. A compromise was sought which would facilitate the component acceptance aspects while still fulfilling industry's original request for world-wide acceptance of the standard. A component handling section has been incorporated in the Cover Document. While this information is considered part of the standard, the determination of compliance with the component requirements is a certification issue which is stated in the following paragraphs.

Evidence of compliance with UL component standards will be the appropriate UL mark. Evidence of compliance with the IEC component standards will be any of the marks of the ″known″ agencies, without UL follow-up. A ″known″ agency is one with which UL is knowledgeable about their testing and certification procedures, as described by internal guidelines. The ″known″ agencies include but are not necessarily limited to the following, at this time:

BSI (Britain)	KEMA (Netherlands)	SEV (Swiss)
DEMKO (Denmark)	NEMKO (Norway)	UTE (France)
IMQ (Italy)	SEMKO (Sweden)	VDE (Germany)
OVE (Austria)	CEBEC (Belgium)	TUV (Product Service) (Germany)

As UL's experience with these and other agencies develops, modifications to this list will be made.

6DV In the U.S. legal system the concept of "failure to warn" has historically proved to be an area associated with negligence if not addressed. Therefore, the letter height and legibility criteria should be no less than previously accepted. The X-radiation marking will be removed when the particular standards are adopted. The long-time and momentary rating markings are for National Electrical Code reasons concerning conductor sizing. The remaining two paragraphs are self-explanatory.

6.2DV The IEC 60601-1 standard permits a 75°C temperature (NORMAL CONDITION) in wiring compartments. As 60°C RATED building wiring is still permitted in North America, the measured maximum value should be reduced to 60°C.

6.6DV Color coding may be employed as a supplementary means of identification only; however, to reduce the risk of mis-identification and resulting improper connections, any color coding used needs to be in accordance with U.S. National Codes for medical EQUIPMENT used in the U.S. market, such as the CGA-9 color coding scheme specified in ANSI/NFPA 99.

10.2.2DV This requirement is based on the National Electrical Code.

14DV This requirement is based on the National Electrical Code.

18DV These additions (M and N) will be moved to the X-Ray particular standards when they are adopted; these are National Electrical Code related.

19.5DV The present U.S. position on LEAKAGE CURRENT is as stated in the ANSI/AAMI Safe Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. Any departure from these limits should be with the agreement of those experts responsible for the

establishment and maintenance of these ANSI Standards. UL believes that the safe current limits should be based on technical factors only and any departure from these limits should be accomplished through the existing balloting procedures of AAMI and NFPA.

UL cannot promote the change in LEAKAGE CURRENT limits to those favored by certain industry segments, due to the nature of the LEAKAGE CURRENT issue. It should also be noted that not all industry representatives favored a move to the IEC values.

UL discussed LEAKAGE CURRENT limits for MEDICAL ELECTRICAL EQUIPMENT with the Chief of the Medical Electronics branch of the FDA. It had been suggested to UL that FDA was in full support of the IEC LEAKAGE CURRENT limits. The FDA Chief indicated that the FDA had not taken a position on ANSI versus IEC LEAKAGE CURRENT limits. However, the FDA does favor harmonization with IEC standards, in general. The FDA Chief was unaware of the activities going on within NFPA and AAMI with regard to LEAKAGE CURRENTS, but he believes that those organizations would ultimately move toward IEC limits and resolve the difference between the current ANSI and IEC limits.

UL has incorporated decisions made as a result of the recent activity within the ANSI/NFPA 99 and ANSI/AAMI groups into this Standard. See 19.5DV.2 and Tables 19.5DV.1 and 19.5DV.2.

22DV (This rationale also applies to 22.4DV, 22.7DV, 28.3DV, 28.4DV.1 and 28.4DV.2.) These additions were developed approximately 10 years ago based on the existing IEC 60601-1 requirements and on then anticipated changes which are reflected in the second (1988) IEC 60601-1 edition.

These additions represent the IAC (UL 187) interpretations and desirable requirements taking into account what was written, what was anticipated and single fault acceptance criteria. Inspection of design data alone is not considered the equivalent of actual (physical) test performance. However, by way of compromise the paragraph after 28.4 in the cover document has been modified to include design data in conjunction with test performance. In other words a single test may represent several similar constructions.

42DV It has been UL's experience that insulating system integrity, when exposed to elevated temperatures, depends partly on the interaction of system components. Acceptance criteria consisting of considering individual material characteristics alone is not sufficient to evaluate insulating systems. Please also refer to the IEEE Standard 1-1969, Rev. of AIEE No. 1, 1962 Part II, paragraphs 1 through 4.

43.2DV The safety hazards associated with oxygen are well known. Materials which burn in air (and some that will not) are easily ignited and burn rapidly in high concentration of oxygen. Although some IEC 60601 particular standards provide guidelines for EQUIPMENT evaluations with oxygen, not enough information is provided in the part one standard. Common information from part two standards has been compiled and replaces much of the information that had been in the UL cover document under 43.2DV. As this is all IEC 60601 developed information, a minimum of conflict/duplicity should be encountered. Once the oxygen guidelines are fully covered by IEC 60601 documents, the corresponding information in the UL cover document can be removed. Note that much of the oxygen related "requirements" in the cover document involve warning markings, the importance of which was cited in the rationale for 6DV. For ease of reference the oxygen related information is in one location in the UL cover document.

55DV Industry concerns over referencing the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C as a general requirement are identified as:

1) **Difficulty in working with the standard.**

2) **Availability of materials RATED 5V.**

3) **Most UL 746C concerns are not addressed in the IEC 60601-1 standard.**

Experience has demonstrated the need for these type evaluations in order to determine the integrity of the ENCLOSURE. The general references to UL 746C have been removed and only references to UL 746C for conductive coatings, flammability, mold stress and mechanical abuse have been retained. Also the 5V requirement has been replaced with a V-0 one for FIXED and STATIONARY EQUIPMENT.

In general, building officials have been expressing a concern that large masses of plastic used in electrical appliances should have the same burning characteristics as the room's building products.

It is important to assess the effect of plastic materials on the fire locale of a room fire, external to the product. There are two existing tests that can be used to provide Flame Spread Information, the ASTM E 84, Steiner Tunnel Test and the ASTM E 162 Radiant Panel Test. UL has begun accepting submittals for testing by these methods with the results published in the ″plastics″ Section of the UL Recognized Component Index.

UL has maintained that a Flame Spread of 75 be applied to products that may be used in a PATIENT care environment. Considering the high probability that this EQUIPMENT will be used attended in a sprinkler room and used by professional staff, UL suggests that E 162 Radiant Panel be required for surface areas greater than 50 square feet and that the E 84 Steiner Tunnel be required for surface areas greater than 100 square feet or single dimension of 12 feet, in view of the larger amount of fuel available.

Although the above sizes of polymeric parts on medical EQUIPMENT are rarely encountered, the importance of addressing this issue is evident in view of fire safety concerns.

56.3DV This is a basic safety concern prompted by recent accidents involving PATIENT injury, including infant deaths. PATIENTS were accidentally being connected to hazardous circuits while being connected to APPLIED PARTS of medical EQUIPMENT, such as an apnea monitor.

57DV The National Electrical Code enables certain types of installations.

57.2DV (This rationale also applies to 57.3DV and 57.5DV.) This requirement is based on the National Electrical Code.

57.9.1DV This provides an explanation as to how to conduct a test given the use of a PTC.

58.2DV This is a basic construction requirement because of its importance and frequency of occurrence in safety related applications.

59.1DV This requirement is based on the National Electrical Code.

60DV Regarding 60DV.1.2 – 60DV.1.2.4.1, for the National Electrical Code and compatibility of use reasons, only the applicable parts of the Standard for Class 2 Power Units, UL 1310 have been referred to for the evaluation of direct plug-in units.

60DV.1.1 The additional concerns for separate power units are in one location for ease of reference and actually only involve markings and USER manual information not specified in IEC 60601-1. These address safety concerns involving using the intended EQUIPMENT instead of EQUIPMENT not evaluated for proper use.

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Subjects 2601 (187, 544)

1285 Walt Whitman Road
Melville, New York 11747
July 16, 1997

TO: **Casualty Council of Underwriters Laboratories Inc.,**
Electrical Council of Underwriters Laboratories Inc.,
Subscribers to UL's Listing and Classification Services for
Medical Electrical Equipment, (PIDF)
Medical and Dental Equipment, (KFBQ)
X-Ray Equipment (ZQOR)

SUBJECT: Announcement of UL Classification Service of Electrode Lead Wires and Patient Cables In Accordance With Code of Federal Regulations

Electrode Lead Wires and Patient Cables can be submitted for evaluation and Classification in accordance with Code of Federal Regulations 21 CFR Section 898.12.

On May 9, 1997, the U.S. FDA issued a final rule announcing the agency's first mandatory standard. The requirements concern the construction and performance of electrode lead wires and patient cables. The requirements are published in the Code of Federal Regulations 21 CFR Section 898.12. Electrode lead wires and patient cables must comply with Amendment 2 (1995) of IEC 601-1 (1988), subclause 56.3 paragraph c, which is shown in Appendix A.

This new service will allow manufacturers to have products evaluated in accordance with the performance and regulatory requirements indicated in 21 CFR Section 898.12. Upon successful evaluation and testing, by UL acting as an independent third-party testing agency, products will be eligible to bear UL's Classification Marking that indicates compliance with the indicated regulations. Investigations of these products will be covered under a new category, Electrode Lead Wires and Patient Cables, (PIEY). The compatibility of these devices for use with specific medical equipment has not been investigated. Equipment evaluated for fire, shock and mechanical hazards is covered in the following categories: Medical and Dental Equipment, (KFBQ), Medical Electrical Equipment, (PIDF), and X-Ray Equipment (ZQOR)

These products are designed for professional use by qualified personnel in hospitals, nursing homes, medical care centers, medical and dental offices, and similar health care facilities in accordance with the instructions provided by the manufacturer. The physiological effects of these products have not been investigated. The effect on a patient of simultaneous use of this equipment with other electrical apparatus has not been investigated.

The FDA compliance date for electrode lead wires and patient cables for use with the following devices is May 11, 1998:

PRODUCT	PRODUCT CODE	21 CFR SECTION
Breathing Frequency Monitor	73BZQ	868.2375
Apnea Monitor	73FLS	868.2375
Electrocardiograph	74DPS	870.2340
Radio Frequency Physiological Signal Transmitter & Receiver	74DRG	870.2910
Cardiac Monitor (including Cardiotachometer & Rate Alarm)	74DRT	870.2300
Electrocardiograph Electrode	74DRX	870.2360
Patient Transducer and Electrode Cable (including connector)	74DSA	870.2900
Medical Magnetic Tape Recorder	74DSH	870.2800
Arrhythmia Detector and Alarm	74DSI	870.1025
Telephone Electrocardiograph Transmitter and Receiver	74DXH	870.2920

The FDA compliance date for electrode lead wires and patient cables for use with **other** devices is May 9, 2000.

Questions regarding products covered by this category or this new service, should be directed to the responsible UL Staff.

Please see Appendix B of this bulletin regarding designated responsibility for the subject product category.

UNDERWRITERS LABORATORIES INC.

RAYMOND M. SUGA (Ext. 22593)
Senior Engineering Associate
Standards Department

REVIEWED BY:

JOSEPH P. MURNANE (Ext. 22247)
Senior Staff Engineer
Engineering Services 213 A

SR:PKW

2601BUL.R03;RMS;mc

APPENDIX A

EXCERPT OF REQUIREMENT FROM AMENDMENT 2 OF IEC 601-1

56.3 *Connections - General*

Add the following new item with an asterisk in front:

*c) Any connector in a lead having a CONDUCTIVE CONNECTION to a PATIENT shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that part of the said connector which is remote from the PATIENT can contact earth or possible hazardous voltages.

Compliance is checked by inspection and by applying to the CONDUCTIVE CONNECTION of that part of the connector identified above those of the following tests which are applicable:

– the said part shall not come into contact with a flat conductive surface of not less than 100 mm diameter;

– for single-pole connectors, the straight unjointed test finger with the same dimensions as the standard test finger of figure 7 shall not make electrical contact with the said part if applied in the least favorable position against the access openings with a force of 10 N ± 2 N;

– if able to be plugged into a mains socket, the said part shall be protected from making contact with parts of mains voltage by insulating means providing a CREEPAGE DISTANCE of at least 1.0 mm and a dielectric strength of 1500 V.

APPENDIX B

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORY

ELECTRODE LEAD WIRES AND PATIENT CABLES (PIEY)

The individuals shown below are involved with the investigation of products covered under the subject category. The Primary Designated Engineer **(shown in UPPERCASE letters)** coordinates the establishment and uniform interpretation of UL requirements applicable to the product category. The Designated Engineers **(shown in lowercase letters)** work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding products covered by this category or this new service, you are encouraged to contact the individual at the office to which you normally submit your products.

The IAC Chairman for the subject category is Steve Hewson at UL's Northbrook office. The IAC Chairman oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIEY	Camas	P. Scherwinski	55654
	Melville	J. MURNANE	22247
	Northbrook	G. Gillerman	42545
	RTP	K. Donohue	11645
	Santa Clara	F. O'Brien	32358
	Japan	J. Jungblut	–
	Taiwan	J. Lee	–

Subjects 2601-1 (544, 187, 3101-1)

1285 Walt Whitman Road
Melville, New York 11747-3081
May 10, 1999

TO: **Electrical Council of Underwriters Laboratories Inc.,**
Subscribers to UL's Standards Service for
Medical Electrical Equipment
Medical and Dental Equipment
X-Ray Equipment
Manufacturers of
Medical and Dental Equipment, Professional (KFBQ)
Medical and Dental Equipment, Professional – Disposal Systems and Accessories (KFBY)
Power Supplies for Use in Health Care Facilities (KFCG)
Uninterruptible Power Supplies for Use In Health Care Facilities (KFFG)
Magnetic Resonance Imaging Equipment (PAZB)
Medical Equipment Classified in Accordance with Specified Medical Standards (PIKF)
Medical and Dental Equipment Power Supplies – Component (QQHM2)
X-Ray Equipment (ZQOR)
X-Ray Equipment, Accessories (ZQVQ)

SUBJECT: Reminder of Effective Date for Withdrawal of UL 544 and UL 187

UL announced, in its bulletin dated June 7, 1994, the schedule that would apply for the withdrawal of UL 544 and UL 187, the Standard for Medical and Dental Equipment and the Standard for X-Ray Equipment, respectively. These standards will eventually be replaced by UL 2601-1, the Standard for Medical Electrical Equipment; Part 1 – General Requirements. UL's June 7, 1994 bulletin stated that UL 544 and UL 187 could be used to evaluate medical and dental products until January 1, 2003, after which UL 2601-1 will be exclusively used for the evaluation of new products. As of January 1, 2005, all Listed, Classified and Recognized medical and dental products, where UL 544 or 187 was used to evaluate the product, must comply with UL 2601-1. It is the manufacturer's responsibility to re-submit these products to UL (for UL 2601-1 evaluation) if UL coverage is to be maintained. The UL coverage will be terminated for those products not found to comply by January 1, 2005.

Date	Action
Jan 1, 2003	New products will be evaluated to UL 2601-1
Jan 1, 2005	All products comply with UL 2601-1. UL 544 and 187 withdrawn

Though the first date is still three years away, UL recommends that manufacturers contact us as soon as practical to develop strategies for their products and the coming transfer dates. An early approach to this work will result in the smoothest transition, with lowest costs and least impact on the manufacturer's production.

There are several specialized UL product categories which presently reference UL 544 or UL 187 to assist in the investigation of any medical/dental aspects of product constructions. They are to be addressed as indicated below.

The following categories, and the corresponding component categories, will be withdrawn after January 1, 2005 since all products covered under them will be covered under category PIDF (following investigation to determine compliance with UL 2601-1). Consequently, any products in the following categories, which have not been evaluated to UL 2601-1, will no longer retain UL Listing or Classification after that date. No File Review will be conducted.

KFBQ – Medical and Dental Equipment, Professional

PAZB – Magnetic Resonance Imaging Equipment

ZQOR – X-Ray Equipment

ZQVQ – X-Ray Equipment, Accessories

The following categories will remain after January 1, 2005; therefore, it will be necessary for UL staff to contact manufacturers to review their products (conduct a File Review) to determine compliance of existing products with the UL 2601-1 requirements:

KFBY – Medical and Dental Equipment, Professional – Disposal Systems and Accessories

KFCG – Power Supplies for Use in Health Care Facilities

KFFG – Uninterruptible Power Supplies for Use In Health Care Facilities

QQHM2 – Medical and Dental Equipment Power Supplies – Component

The guide cards covering these categories (and any UL standards referencing UL 544 and/or UL 187 for medical/dental aspects of the product) will be revised to reference only UL 2601-1 and delete any references to UL 544 or UL 187. Accordingly, Listing, Recognition, or Classification of products that have not been evaluated to UL 2601-1 requirements will be discontinued as of January 1, 2005, and use of the UL Mark will cease on that date.

Similar Changes in "Certified for Canada" Product Categories

As a related issue, UL is also announcing similar changes in UL categories that cover the Listing, Recognition and/or Classification of products to Canadian National Standards. CSA 22.2 No. 114, which corresponds to UL 187, is being discontinued as of January 1, 2005. CSA 22.2 No. 125, which corresponds to UL 544, is also being discontinued by January 1, 2005. After that date, all equipment previously manufactured and certified to the requirements of standards C22.2 No. 114 or C22.2 No. 125 must comply with the requirements of CSA Standard C22.2 No. 601.1, Part 2 Series, and Collateral Standards, as applicable. Consequently, UL will have to review the following product categories to make sure all products comply with CSA 22.2 No. 601.1 as of January 1, 2005:

KFBQ7/8 – Medical and Dental Equipment, Professional, Certified for Canada – Components

KFBY7/8 – Professional Disposal Systems and Accessories, Certified for Canada – Components

KFCG7 – Power Supplies for Use in Health Care Facilities, Certified for Canada

KFFG7/8 – Uninterruptible Power Supplies for Use in Health Care Facilities, Certified for Canada

PAZB7/8 – Magnetic Resonance Imaging Equipment/Components

QQHM8 – Power Supplies, Medical and Dental, Certified for Canada – Components

ZQOR7/8 – X-Ray Equipment, Certified for Canada – Components

ZQVQ7 – X-Ray Equipment, Accessories, Certified for Canada

Non-Medical X-Ray Equipment

As announced above, UL product categories ZQOR and ZQVQ will cease to exist after the January 1, 2005 implementation date. It is anticipated that most of the medical-equipment x-ray-type products will relocated to category PIDF; however, there are some non-medical types of x-ray equipment (such as baggage inspection systems, open field inspection systems for air frames and piping, etc.) that will need to be relocated to a new UL product category (because of its non-medical application). UL has decided that category NYOK is a suitable place for that equipment. The base standard that UL uses to investigate products submitted under NYOK/NYOK2 is UL 3101-1 which corresponds to IEC 601010-1. The UL contact personnel for categories NYOK and NYOK2 is listed in Appendix C. Manufactures should contact UL staff well in advance of the implementation date to develop a plan for continued coverage.

This bulletin should be kept with your copy of the standard.

Questions regarding interpretation of requirements should be directed to the responsible UL Staff. Please see Appendix A, Appendix B, and Appendix C of this bulletin regarding designated responsibility for the subject product categories.

UNDERWRITERS LABORATORIES INC.

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2601BUL.R04;RMS;mc

APPENDIX A

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORIES

KFBQ, Medical and Dental Equipment, Professional
KFBY, Medical and Dental Equipment, Professional – Disposal Systems and Accessories
KFCG, Power Supplies for Use in Healthcare Facilities
KFFG, Uninterruptible Power Supplies for Use in Healthcare Facilities
PAZB, Magnetic Resonance Imaging Equipment
PIKF, Medical Equipment Classified in Accordance with Specified Medical Standards
QQHM2, Medical and Dental Equipment Power Supplies
ZQOR, X-Ray Equipment
ZQVQ, X-Ray Equipment, Accessories

The individuals shown in the following tables are involved with the investigation of products covered under the subject categories. The Primary Designated Engineer **(shown in UPPERCASE letters)** coordinates the establishment and uniform interpretation of UL requirements applicable to the product categories. The Designated Engineers **(shown in lowercase letters)** work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding any adopted requirements that affect your product, you are encouraged to contact the individual at the office to which you normally submit your products.

The Industry Advisory Conference (IAC) Chairman for the subject categories is Gary Schrempp at UL's RTP office. The IAC Chairman oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBQ	Camas	R. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	UK	D. Bejnarowicz	44-1483-302-130
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFCG	Melville	G. Luchen	22365
	Northbrook	D. THOMPSON	43686
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	Taiwan	K. Chen	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFFG	Melville	T. Lanzisero	22464
	Northbrook	D. ACKERMAN	42907
	RTP	P. Gwynn	11697
	Santa Clara	C. Nelson	32625
	Canada	B. Black	416-757-3611
	Hong Kong	C. Chan	852-2695-9599
	Taiwan	C. Sun	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
PAZB	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIKF	Camas	R. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	K. Donohue	11645
	Santa Clara	B. Blair	32024
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
QQHM2	Camas	P. Scherwinski	55654
	Melville	G. Luchen	22365
	Northbrook	D. THOMPSON	43686
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	UK	D. Bejnarowicz	44-1483-302-130

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQOR	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	Europe	D. Bejnarowicz	44-1483-302-130

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQVQ	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611

APPENDIX B

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORIES

KFBY, Medical/Dental Equipment, Professional, Disposal Systems and Accessories

The individuals shown in the following table are involved with the investigation of products covered under the subject categories. The Primary Designated Engineer **(shown in UPPERCASE letters)** coordinates the establishment and uniform interpretation of UL requirements applicable to the product categories. The Designated Engineers **(shown in lowercase letters)** work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding any adopted requirements that affect your product, you are encouraged to contact the individual at the office to which you normally submit your products.

The Responsible Department Manager for the subject categories is Raymond E. Burg at UL's Northbrook office. The Responsible Department Manager oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBY	Northbrook	S. Sajid	43503

APPENDIX C

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORIES

NYOK, Inspection and Measuring Electrical Equipment

The individuals shown in the following table are involved with the investigation of products covered under the subject category. The Primary Designated Engineer **(shown in UPPERCASE letters)** coordinates the establishment and uniform interpretation of UL requirements applicable to the product category. The Designated Engineers **(shown in lowercase letters)** work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding any adopted requirements that affect your product, you are encouraged to contact the individual at the office to which you normally submit your products.

The Responsible Department Manager for the subject categories is Leonard B. Zafonte at UL's Melville office. The Responsible Department Manager oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
NYOK	Melville	G. Luchen	22365
	Northbrook	S. Sajid	43503
	RTP	L. Green	11533
	Santa Clara	K. Jones	32371
	Camus	R. Boonstra	55652
	United Kingdom	D. Bejnarowicz	44-1483-302-130

Subject 2601-1 (187, 544)

1285 Walt Whitman Road
Melville, NY 11747
June 16, 2000

TO: **Casualty Council of Underwriters Laboratories Inc.,**
Electrical Council of Underwriters Laboratories Inc.,
Subscribers to UL's Listing and Classification Services for
Medical Electrical Equipment,
Medical and Dental Equipment,
X-Ray Equipment

SUBJECT: Announcement Regarding Certification of Medical Electrical Equipment

This bulletin should be kept with your copy of the standard.

In accordance with the references shown below for UL 2601-1, all ACCESSORIES specifically noted in the ACCOMPANYING DOCUMENTS for the medical electrical equipment would be expected to comply with the relevant IEC (International Electrotechnical Commission) safety Standard. The resulting medical electrical equipment system would need to comply with IEC 60601-1-1.

IEC 60601-1	Introduction
UL 2601-1	Introduction
	Clause 2.2.15 (Amendment 2)
	6.8.2 a) – 4th dash
	6.8.2 c)
	19.2 b) – 1st dash
	19.2 c)

UL is announcing that the ACCESSORIES specifically noted in the ACCOMPANYING DOCUMENTS may optionally be shown to comply with UL 544, the Standard Medical and Dental Equipment, or UL 187, the Standard for X-Ray Equipment (which are not IEC harmonized). This means that products that are compliant with UL 544 and UL 187 will be considered to be equivalent to IEC - XXX Standards in the context of determining compliance with sub-clause BBB.4 (in the BBB Annex) in IEC 60601-1-1. As a result, such ACCESSORIES can be automatically considered as IEC-XXX equipment in UL 2601-1 evaluated products without being found, by separate investigation, to comply with the IEC-XXX Standard. Furthermore, by complying with the provisions below, it may not be necessary to evaluate the combination of products as a system unless specifically requested by a manufacturer.

* These ACCESSORIES are limited to those referenced in the ACCOMPANYING DOCUMENTS and are intended to be connected to SIPs/SOPs (Signal Input Ports/Signal Output Ports) of medical electrical equipment that bear the UL Mark (typically Classification).

* Any APPLIED PARTS that are directly connected to the product being UL Classified (whether shipped with the product or not) must meet all UL 2601-1 requirements.

* If an ACCESSORY is shipped with the medical electrical equipment (such as a foot switch) it must meet all UL 2601-1 requirements.

* This approach covers evaluations resulting in a UL Mark and/or a Mark for Canada (typically Classification). If asked to issue a CB Report for a product, this decision does not apply and all of the requirements in IEC 60601-1 must be met.

The decision to allow the use of certain types of ACCESSORIES to provide SIP/SOP interface to the medical electrical equipment is due to (1) the known and acceptable level of safety that UL 187 and UL 544 products provide and (2) a demonstrated field service record. This decision is also based on comments from manufacturers citing the above.

Other than this, there are no changes to the way these Standards are applied. This approach will remain in effect until UL 187 and UL 544 are withdrawn on January 1, 2005. After that, this option will be withdrawn and UL 2601-1 and IEC 60601-1 are to be applied as written (i.e., the ACCESSORIES will have to be compliant with IEC-XXX). This decision will also apply with regard to investigations resulting in a UL Mark for Canada involving CAN/CSA C22.2 No. 601.1 which covers similar medical electrical equipment.

Questions regarding products covered by this category or the standards eligible should be directed to the responsible UL Staff. Please see Appendix A of this bulletin regarding designated UL staff responsibility for the subject product categories.

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APPENDIX A

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORIES

KFBQ, PROFESSIONAL MEDICAL AND DENTAL EQUIPMENT
PIDF, MEDICAL ELECTRICAL EQUIPMENT
ZQOR, X-RAY EQUIPMENT

The individuals shown on the back side of this sheet are involved with the investigation of products covered under the subject categories. The Primary Designated Engineer **(shown in UPPERCASE letters)** coordinates the establishment and uniform interpretation of UL requirements applicable to the product categories. The Designated Engineers **(shown in lowercase letters)** work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding products covered by this category or standards eligible, you are encouraged to contact the individual at the office to which you normally submit your products.

The Industry Advisory Conference (IAC) Chairman for the subject categories is Gary Schrempp at UL's RTP office. The IAC Chairman oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBQ[a]	Camas	B. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Japan	R. Tria	(03) 5351-1971
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIDF[a]	Camas	B. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQOR[a]	Camas	B. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024

[a] See previous page for an explanation of the type of equipment covered under this category.