IEC 60601-1-2

Edition 4.1 2020-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014-02+AMD1:2020-09 CSV(en)

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REDLINE VERSION

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Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral Standard: Electromagnetic disturbances – Requirements and tests

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-2 edition 4.1 contains the fourth edition (2014-04) [documents 62A/916/FDIS and 62A/924/RVD] and its amendment 1 (2020-09) [documents 62A/1390/FDIS and 62A/1405/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-1-2 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition constitutes a technical revision.

This fourth edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

The most significant changes with respect to the previous edition include the following modifications:

– specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;
– specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT than was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;
– specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;
– specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and
– better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term “life-supporting”;

and the following additions:

– guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;
– guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;
– guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and
– guidance on identification of IMMUNITY pass/fail criteria.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this collateral standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 1 includes 1.1, 1.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 1.1, 1.2 and 1.3.1 are all subclauses of Clause 1).

References to clauses within this collateral standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this collateral standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this collateral standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this collateral standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this collateral standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this collateral standard;

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

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

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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

INTRODUCTION

The need for establishing specific standards for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

The requirements and tests specified by this collateral standard are generally applicable to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS as defined in 3.63 and 3.64 in the general standard. For certain types of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, these requirements might need to be modified by the special requirements of a particular standard. Writers of particular standards are encouraged to refer to Annex D for guidance in the application of this collateral standard.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE without interfering with other equipment and systems in the ELECTROMAGNETIC ENVIRONMENTS in which they are intended by their MANUFACTURER to be used. The application of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

– safety services;
– other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;
– non-ME EQUIPMENT (e.g. computers);
– telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the application of ELECTROMAGNETIC IMMUNITY standards is essential to ensure safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. To ensure safety, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE in the ELECTROMAGNETIC ENVIRONMENTS of INTENDED USE throughout their EXPECTED SERVICE LIFE.

This collateral standard specifies IMMUNITY TEST LEVELS for safety for ME EQUIPMENT and ME SYSTEMS intended by their MANUFACTURER for use in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. It recognizes that RF wireless communications equipment can no longer be prohibited from most PATIENT ENVIRONMENTS because in many cases it has become essential to the efficient provision of healthcare. This collateral standard also recognizes that, for certain SPECIAL ENVIRONMENTS, higher or lower IMMUNITY TEST LEVELS than those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT might be appropriate. This collateral standard provides guidance in determining appropriate IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.

The IMMUNITY TEST LEVELS specified for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on the reasonably foreseeable maximum of the ELECTROMAGNETIC DISTURBANCE phenomena in the applicable environments of INTENDED USE.

Not all ELECTROMAGNETIC DISTURBANCE phenomena are covered by this collateral standard, as it is not practical to do so. MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS need to address this during their RISK ASSESSMENT and evaluate if other ELECTROMAGNETIC DISTURBANCE phenomena could make their product unsafe. This evaluation should be based on the environments of INTENDED USE and the reasonably foreseeable maximum levels of ELECTROMAGNETIC DISTURBANCES expected throughout the EXPECTED SERVICE LIFE.

This collateral standard recognizes that the MANUFACTURER has the responsibility to design and perform VERIFICATION of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS to meet the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will remain safe throughout its EXPECTED SERVICE LIFE.

This collateral standard provides guidance in incorporating considerations regarding ELECTROMAGNETIC DISTURBANCES into the RISK MANAGEMENT PROCESS.

This collateral standard is based on existing IEC standards prepared by subcommittee 62A, technical committee 77 (ELECTROMAGNETIC COMPATIBILITY between electrical equipment including networks), ISO (International standards organization), and CISPR (International special committee on radio interference).

INTRODUCTION to Amendment 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS in the presence of ELECTROMAGNETIC DISTURBANCES and to ELECTROMAGNETIC DISTURBANCES emitted by ME EQUIPMENT and ME SYSTEMS.

BASIC SAFETY with regard to ELECTROMAGNETIC DISTURBANCES is applicable to all ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES and for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone ~~(IEC 60601-1:2005+A1:2012)~~, including any amendments;

– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

IEC 60601-1:2005~~1)~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-8:2006~~2)~~, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-11:~~2010~~2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
Amendment 1:2020

IEC 60601-1-12:2014~~3)~~ *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-3:2012, *Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment*

IEC 61000-3-2:2005[4)], *Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
Amendment 1:2008
Amendment 2:2009

IEC 61000-3-3:2013, *Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

~~1) There exists a consolidated edition 3.1, including IEC 60601-1:2005 and its Amendment 1:2012.~~

~~2) There exists a consolidated edition 2.1, including IEC 60601-1-8:2006 and its Amendment 1:2012.~~

~~3) To be published.~~

4) There exists a consolidated edition 3.2, including IEC 61000-3-2:2005 and its Amendment 1:2008 and Amendment 2:2009.

IEC 61000-4-3:2006[5], *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*
Amendment 1:2007
Amendment 2:2010

IEC 61000-4-4:2012, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5:~~2005~~2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017

IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8:2009, *Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test*

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques –Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

IEC 61000-4-39:2017, *Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test*

CISPR 11:~~2009~~2015~~[6]~~, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
Amendment 1:~~2010~~2016
Amendment 2:2019

CISPR 14-1:~~2005~~2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

~~CISPR 16-1-2:2003[7], *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Ancillary equipment – Conducted disturbances*~~
~~Amendment 1:2004~~
~~Amendment 2:2006~~

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*
Amendment 1:2017

CISPR 32:~~2012~~2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*

~~ISO 7137:1995, *Aircraft – Environmental conditions and test procedures for airborne equipment*~~

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5) There exists a consolidated edition 3.2, including IEC 61000-4-3:2006 and its Amendment 1:2007 and Amendment 2:2010.

~~6) There exists a consolidated edition 5.1, including CISPR 11:2009 and its Amendment 1:2010.~~

~~7) There exists a consolidated edition 1.2, including CISPR 16-1-2:2003 and its Amendment 1:2004 and Amendment 2:2006.~~

ISO 7637-2:2011, *Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only*

ISO 14971:~~2007~~2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

~~For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-11:2010, IEC 60601-1-12:--- [8)] IEC 60601-2-2:2009, IEC 60601-2-3:2012 and the following definitions apply.~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012+A2:2020, IEC 60601-1-8:2006+A1:2012+A2:2020, IEC 60601-1-11:2015+A1:2020, IEC 60601-1-12:2014+A1:2020, IEC 60601-2-2:2009, IEC 60601-2-3:2012 and the following definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

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

NOTE 3 An index of defined terms is found beginning on page 113.

3.1
*** EFFECTIVE RADIATED POWER** (of any device in a given direction)
ERP
the power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

Note 1 to entry: As used by the ITU and as used in Chapter 712 of the International Electrotechnical Vocabulary, the term “EFFECTIVE RADIATED POWER” appears without qualification only when the reference antenna is a half-wave dipole.

[SOURCE: IEC 60050-161:1990, 161-04-16, modified — Note 1 has been made clearer.]

3.2
ELECTROMAGNETIC COMPATIBILITY
EMC
ability of ME EQUIPMENT or an ME SYSTEM to function satisfactorily in its EM ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment

[SOURCE: IEC 60050-161:1990, 161-01-07, modified — “an equipment or system” has been changed to “ME EQUIPMENT or an ME SYSTEM”.]

3.3
ELECTROMAGNETIC DISTURBANCE
EM DISTURBANCE
any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

Note 1 to entry: An ELECTROMAGNETIC DISTURBANCE can be ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

~~8) To be published.~~

[SOURCE: IEC 60050-161:1990,161-01-05, modified — “which” has been changed to “that” and “may” has been changed to “could” and “can”, respectively, and the phrase "or adversely affect living or inert matter" has been deleted.]

3.4
(ELECTROMAGNETIC) EMISSION
the phenomenon by which electromagnetic energy emanates from a source

[SOURCE: IEC 60050-161:1990, 161-01-08]

3.5
ELECTROMAGNETIC ENVIRONMENT
EM ENVIRONMENT
the totality of electromagnetic phenomena existing at a given location

Note 1 to entry: In general, the EM ENVIRONMENT is time dependent and its description might need a statistical approach.

[SOURCE: IEC 60050-161:1990, 161-01-01, modified — “may” has been changed to “might” in the note.]

3.6
ELECTROSTATIC DISCHARGE
ESD
a transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact

[SOURCE: IEC 60050-161:1990, 161-01-22]

3.7
ENCLOSURE PORT
physical boundary of the ME EQUIPMENT or ME SYSTEM that electromagnetic fields can radiate through or impinge on

Note 1 to entry: According to Annex A of the general standard, the ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.

[SOURCE: IEC 61000-6-1:2005, 3.2, modified — clarification added, “apparatus” changed to “ME EQUIPMENT or ME SYSTEM”, “may” changed to “can”, “which” changed to “that” and rationale from IEC 60601-1 for the definition of ENCLOSURE added in the form of a note to entry.]

3.8
*** IMMUNITY (TO A DISTURBANCE)**
the ability of ME EQUIPMENT or an ME SYSTEM to perform without degradation in the presence of an ELECTROMAGNETIC DISTURBANCE

[SOURCE: IEC 60050-161:1990, 161-01-20, modified — “a device, equipment or system” has been changed to “ME EQUIPMENT or an ME SYSTEM”.]

3.9
IMMUNITY TEST LEVEL
the level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test

[SOURCE: IEC 60050-161:1990, 161-04-41]

3.10
INFORMATION TECHNOLOGY EQUIPMENT
ITE
equipment designed for the purpose of

a) receiving data from an external source (such as a data input line or via a keyboard);
b) performing some processing functions on the received data (such as computation, data transformation or recording, filing, sorting, storage, transfer of data);
c) providing a data output (either to other equipment or by the reproduction of data or images)

Note 1 to entry: This definition includes electrical or electronic units or systems that predominantly generate a multiplicity of periodic binary pulsed electrical or electronic waveforms and are designed to perform data processing functions such as word processing, electronic computation, data transformation, recording, filing, sorting, storage, retrieval and transfer, and reproduction of data as images.

[SOURCE: IEC 60050-161:1990, 161-05-04]

3.11
INTERMITTENT MODE
for an X-ray generator, mode of loading an X-ray tube where the electric energy is supplied to the tube in single, intermittent or pulsed loadings, as for example in radiography, cineradiography

[SOURCE: IEC/TR 60788:2004, rm-36-41]

3.12
LARGE ME EQUIPMENT
ME EQUIPMENT that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables

3.13
LARGE ME SYSTEM
ME SYSTEM that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables; this includes distributed ME SYSTEMS

3.14
LOW VOLTAGE
line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V a.c. or 1 500 V d.c.

3.15
PATIENT-COUPLED
term referring to the presence of a path for the transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

3.16
PATIENT COUPLING POINT
a sensing or treatment point of ME EQUIPMENT that is necessary to achieve the INTENDED USE of the ME EQUIPMENT or an ME SYSTEM and that provides a path for transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

3.17
PORT
access to a device or network where electromagnetic energy or signals can be supplied or received or where the device or network variables can be observed or measured

Note 1 to entry: Examples of PORTS include terminal pairs, PATIENT cables (PATIENT CONNECTIONS), SIGNAL INPUT/OUTPUT PARTS such as data ports and USB connections, battery charger connections, and the ENCLOSURE itself (i.e. ENCLOSURE PORT).

[SOURCE: IEC 60050-131:2002, 131-12-60, modified — "may" has been changed to "can" and more examples have been added to the note to entry.]

3.18
*** PUBLIC MAINS NETWORK**
LOW VOLTAGE electricity power lines to which all categories of consumers have access

3.19
RADIO FREQUENCY
RF
a frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission

[SOURCE: ANSI C63.14 4.313, modified — the note regarding the practical limits of RADIO FREQUENCY has been omitted.]

3.20
SPECIAL ENVIRONMENT
ELECTROMAGNETIC ENVIRONMENT with electromagnetic characteristics different from those specified in this collateral standard in Table 2 through Table 9 and Table 11 or that requires EMISSIONS limits, IMMUNITY TEST LEVELS or test methods that are different from those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT

4 General requirements

4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS

RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS.

NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS.

NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities.

Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.

4.2 * Non-ME EQUIPMENT used in an ME SYSTEM

In addition to 16.1 of the general standard:

– non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment;

– non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard.

4.3 General test conditions

4.3.1 * Configurations

ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK. as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting.

These configurations shall include:

– attachment of cables to all PORTS as necessary to achieve the INTENDED USE (including SIP/SOPs and, if applicable, the POTENTIAL EQUALIZATION CONDUCTOR);

– attachment of all tubing and filling of all fluid containers;

– termination of the cables with the intended equipment, subsystem simulators as specified in 7.1.4 and 8.5, PATIENT physiological simulators as specified in 7.1.9 and 8.2 or artificial hands as specified in 7.1.10 and 8.4;

– earthing on the ENCLOSURE PORT, if applicable, including connections to the terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR;

– use of cables and connectors that meet the specifications of the ME EQUIPMENT or ME SYSTEM MANUFACTURER.

Special ME EQUIPMENT or ME SYSTEM hardware or software might be needed to perform the tests specified in Clause 7 and Clause 8. If so, this should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

4.3.2 Artificial hand

Where an artificial hand is required by this collateral standard, it shall be connected as follows:

– For PATIENT COUPLING POINTS that do not have a conductive contact, the PATIENT COUPLING POINT is terminated with the artificial hand and (series) RC element shown in Figure 9a of 8.3 of CISPR 16-1-2 (see Figure 1). The metal foil of the artificial hand is sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of the RC element and the other terminal of the RC element is connected to the ground reference plane.

– For PATIENT COUPLING POINTS that have conductive contact to the PATIENT (PATIENT CONNECTION), terminal M of the RC element is connected directly to the PATIENT COUPLING POINT, and the other terminal of the RC element is connected to the ground reference plane. If normal operation of the ME EQUIPMENT or ME SYSTEM cannot be verified with terminal M connected to the PATIENT COUPLING POINT, an insulating material with a maximum thickness of 5 mm may be applied between the metal foil of the artificial hand and the PATIENT COUPLING POINT. In this case, the metal foil of the artificial hand is to be sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE, and terminal M of the RC element is to be connected to the metal foil but not to the PATIENT COUPLING POINT. The other terminal of the RC element is connected to the ground reference plane in all cases.

– For ME EQUIPMENT and ME SYSTEMS that have multiple PATIENT COUPLING POINTS intended to be connected to a single PATIENT, each PATIENT COUPLING POINT and each PATIENT-COUPLED part is to have an artificial hand applied as specified above. The artificial hands are connected to a single common connection and this common connection is connected to terminal M of the RC element, as specified in 8.3 of CISPR 16-1-2. For ME EQUIPMENT and ME SYSTEMS intended to be connected to multiple PATIENTS, artificial hands are to be applied as specified above and a separate common connection and RC element is to be used for each PATIENT for which the capacitive coupling effect and RF impedance is to be

simulated. The other terminal of each RC element is connected to the ground reference plane in all cases.

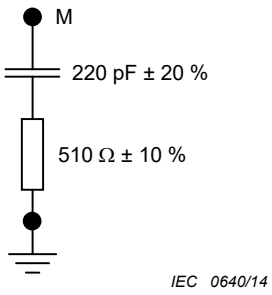


Figure 1 – RC element of the artificial hand

4.3.3 * Power input voltages and frequencies

If a test is applicable, it shall be performed using the power input voltages and frequencies specified in Table 1. The test report shall list the actual voltages and frequencies used during testing.

Compliance is checked by inspection of the test report.

Table 1 – Power input voltages and frequencies during the tests *(1 of 2)*

Test	Power input voltage	~~Line~~ Power frequency
~~Mains terminal disturbance voltage (conducted EMISSIONS)~~ Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	~~Any one voltage a)~~ Minimum and maximum RATED voltage c) d)	Any one frequency b)
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Any one voltage a)	Any one frequency b)
Harmonic current EMISSIONS IEC 61000-3-2	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 240 V or 380 V to 415 V: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz or 60 Hz
Voltage changes, voltage fluctuations and flicker EMISSIONS IEC 61000-3-3	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 250 V line to neutral: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz
ELECTROSTATIC DISCHARGE IMMUNITY IEC 61000-4-2	Any one voltage a)	Any one frequency b)
Radiated RF electromagnetic field IMMUNITY IEC 61000-4-3	Any one voltage a)	Any one frequency b)
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	Any one voltage a)	Any one frequency b)
Electrical fast transient/burst IMMUNITY – a.c. mains IEC 61000-4-4	Any one voltage a)	Any one frequency b)
Electrical fast transient/burst IMMUNITY – I/O SIP/SOP PORTS IEC 61000-4-4	Any one voltage a)	Any one frequency b)
Surge IMMUNITY IEC 61000-4-5	Any one voltage a)	Any one frequency b)
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) – a.c. mains IEC 61000-4-6	Any one voltage a)	Any one frequency b)
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted DISTURBANCE IMMUNITY) – SIP/SOP PORTS IEC 61000-4-6	Any one voltage a)	Any one frequency b)

Table 1 *(2 of 2)*

Test	Power input voltage	Line frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage [a]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the line frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. [b]
Voltage dips, short interruptions and voltage variations IMMUNITY IEC 61000-4-11	If the RATED voltage range < 25 % of the lowest RATED input voltage, one RATED input voltage. Otherwise, minimum and maximum RATED voltage [c] [d]	Any one frequency [b]

NOTE "Mains terminal disturbance voltage" is a CISPR 11 term for what is commonly referred to as "mains conducted EMISSIONS".

[a] The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

[b] The test may be performed at any one line frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one line frequency, it is not necessary to re-test at additional frequencies.

[c] Examples:

- The RATED voltage range is 100 V a.c. to 240 V a.c.
  240 V a.c. – 100 V a.c. = 140 V a.c. (range)
  25 % of 100 V a.c. is 25 V a.c.
  140 V a.c. > 25 V a.c.
  Therefore, the ME EQUIPMENT or ME SYSTEM is tested at the minimum and maximum RATED voltage.
- The RATED voltage range is 220 V a.c. to 240 V a.c.
  240 V a.c. – 220 V a.c. = 20 V a.c. (range)
  25 % of 220 V a.c. is 55 V a.c.
  20 V a.c. < 55 V a.c.
  Therefore, the ME EQUIPMENT or ME SYSTEM is tested at one voltage within the RATED range.

[d] ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

Test	Power input voltage	Power frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage [a]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the power frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. [b]
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage [c] [d]	Any one frequency [b]
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage [a]	Any one frequency [b]
Proximity magnetic fields IEC 61000-4-39	Any one voltage [a]	Any one frequency [b]

[a] The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

[b] The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.

[c] If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.

[d] ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

5.1 Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT

In addition to the requirements of 7.2 of the general standard, ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT shall be labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location.

Compliance is checked by inspection of the ME EQUIPMENT or ME SYSTEM.

5.2 ACCOMPANYING DOCUMENTS

5.2.1 Instructions for use

5.2.1.1 * General

In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following:

a) * a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

b) * the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

c) * a warning statement to the effect that "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper

operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.

d) * a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE).

Transducers and cables specified by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components need not be listed.

e) * a warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

f) * a warning statement to the effect that: "WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

In the above warning, "[ME EQUIPMENT or ME SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.

If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in 8.10.

5.2.1.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11

In addition to the requirements of 7.9.2 of the general standard, for ME EQUIPMENT and ME SYSTEMS that are classified class A according to CISPR 11, the instructions for use shall include the following note:

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

5.2.2 Technical description

5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

In addition to the requirements of 7.9.3 of the general standard, the technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES.

For all ME EQUIPMENT and ME SYSTEMS, the technical description shall include the following information:

a) the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL;

b) any deviations from this collateral standard and allowances used;

c) * all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

5.2.2.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location (see 7.1.5), the technical description shall include the following information:

a) a warning to the effect that: “WARNING: Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services”;

b) specifications for the shielded location, including:
   – minimum RF shielding effectiveness;
   – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and
   – the frequency range(s) over which the specifications apply;

c) recommended test methods for measurement of RF shielding effectiveness and RF filter attenuation;

d) one or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location:
   – a specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM;
   – a list of specific equipment allowed;
   – a list of types of equipment prohibited.

5.2.2.3 Requirements applicable to ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation (RF receivers), the technical description shall include the following information:

– each frequency or frequency band of reception;

– the preferred frequency or frequency band, if applicable; and

– the bandwidth of the receiving section of the ME EQUIPMENT in those bands.

5.2.2.4 Requirements applicable to ME EQUIPMENT that includes RF transmitters

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that includes RF transmitters, the technical description shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.

5.2.2.5 Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

In addition to the requirements of 7.9.3 of the general standard, for PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, the technical description shall include the following information:

a) a statement that an exemption has been used and that the equipment has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 000 MHz;

b) a warning to the effect that “WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation”; and

c) a list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

5.2.2.6 Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT, the technical description shall include a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery.

For all of 5.2, compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

6 Documentation of the tests

6.1 General

The documentation of the tests shall contain all the information necessary to facilitate adequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced.

Compliance is checked by inspection of the test report.

6.2 Test plan

Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory. Deviations from the test plan shall be documented in the test report. See Annex G for guidance on the recommended content of a test plan.

6.3 Test report

The test report shall meet the requirements of Clause 9.

7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

7.1 Protection of radio services and other equipment

7.1.1 * General

Unless otherwise specified herein, ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 11. See Annex C for guidance on classification according to CISPR 11.

NOTE For further guidance on test setups, see CISPR 16-2-3.

7.1.2 Operating modes

During EMISSIONS testing, the ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS. In addition to testing for EMISSIONS in active modes, inclusion of standby mode should be considered. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report.

7.1.3 Multimedia equipment

Multimedia equipment connected to ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 32. If CISPR 32 class A equipment is supplied as part of an ME SYSTEM, the ME SYSTEM shall be classified class A.

NOTE Multimedia equipment includes INFORMATION TECHNOLOGY EQUIPMENT (ITE).

7.1.4 * Subsystems

Compliance with CISPR 11 may be demonstrated by testing each subsystem of an ME SYSTEM on a subsystem basis, provided the requirements of CISPR 11 for evaluation of equipment that interacts with other equipment to form a system are met.

7.1.5 ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements specified below.

For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that enter or exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified below.

a) The specified RF shielding effectiveness and RF filter attenuation shall;
   - be expressed in dB;
   - be rounded to the nearest integer; and
   - be at least 20 dB.

b) The RF shielding effectiveness and RF filter attenuation specification shall include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range shall be at least one decade in width.

c) The specified value(s) for minimum RF filter attenuation shall be identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified.

d) In frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation shall be assumed to be 0 dB for the purpose of this collateral standard.

7.1.6 ME EQUIPMENT and ME SYSTEMS that include radio equipment

ME EQUIPMENT and ME SYSTEMS that include radio equipment (e.g. RF transmitters, receivers, transceivers) and have been tested together with the radio equipment and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this collateral standard in the dedicated transmission band of the transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this collateral standard shall apply.

7.1.7 * ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

The scope of this collateral standard includes ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices. Examples include motor-driven electromedical apparatus such as simple dental drills and simple operation tables. Unless the ME EQUIPMENT intentionally generates RF energy or is intended for illumination, it may be classified in accordance with CISPR 14-1. If so, the corresponding limits of CISPR 14-1 shall apply.

7.1.8 ME EQUIPMENT and ME SYSTEMS containing X-ray generators

For diagnostic X-ray generators and ME SYSTEMS that include X-ray generators operating in INTERMITTENT MODE, the quasi-peak limits to discontinuous radiated and conducted DISTURBANCES can be relaxed by 20 dB. This relaxation does not apply to average limits.

7.1.9 PATIENT physiological simulation

If PATIENT physiological simulation is required for normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during the test. PATIENT physiological simulation shall not provide, to PATIENT-COUPLED connections, an intentional conductive or capacitive connection to earth during testing except as specified in 4.3.2.

As an alternative to the termination methods specified in 4.3.2, if PATIENT physiological simulation is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulation shall provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified in 4.3.2.

Any PATIENT simulation used should be documented in the test plan and shall be documented in the test report.

7.1.10 Artificial hand

The artificial hand requirements of CISPR 11 apply to mains terminal disturbance EMISSIONS testing (see the NOTE in Table 1) with the additional requirement that PATIENT-COUPLED parts of ME EQUIPMENT and ME SYSTEMS and ME EQUIPMENT intended to be HAND-HELD shall be terminated during the test as specified in 4.3.2.

7.1.11 PATIENT-coupled cables

PATIENT-COUPLED cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11.

7.1.12 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:

– on a test site as a system;

– on a test site on a subsystem basis;

– *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS that comply with CISPR 11 group 1 class A or class B limits may be tested *in situ* and shall comply with the CISPR 11 limits for equipment measured on a test site.

Compliance with 7.1 is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.2 Protection of the PUBLIC MAINS NETWORK

7.2.1 * Harmonic distortion

ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that are intended to be connected to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-2. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current

ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-2.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.2.2 * Voltage fluctuations and flicker

ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that is intended for connection to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-3. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-3.

NOTE Subclause 6.1 of IEC 61000-3-3 begins as follows: "Tests need not be made on equipment which is unlikely to produce significant voltage fluctuations or flicker… It may be necessary to determine, by examination of the circuit diagram and specification of the equipment and by a short functional test, whether significant voltage fluctuations are likely to be produced".

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.3 EMISSIONS requirements summary

The EMISSIONS requirements are summarized in Table 2.

Table 2 – EMISSION limits per environment

Phenomenon	Professional healthcare facility environment [a]	HOME HEALTHCARE ENVIRONMENT [a]
Conducted and radiated RF EMISSIONS	CISPR 11	CISPR 11 [c], ~~[d]~~
Harmonic distortion	See IEC 61000-3-2 [b]	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3 [b]	See IEC 61000-3-3

[a] See 8.9 for information about the environments of INTENDED USE.

[b] This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

[c] ~~ME EQUIPMENT and ME SYSTEMS intended for use in aircraft shall meet the RF EMISSIONS requirements of ISO 7137. The conducted RF EMISSIONS test is applicable only to ME EQUIPMENT and ME SYSTEMS that are intended to be connected to aircraft power. ISO 7137 is identical to RTCA DO-160C:1989 and EUROCAE ED-14C:1989. The latest editions are RTCA DO-160G:2010 and EUROCAE ED-14G:2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered.~~

Standards applicable to modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

~~[d] Standards applicable to other modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.~~

8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

8.1 * General

The IMMUNITY test requirements for ME EQUIPMENT and ME SYSTEMS are specified by this collateral standard on a PORT-by-PORT basis. This follows the convention of the IEC 61000-6 series of Generic EMC standards. Figure 2 shows the PORTS of ME EQUIPMENT and ME SYSTEMS for the purpose of IMMUNITY testing.

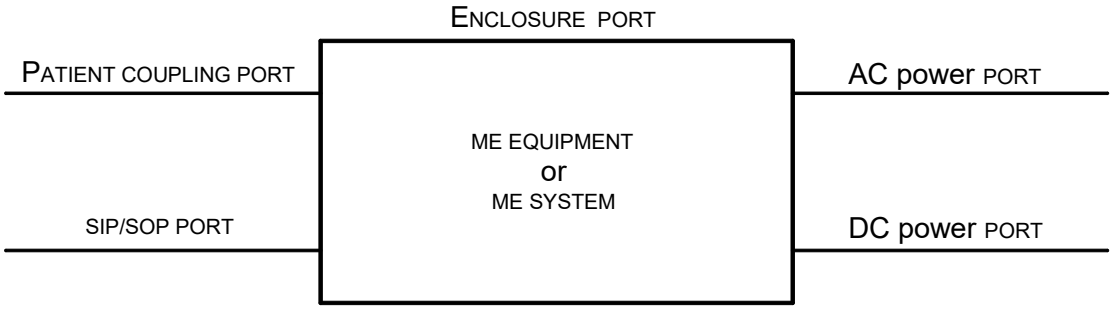


Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS

ELECTROMAGNETIC IMMUNITY tests:

– shall be performed in a well-defined and reproducible manner,
– shall be performed individually as single tests in sequence, and
– may be performed in any order.

At least one of each type of PORT (e.g. having the same input or output electronic circuits, loads, connected equipment) shall be connected during IMMUNITY testing. If the ME EQUIPMENT or ME SYSTEM has multiple identical PORTS, it is only necessary to test one of each type during IMMUNITY testing.

For the case in which the ME EQUIPMENT or ME SYSTEM is damaged by an IMMUNITY test signal, Table 3 specifies how to proceed with the remainder of the IMMUNITY test.

NOTE 1 For example, if an expensive ME SYSTEM is damaged by the first ESD discharge, it can be assumed that little useful information will be gained by making nine more identical discharges to the same test point to the same or to equivalent ME SYSTEMS.

Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal

Type of test	Reaction of ME EQUIPMENT or ME SYSTEM during test	How to continue with testing
Transient [a)]	The ME EQUIPMENT or ME SYSTEM is permanently damaged. However, BASIC SAFETY and ESSENTIAL PERFORMANCE continue to be provided.	The test sequence shall be repeated two times with this IMMUNITY TEST LEVEL and polarity. The ME EQUIPMENT or ME SYSTEM passes the test if it continues to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE. If any equipment is damaged, it can continue to be used for the IMMUNITY test for this specific phenomenon, as long as it can be proven (e.g. by RISK MANAGEMENT, engineering analysis, experience, redundancy) that the ability of the ME EQUIPMENT or ME SYSTEM to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE can still be determined while using the damaged equipment. If a PORT of the ME EQUIPMENT or ME SYSTEM is damaged and the ME EQUIPMENT or ME SYSTEM has multiple identical ports, the test shall not be repeated on any of the identical ports. To test the next non-identical PORT, the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation. To continue with the IMMUNITY test of the next EM phenomenon, the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation.
	The ME EQUIPMENT or ME SYSTEM is permanently damaged. BASIC SAFETY or ESSENTIAL PERFORMANCE does not continue to be provided.	The ME EQUIPMENT or ME SYSTEM has failed the test.
Continuous [b)]	The ME EQUIPMENT or ME SYSTEM is permanently damaged. However, BASIC SAFETY and ESSENTIAL PERFORMANCE continue to be provided.	The test sequence shall be repeated two times with this IMMUNITY TEST LEVEL and polarity or frequency. BASIC SAFETY and ESSENTIAL PERFORMANCE shall continue to be provided. To continue with the next frequency step the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation.
	The ME EQUIPMENT or ME SYSTEM is permanently damaged. BASIC SAFETY or ESSENTIAL PERFORMANCE does not continue to be provided.	The ME EQUIPMENT or ME SYSTEM has failed the test.

[a)] Tests according to IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5 and IEC 61000-4-11

[b)] Tests according to IEC 61000-4-3, IEC 61000-4-6 and IEC 61000-4-8

The IMMUNITY test requirements shall be applied to the PORTS of the ME EQUIPMENT or ME SYSTEM as specified in Table 4 through Table 9 and 8.11 according to the environments (locations) of INTENDED USE (see Figure 3). Table 4 through Table 9 and 8.11 specify IMMUNITY requirements and test conditions for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. The procedure specified in Annex E can be used to determine IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS or, if justified, can be used to modify the IMMUNITY TEST LEVELS of Table 4 through Table 9 and 8.11 (higher or lower, as appropriate), based on specific EM characteristics of specific environments or specific mitigations that might be provided by the ME EQUIPMENT or ME SYSTEM or the conditions of INTENDED USE. If justified, higher or lower IMMUNITY TEST LEVELS determined using the procedure specified in Annex E may be used in place of those specified in Table 4 through Table 9 and 8.11.

NOTE 2 IMMUNITY TEST LEVELS are calculated individually for each phenomenon.

NOTE 3 Use of Annex E can permit more precise assessment of the EM phenomena and EM DISTURBANCES in the EM ENVIRONMENTS of INTENDED USE and these can be used to determine IMMUNITY TEST LEVELS that are more specific to the INTENDED USE of the ME EQUIPMENT or ME SYSTEM.

For ME EQUIPMENT and ME SYSTEMS for which the INTENDED USE includes types of transportation (e.g. land, sea and air vehicles) or other locations in the HOME HEALTHCARE ENVIRONMENT such as those that can be accessed by walking (e.g. near radiofrequency identification (RFID) systems, anti-theft systems), if additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher than those specified in Table 4 through Table 9 and 8.11 are appropriate or are specified by standards applicable to a mode or EM ENVIRONMENT of transportation, these additional tests and higher IMMUNITY TEST LEVELS shall apply.

NOTE 4 An example of a standard that might be applicable to ME EQUIPMENT and ME SYSTEMS with INTENDED USE that includes aircraft is EUROCAE ED-14G [39] or RTCA DO-160G [40].

ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT shall meet the requirements of Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT, and 8.11. If locations in the EMERGENCY MEDICAL SERVICES ENVIRONMENT are identified for which the specifications for the HOME HEALTHCARE ENVIRONMENT are not adequate, Annex E may be used to determine appropriate IMMUNITY TEST LEVELS.

Test methods and test equipment are specified in the test methods and Basic EMC standards referenced in Table 4 through Table 9 and 8.11. The entire contents of the Basic EMC standards are not repeated here; however, modifications or additional information needed for the practical application of the tests to ME EQUIPMENT and ME SYSTEMS are given in this collateral standard.

If the INTENDED USE of the ME EQUIPMENT or ME SYSTEM includes more than one environment, the most stringent IMMUNITY TEST LEVELS among all the applicable environments shall apply.

If testing is performed according to the requirements for the HOME HEALTHCARE ENVIRONMENT as specified in Table 4 through Table 8, additional testing according to the requirements of the professional healthcare environment as specified in Table 4 through Table 8 is not required.

The dwell time for IMMUNITY tests shall be based on the settling time of the test system and the time required for the ME EQUIPMENT or ME SYSTEM to be exercised (if applicable) and adequately respond to the test signal.

The power frequency for all IMMUNITY tests may be selected at any one of the NOMINAL power frequencies of the ME EQUIPMENT or ME SYSTEM, except as otherwise specified in Table 1 ~~and Table 4 through Table 9~~.

Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE.

IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK.

NOTE 5 Guidance and examples for determining specific, detailed IMMUNITY pass/fail criteria are provided in Annex I.

ME EQUIPMENT and ME SYSTEMS shall meet the IMMUNITY pass/fail criteria during and after the IMMUNITY tests. For transient phenomena for which it might not be practical to assess performance during the application of the transient, assessing performance before and after the test is acceptable.

Table 10 requires that the effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES shall be documented in the test report (see Clause 9).

Following the tests, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the on-going RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by application of the tests specified in Table 4 through Table 9 and 8.11, as applicable. If the ME EQUIPMENT or ME SYSTEM meets its specified IMMUNITY pass/fail criteria before, during and after these tests and the compliance tests of the individual subclauses of this clause are met, then compliance with Clause 8 is verified.

8.2 PATIENT physiological simulation

If simulation of the PATIENT is required to verify normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during IMMUNITY testing. During testing according to IEC 61000-4-4 and IEC 61000-4-6, PATIENT physiological simulation shall not provide additional conductive or capacitive connection to earth (other than needed to simulate the PATIENT or OPERATOR) except as specified in 4.3.2.

As an alternative to the termination methods specified in 4.3.2, for the IMMUNITY tests for which they are required by 8.3 to be used, if PATIENT physiological simulation is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulation shall provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified in 4.3.2.

Prior to the beginning of the test, the amplitude of simulated PATIENT physiological signals shall be adjusted to be consistent with normal operation of the ME EQUIPMENT or ME SYSTEM, as specified by the MANUFACTURER, with the exception that if applicable, the amplitude of simulated PATIENT physiological signals shall be adjusted to approximately twice the detection threshold.

NOTE The signal is set close to the threshold but above it, so that the outcome of the test is not penalized by the statistics of detection and the noise floor of the detection circuitry. Setting the simulated signal at twice the threshold of detection (detection threshold plus 6 dB) puts the signal close to and above but not at the threshold of detection.

Compliance is checked by inspection of the test report.

8.3 Termination of PATIENT-COUPLED parts

For testing according to IEC 61000-4-4 and IEC 61000-4-6, the conditions specified in 4.3.2 apply. These conditions may also be used in other tests, as specified by the MANUFACTURER.

8.4 HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD

For testing according to IEC 61000-4-4 and IEC 61000-4-6 the following condition applies:

HAND-HELD ME EQUIPMENT and parts of ME EQUIPMENT intended to be HAND-HELD while providing its INTENDED USE shall be tested with an artificial hand applied as specified in 8.3 of CISPR 16-1-2, sized and placed to simulate the approximate area and location of OPERATOR coupling while providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of an RC element, as specified in 8.3 of CISPR 16-1-2 (see Figure 1), and the other terminal of the RC element shall be connected to the ground reference plane. These conditions may also be used in other tests, as specified by the MANUFACTURER. If HAND-HELD ME EQUIPMENT also has PATIENT-COUPLED parts, the PATIENT-COUPLED parts shall also have artificial hands applied as specified in 4.3.2, consistent with INTENDED USE.

8.5 * Subsystems

Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

8.6 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:

– on a test site as a system;

– on a test site on a subsystem basis;

– *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS that are constructed in such a way that simulated operation of subsystems is not feasible are exempt from the testing requirements of IEC 61000-4-3 specified in 8.9 and 8.10. If this exemption is used, such PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be tested for IMMUNITY to this phenomenon by TYPE TEST, either at one installation site or on an open area test site, using the RF sources (e.g. radio (mobile/cellular/cordless) telephones, walkie-talkies, radio-frequency identification (RFID) systems, other legal transmitters) that are expected to be operating in any of the locations of INTENDED USE. In addition, testing shall be performed in the range 80 MHz to 6 GHz at frequencies designated by the International Telecommunications Union (ITU) for ISM use. The power of, and distance from, any source used shall be adjusted to provide the applicable IMMUNITY TEST LEVELS of Table 4 according to the locations of INTENDED USE and the IMMUNITY TEST LEVELS of Table 9, with the exception that the actual modulations may be used (e.g. for radio (mobile/cellular/cordless) telephones, walkie-talkies).

The frequencies designated by the ITU for ISM use can be found in Volume I of the ITU Regulations ([31]) and in CISPR 11, Table 1.

NOTE Use of 1 kHz AM instead of actual modulation could be especially useful in the ISM bands.

This exemption applies only to the test methods specified by IEC 61000-4-3. Except as specified in this paragraph, the other requirements of 8.9 ~~and~~, 8.10 and 8.11 apply to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS. The exception is that if the applicable Basic EMC standard allows *in situ* testing, the allowance in the Basic EMC standard shall take precedence.

Compliance is checked by inspection of the test report.

8.7 * Operating modes

During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. If the ME EQUIPMENT or ME SYSTEM is not RATED for continuous duty, a duty cycle may be selected that is appropriate for the ME EQUIPMENT or ME SYSTEM under test. The standby mode should be considered for inclusion in IMMUNITY testing, particularly for ME EQUIPMENT and ME SYSTEMS that are in standby mode for long periods of time in the presence of PATIENTS or OPERATORS. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report.

8.8 * Non-ME EQUIPMENT

Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

8.9 * IMMUNITY TEST LEVELS

IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS shall be according to the professional healthcare facility environment, HOME HEALTHCARE ENVIRONMENT, and SPECIAL ENVIRONMENT, based on the locations of INTENDED USE as shown in Figure 3 and specified in Table 4 through Table 9 and 8.11. If applicable, an INTENDED USE location not shown in Figure 3 shall be assigned to an environment with a similar location, as determined by the MANUFACTURER.

~~NOTE Local regulations might need to be considered.~~

When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS. Annex E may be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 4 through Table 9 and 8.11 and, when justified, to adjust the specified IMMUNITY TEST LEVELS based on e.g. mitigations or conditions of INTENDED USE. If this determination or adjustment is made, the following information should be documented in the test plan, as specified in Table G.1, and shall be documented in the RISK MANAGEMENT FILE and in the test report, as specified in Table 10:

a) justification for any SPECIAL ENVIRONMENTS identified or adjustments made;

b) the adjusted reasonably foreseeable maximum EM DISTURBANCE levels;

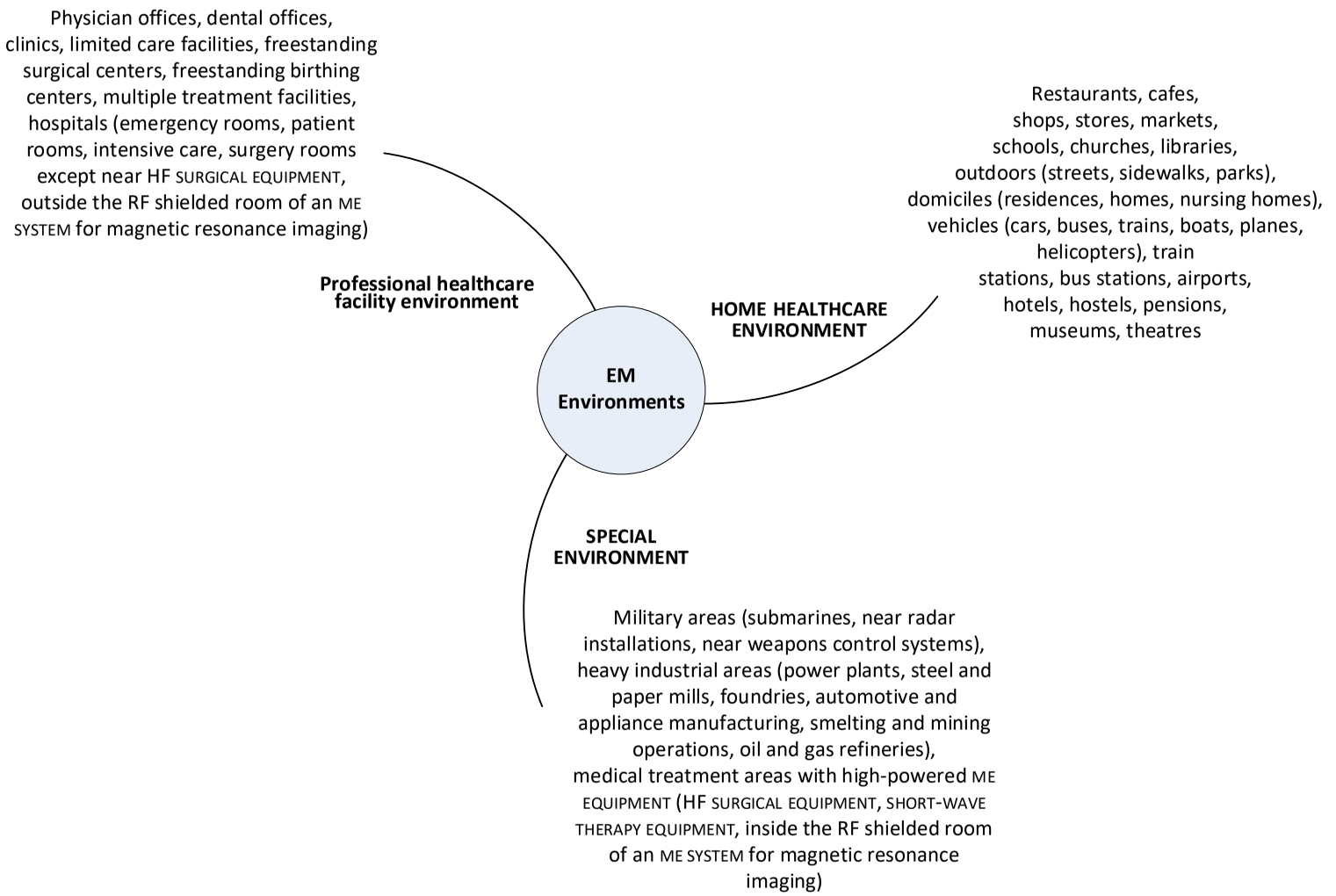
c) the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit;

d) details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS.

If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include documentation explaining how it can be reasonably expected that the mitigations will continue to be effective over the EXPECTED SERVICE LIFE in all locations in which the ME EQUIPMENT or ME SYSTEM is expected to be used.

In all cases, the IMMUNITY TEST LEVELS used should be documented in the test plan (see Annex G) and shall be documented in the test report (see Clause 9).

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.



Although healthcare professionals are present in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, the ELECTROMAGNETIC ENVIRONMENT is similar to that of the HOME HEALTHCARE ENVIRONMENT. Therefore, for the purposes of this collateral standard, the EMISSIONS and IMMUNITY requirements of the HOME HEALTHCARE ENVIRONMENT apply to ME EQUIPMENT and ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT. An example of such a location is an ambulance.

Figure 3 – Examples of ~~environments of INTENDED USE~~ locations within EM ENVIRONMENTS

Table 4 – * ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]	10 V/m [f)] 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10.	
RATED power frequency magnetic fields [d)] ~~e)~~	IEC 61000-4-8	30 A/m ~~g)~~ 50 Hz or 60 Hz	
Proximity magnetic fields	IEC 61000-4-39	See 8.11.	

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) ~~During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).~~ Void

f) Before modulation is applied.

~~g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.~~

Table 5 – * Input a.c. power PORT *(1 of 2)*

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts ~~a)~~ l) o)	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges ~~a)~~ b) j) o) Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges ~~a)~~ b) j) k) o) Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields c) d) o)	IEC 61000-4-6	3 V m) 0,15 MHz – 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)	3 V m) 0,15 MHz – 80 MHz 6 V m) in ISM and amateur radio bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)
Voltage dips f) p) r)	IEC 61000-4-11	0 % U_T; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° q)	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles h) Single phase: at 0°	
Voltage interruptions f) i) o) ~~r)~~	IEC 61000-4-11	0 % U_T; 250/300 cycle h)	

a) ~~The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.~~ Void

b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

Table 5 *(2 of 2)*

j)	ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
k)	Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
l)	Direct coupling shall be used.
m)	r.m.s., before modulation is applied.
n)	The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
o)	Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
p)	Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
q)	At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r)	For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the ~~minimum and maximum RATED~~ power input voltage specified in Table 1. ~~ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.~~

Table 6 – Input d.c. power PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts [a) g)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) g)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) g)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [a) c) d) i)]	IEC 61000-4-6	3 V [h)] 0,15 MHz – 80 MHz 6 V [h)] in ISM bands between 0,15 MHz and 80 MHz [j)] 80 % AM at 1 kHz [e)]	3 V [h)] 0,15 MHz – 80 MHz 6 V [h)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [j)] 80 % AM at 1 kHz [e)]
Electrical transient conduction along supply lines [f)]	ISO 7637-2	Not applicable	As specified in ISO 7637-2

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.

b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test

c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.

d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems

g) Direct coupling shall be used.

h) r.m.s., before modulation is applied.

i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

j) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 7 – * PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE [c]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0,15 MHz – 80 MHz 6 V [b] in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V [b] 0,15 MHz – 80 MHz 6 V [b] in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

[a] The following apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] r.m.s., before modulation is applied

[c] Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 8 – ~~Signal input/output parts~~ SIP/SOP PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE [e]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	
Surges Line-to-ground [a]	IEC 61000-4-5	± 2 kV	
Conducted disturbances induced by RF fields ~~[b]~~ [d] [g] [j] [k]	IEC 61000-4-6	3 V [h] 0,15 MHz – 80 MHz 6 V [h] in ISM bands between 0,15 MHz and 80 MHz [i] 80 % AM at 1 kHz [c]	3 V [h] 0,15 MHz – 80 MHz 6 V [h] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [i] 80 % AM at 1 kHz [c]

[a] This test applies only to output lines intended to connect directly to outdoor cables.

[b] SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

[c] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

[d] Calibration for current injection clamps shall be performed in a 150 Ω system.

[e] Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

[f] Capacitive coupling shall be used.

[g] If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

[h] r.m.s., before modulation is applied.

[i] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[j] See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

[k] SIP/SOPS whose maximum cable length is less than 1 m are excluded.

8.10 * IMMUNITY to proximity fields from RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table 9 using the test methods specified in IEC 61000-4-3.

The frequencies and services listed in Table 9 are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.

8.11 * IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz shall be evaluated according to steps a) through d) below. MANUFACTURERS may proceed directly to step d). The result of the evaluation for each applicable step shall be documented in the test report or RISK MANAGEMENT FILE, as applicable. See also Figure A.3.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

a) ME EQUIPMENT and ME SYSTEMS that do not contain magnetically sensitive components or circuitry within the ENCLOSURE or as part of an attached ACCESSORY need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

b) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in Table 11 is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

c) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, then the tests of Table 11 need not be performed; otherwise,

d) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry not meeting the separation distance criteria in b) or the RISK acceptability criteria in c) shall be tested for IMMUNITY to magnetic fields as specified in Table 11 using the test methods specified in IEC 61000-4-39. The magnetic field shall be applied only to those surfaces of the ENCLOSURE or attached ACCESSORIES that are accessible during INTENDED USE. The test windows to be used with IEC 61000-4-39 may be selected to illuminate only the area of the magnetically sensitive components or circuitry. The location of application of the magnetic field should be specified in the test plan and shall be documented in the test report.

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

9 * Test report

The test report shall include the items listed in Table 10. Additional information may be added to the test report as necessary.

Table 10 – * Minimum test report contents *(1 of 2)*

No.	Item	Additional detail
1	Name and location of the test facility	
2	Names and functions or equivalent identification of the persons authorizing the test report	
3	Description of the ME EQUIPMENT or ME SYSTEM	Include the device name, model number and MANUFACTURER.
4	Description of the BASIC SAFETY AND ESSENTIAL PERFORMANCE including a description how the BASIC SAFETY AND ESSENTIAL PERFORMANCE were monitored during each test	
5	ME EQUIPMENT or ME SYSTEM software / firmware version	
6	Prototype or production version of the ME EQUIPMENT or ME SYSTEM	Additionally, the relationship of the model tested to production models may be described.
7	Units tested and the rationale for the selected sample size.	Include serial numbers.
8	INTENDED USE and intended environments	
9	Applicable standards and test methods	A list of the standards (with dates) and EMISSIONS limits or IMMUNITY TEST LEVELS
10	Deviations from the Basic EMC standards or from this collateral standard	
11	Applicability / tests not performed	The decision and justification not to perform a measurement or test shall be documented.
12	If the procedure specified by Annex E or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made – the adjusted reasonably foreseeable maximum EM DISTURBANCE levels – the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit – details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS	
13	IMMUNITY TEST LEVEL for each IMMUNITY test and EMISSIONS compliance class and group	
14	IMMUNITY pass/fail criteria	Specific IMMUNITY criteria for BASIC SAFETY AND ESSENTIAL PERFORMANCE per the RISK ANALYSIS.
15	Environmental conditions as required by the relevant Basic EMC standards	
16	Compliance summary statement	Compliance of the ME EQUIPMENT or ME SYSTEM with each test.
17	Test data that support the compliance determination for each test performed	Include units of measurement
18	ME EQUIPMENT or ME SYSTEM configuration during the test, including a block diagram	Block diagram of the ME EQUIPMENT or ME SYSTEM and all peripherals and auxiliary equipment used.
19	ME EQUIPMENT or ME SYSTEM settings and operating modes	List by test.
20	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	Record the ME EQUIPMENT or ME SYSTEM power input voltages and frequencies for each test.

Table 10 *(2of 2)*

No.	Item	Additional detail
21	Any connections to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR, if used	Include information on connection to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR used during testing, if any.
22	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or LARGE ME SYSTEM: Frequencies, power and modulation of the RF test sources and test distances used.	
23	Use of SIP/SOPS, as applicable	
24	Description of any PATIENT-COUPLED cable termination used	
25	Description and position of interconnecting cables. The layout of excess cable shall be noted.	The length, shielding, ferrites and other construction details should be described. Photographs are also helpful.
26	Simulators, ACCESSORIES and auxiliary equipment	Describe simulators, accessories and auxiliary equipment used, including PATIENT physiological and subsystem simulation.
27	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
28	Test equipment used, including calibration or maintenance dates	
29	Test parameters used, e.g. frequencies, phase angles, as applicable	
30	Dwell time for each IMMUNITY test requiring a dwell time	
31	ESD test points	Photograph or drawing depicting the exact ESD test points with discharge method identified
32	Measured conducted and radiated EMISSIONS	Tabular data of at least the six highest EMISSIONS for each test shall be included.
33	The methods used to reduce the impact of ambients	
34	Measured harmonics and flicker EMISSIONS	
35	ME EQUIPMENT OR ME SYSTEM modifications	Describe ME EQUIPMENT or ME SYSTEM modifications needed in order to pass any of the EMISSIONS or IMMUNITY tests. A statement that they will all be incorporated into production units.
36	Effects on the ME EQUIPMENT or ME SYSTEM that were observed during or after the application of the test DISTURBANCES, and the duration for which these effects persisted	
37	Photographs of each test setup including the ME EQUIPMENT or ME SYSTEM and all peripherals and auxiliary equipment used.	
38	The locations of application of proximity magnetic fields.	If the testing according to 8.11 step d) is performed.
NOTE This table provides additional detail to 5.10 of ISO 17025:2005 [25].		

Annex A
(informative)

General guidance and rationale

A.1 Safety and performance

The scope of this collateral standard includes safety (BASIC SAFETY and ESSENTIAL PERFORMANCE) with regard to ELECTROMAGNETIC DISTURBANCES, which is also called EMC for safety.

The words “Electromagnetic compatibility” have been deleted from the title of this collateral standard based on the following text from IEC/TS 61000-1-2:2001 [7]:

Whether a test on the influence of an electromagnetic phenomenon on the behaviour of an equipment [sic] should be included in an EMC standard (or clause) or in a safety standard (or clause) is dependent on the approval criterion:

– If it is required that during or after the test the equipment continue to operate as intended, the test should be included in an EMC IMMUNITY standard (or clause) of a product (product family).
– If it is required that during or after the test no unsafe situation occurs (performance may be degraded incidentally or permanently, but not resulting in an unsafe situation), the test should be included in a safety standard (or clause). It is obvious that for products with safety functions the IMMUNITY levels may be chosen to be higher than in the generic standards for that environment.

NOTE The text above was removed from ~~IEC/TS 61000-1-2 in the 2008 edition [8]~~ IEC/TS 61000-1-2:2008 in favour of “EMC for functional safety”.

Because this collateral standard is a safety standard, it is clear that the term “EMC” should not be used without qualification to refer to the requirements.

A.2 Testing of normally non-observable functions

If a function associated with ESSENTIAL PERFORMANCE (e.g. HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS) cannot normally be observed or verified during IMMUNITY testing, a method should be provided (e.g. display of internal parameters) for determining compliance. The use of special software or hardware might be needed.

A.3 Rationale for particular clauses and subclauses

Subclause 1.1 – Scope

Electrical/electronic infrastructure (e.g. existing local area networks, telecommunications networks, power networks) need not be tested in accordance with this collateral standard as part of an ME SYSTEM. However, the effects of such electrical/electronic infrastructure should be considered as part of RISK MANAGEMENT in accordance with ISO 14971, and electrical/electronic infrastructures intended to be used as part of an ME SYSTEM should be simulated during testing or assumed to fail. Equipment provided by the MANUFACTURER of the ME SYSTEM and intended to be connected to the ME SYSTEM by way of existing electrical/electronic infrastructure should meet the requirements of this collateral standard. If local area networks or telecommunications networks are supplied as part of an ME SYSTEM by the MANUFACTURER of the ME SYSTEM, they should be tested as specified in this collateral standard, as part of the ME SYSTEM.

Definition 3.1 – EFFECTIVE RADIATED POWER

The definition implies that the substitution method is used. Thus, to find the ERP, the power flux density is measured at a specified distance and direction. Then a lossless half-wave dipole is substituted for the equipment under test and the input power is adjusted to produce the same power flux density at the specified distance and direction. This input power is then the ERP.

If for example the reference antenna is isotropic instead of a half-wave dipole, then the term does receive qualification and becomes "effective isotropically radiated power" (EIRP).

Definition 3.8 – IMMUNITY (TO A DISTURBANCE)

IMMUNITY is the case in which there is no degradation. While the tests check for no degradation, some specified amount of degradation is usually considered a "pass" (acceptable) according to the pass/fail criteria and the RISK MANAGEMENT PROCESS.

Definition 3.18 – PUBLIC MAINS NETWORK

In CISPR 11, the PUBLIC MAINS NETWORK is called the "low-voltage power supply network which supplies buildings used for domestic purposes" and "domestic electricity power supplies". In IEC 61000-3-2 and IEC 61000-3-3 it is called the "public supply system", the "public low-voltage system", and the "public low-voltage distribution system".

ME EQUIPMENT and ME SYSTEMS are not connected to the PUBLIC MAINS NETWORK if they are used in locations, e.g. hospitals, in which the mains connection is isolated from the public LOW-VOLTAGE power supply network by transformers or substations.

Subclause 4.2 – Non-ME EQUIPMENT used in an ME SYSTEM

The purpose of this subclause is to limit additional (duplicative) testing of non-ME EQUIPMENT used in an ME SYSTEM to the non-ME EQUIPMENT that can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

The MANUFACTURER needs to perform an analysis on the ME SYSTEM to determine whether or not interference with the non-ME EQUIPMENT can result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. This analysis is part of the RISK MANAGEMENT PROCESS.

If the analysis shows that interference with the non-ME EQUIPMENT can result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, then the non-ME EQUIPMENT is required to be tested as part of the ME SYSTEM. If non-ME EQUIPMENT has previously been tested to its respective IEC or ISO EMC standards with equivalent test procedures and the same or higher IMMUNITY TEST LEVELS, the MANUFACTURER still needs to assess whether the acceptance (pass/fail) criteria were equivalent to those that would show that BASIC SAFETY and ESSENTIAL PERFORMANCE would not be affected.

For example:

EMISSIONS:

If non-ME EQUIPMENT is used in an ME SYSTEM, the non-ME EQUIPMENT should fulfil the same EMISSIONS requirements as the ME SYSTEM, proven by the applicable product standards of the non-ME EQUIPMENT.

IMMUNITY:

Consider if failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

– If failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, apply to the non-ME EQUIPMENT the same IMMUNITY TEST LEVELS specified for the ME SYSTEM, based on the environments of INTENDED USE.

– If failure or degradation of the non-ME EQUIPMENT does not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, compliance with the product standard of the non-ME EQUIPMENT is sufficient.

When the non-ME EQUIPMENT only needs to meet its respective EMC standards, the appropriate documentation such as a declaration of conformity can be obtained from the original equipment MANUFACTURER and included in the design documentation.

Subclause 4.3.3 – Power input voltages and frequencies

The specifications for the IEC 61000-3-2 and IEC 61000-3-3 tests are copied directly from the Basic EMC standards.

IEC 61000-3-2:2005 Clause 6 states: “The requirements and limits specified in this clause are applicable to the power input terminals of equipment intended to be connected to 220/380 V, 230/400 V and 240/415 V systems operating at 50 Hz or 60 Hz. Requirements and limits for other cases are not yet considered.”

The Scope of IEC 61000-3-3:2013 states: “This part of IEC 61000 is applicable to electrical and electronic equipment having an input current equal to or less than 16 A per phase, intended to be connected to public low-voltage distribution systems of between 220 V and 250 V line to neutral at 50 Hz, and not subject to conditional connection.” In addition, subclause 6.3 states: “The test supply voltage (open-circuit voltage) shall be the RATED voltage of the equipment. If a voltage range is stipulated for the equipment, the test voltage shall be 230 V single-phase or 400 V three-phase.”

See also the rationale for 7.2.1 and 7.2.2.

Table 1, table footnote c), provides the MANUFACTURER with an allowance to perform testing at any one RATED input voltage when the difference between the maximum and minimum RATED input voltage is less than 25 % of the highest RATED input voltage. Table A.2 provides several examples of the calculation and associated conclusion for testing at a single RATED input voltage.

Table A.2 – Example calculations for applying the allowance to test at a single RATED power input voltage

Min. V	Max. V	Max. – Min. V	25 % of Max. V	(Max. – Min.) < 25 % of Max.?	Testing at one voltage allowed?
100	120	20	30	Yes	Yes
100	127	27	31,75	Yes	Yes
100	240	140	60	No	No
200	240	40	60	Yes	Yes
380	480	100	120	Yes	Yes

Subclause 5.2.1.1 – General

Additional requirements for the Instructions for use have been added in this edition of this collateral standard to help improve the safe use of ME EQUIPMENT and ME SYSTEMS with regard to EM DISTURBANCES.

NOTE Defined terms are not printed in SMALL CAPITALS in the sample text for warning statements that are required to appear in the instructions for use or the technical description because they are intended for the OPERATOR or RESPONSIBLE ORGANIZATION, who might not be familiar with the defined terms of IEC 60601 standards.

Subclause 5.2.1.1 a), Environments of INTENDED USE

Because some EMISSIONS and IMMUNITY requirements are different for the different EM ENVIRONMENTS of INTENDED USE, it is important that users have access to this information so that they can select ME EQUIPMENT and ME SYSTEMS appropriately and assure that they are used in the appropriate EM ENVIRONMENTS.

Subclause 5.2.1.1 b), ESSENTIAL PERFORMANCE

This information is required because different MANUFACTURERS might identify different ESSENTIAL PERFORMANCE for the same type of ME EQUIPMENT or ME SYSTEM, it is not possible to assure IMMUNITY under all possible conditions and because the MANUFACTURER might have observed performance degradation during the tests specified by this collateral standard, e.g. at an IMMUNITY TEST LEVEL that might have been higher than required. This requirement does not mention BASIC SAFETY and reminds the user of this collateral standard that the defined term "ESSENTIAL PERFORMANCE" need not be used in this statement, as does 5.2.2.1 c), because OPERATORS cannot be expected to know about the defined terms of IEC 60601 standards.

Subclause 5.2.1.1 c), Adjacent and stacked use warning

The adjacent and stacked use warning has been moved to the Instructions for use because the Instructions for use is the preferred location for warnings. This warning is needed because this collateral standard does not yet specify IMMUNITY tests for proximity magnetic or electric fields.

Subclause 5.2.1.1 d), List of cables, etc.

This list or specification is intended to be used with the ACCESSORY warning discussed below and it is important because ACCESSORIES, transducers and cables can affect the EMISSIONS and IMMUNITY of ME EQUIPMENT and ME SYSTEMS.

Subclause 5.2.1.1 e), ACCESSORY warning

This warning is intended to assure that for ACCESSORIES, transducers and cables that can affect the EMISSIONS or IMMUNITY of the ME EQUIPMENT or ME SYSTEM, ACCESSORIES, transducers and cables are chosen that will allow the ME EQUIPMENT or ME SYSTEM to continue to meet the EMISSIONS and IMMUNITY requirements of this collateral standard.

Subclause 5.2.1.1 f), PORTABLE RF communications equipment warning

This warning is intended to make PATIENTS and OPERATORS aware of the minimum separation distance that should be maintained between PORTABLE RF communications equipment and ME EQUIPMENT and ME SYSTEMS in order to avoid potential performance degradation and compromise of BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 5.2.2.1 a), Compliance for each EMISSIONS and IMMUNITY standard

This requirement replaces in part the requirements specified in Edition 3 to include tables of compliance levels and EMC guidance in the ACCOMPANYING DOCUMENTS. While a MANUFACTURER can choose to put the information in such a format, this collateral standard does not mandate the format for this information. This labelling requirement is particularly important because if the procedure in Annex E is used, IMMUNITY TEST LEVELS might be different from those expected, i.e. those specified in Table 4 through Table 9 and 8.11. Furthermore, RESPONSIBLE ORGANIZATIONS might not be familiar with this collateral standard and thus might not be aware of the IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11.

Subclause 5.2.2.1 c)

Providing the RESPONSIBLE ORGANIZATION with maintenance instructions with regard to EM DISTURBANCES is a good and practical way for the MANUFACTURER to assure that the ME EQUIPMENT or ME SYSTEM remains safe with regard to EM DISTURBANCES throughout the EXPECTED SERVICE LIFE.

For example, the technical description could include the following recommendations for actions that are known to affect the EMISSIONS and IMMUNITY of equipment throughout the EXPECTED SERVICE LIFE:

- recommendations for maintenance or service intervals;
- service procedures to maintain effectiveness of shields and grounds;
- precautions to take if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas.

NOTE AAMI TIR 18 [28] provides guidance in management of the EM ENVIRONMENT and management of medical devices for EMC, including assessment of the EM ENVIRONMENT, investigation and reporting of EMI problems and site selection, design, and construction of new healthcare facilities. Table A.3 of AAMI TIR 18:2010 shows field strengths at 1 km from FIXED transmitters such as AM, FM and TV broadcast antennas.

Subclause 7.1.1 – General

The EMISSIONS requirements have been simplified compared to those of IEC 60601-1-2:2007. As part of this simplification, references to CISPR 15 are not included in this collateral standard. These references sometimes caused confusion. In addition, CISPR 14-1 limits (other than for toys) on radiated disturbances only cover up to 1 GHz, which is not adequate for ME EQUIPMENT and ME SYSTEMS. The scope of CISPR 15 is limited to lighting equipment and does not include ME EQUIPMENT or ME SYSTEMS explicitly, thus causing confusion by being referenced from IEC 60601-1-2:2007. The scope of CISPR 15 excludes equipment for which the EMC requirements in the radio-frequency range are explicitly formulated in other IEC or CISPR standards. Therefore, this collateral standard specifies CISPR 11 for all ME EQUIPMENT and ME SYSTEMS except where indicated otherwise.

Subclause 7.1.4 – Subsystems

Care needs to be taken that testing on a subsystem basis is appropriate. For example, if EMISSION amplitudes add, because two or more subsystems have the same clock frequency, unless this is adequately simulated, it would be more appropriate to test the equipment as a system. This might also be the case if MANUFACTURERS of connected subsystems have different specifications for the interconnecting cables.

Subclause 7.1.7 – ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

According to CISPR 14-1, the scope includes such equipment as: household electrical appliances, electric tools, regulating controls using semiconductor devices, motor-driven electro-medical apparatus, electric/electronic toys, automatic dispensing machines as well as cine or slide projectors. Both mains powered appliances and battery powered appliances are included.

An example of ME EQUIPMENT that cannot be classified according to CISPR 14-1, because it intentionally generates RF energy, is SHORT-WAVE THERAPY EQUIPMENT. Examples of ME EQUIPMENT that cannot be classified according to CISPR 14-1 because they are intended for illumination are surgical lights and examination lights.

Subclause 7.1.12 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for EMISSION testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;

– on a test site on a subsystem basis;

– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For some ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation, or equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT or ME SYSTEMS that cannot fit within a 2 m x 2 m x 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration. Such a test would likely not fulfil the "worst case" or "modes that maximize EMISSIONS" approach of CISPR 11/IEC 60601-1-2 without several re-configurations and extensive test time.

In situ testing – testing at the place of installation – as a system, at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility. The ME SYSTEM might be in use and might not present the maximum configuration. Furthermore, it might not be possible to be tested in the modes that maximize EMISSIONS as required by this subclause because the available configuration for such testing is limited to what the customer/RESPONSIBLE ORGANIZATION has installed.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the equipment under test (EUT) is likely to be fully available and testing in representative configurations is usually possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement distance and positions should be achievable, and for EMISSION testing at the MANUFACTURER's premises, a measurement distance of at least 3 m should be maintained. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report. The measurement locations, including distance to the EUT, should be documented in the test report.

Subclause 7.2.1 – Harmonic distortion

Systems with RATED input voltage less than 220 V a.c. are exempt from this requirement because, according to the scope of IEC 61000-3-2, "the limits have not yet been considered."

See also the rationale for Subclause 4.3.3.

Subclause 7.2.2 – Voltage fluctuations and flicker

Systems with RATED input voltage less than 220 V a.c. are exempt from this requirement, as justified by the following note from the scope of IEC 61000-3-3:

NOTE 2 The limits in this standard are based mainly on the subjective SEVERITY of flicker imposed on the light from 230 V/60 W coiled-coil filament lamps by fluctuations of the supply voltage. For systems with NOMINAL voltage less than 220 V line to neutral and/or frequency of 60 Hz, the limits and reference circuit values are under consideration.

See also the rationale for Subclause 4.3.3.

Subclause 8.1 – General

PORTS

Figure A.1 below is Figure 1 from IEC 61000-6-1:2005.

NOTE 1 For the purposes of this collateral standard, the "Apparatus" is the ME EQUIPMENT or ME SYSTEM and the "Signal PORT" is the PATIENT COUPLING PORT or the SIP/SOPS PORT, as shown in Figure 2.

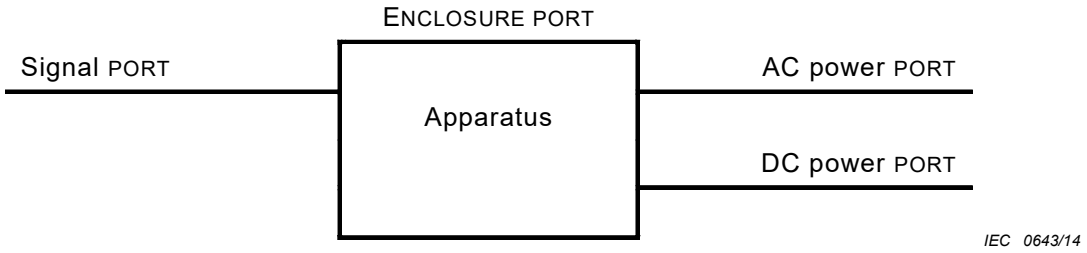


Figure A.1 – Examples of PORTS (from IEC 61000-6-1:2005)

NOTE 2 For ELECTROMAGNETIC IMMUNITY, the ENCLOSURE IS considered to be a PORT.

IMMUNITY pass/fail criteria

It should be noted that the IMMUNITY pass/fail criteria (formerly IMMUNITY compliance criteria) are specified differently in this edition than they were in previous editions. Previous editions specified a list of degradations that were not allowed with regard to the BASIC SAFETY and ESSENTIAL PERFORMANCE in response to the electromagnetic test signal. This edition includes a similar list (see I.3.1); however, the list is intended as general examples. The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM is required to specify specific IMMUNITY pass/fail criteria for the ME EQUIPMENT or ME SYSTEM under test before the test is performed. Annex I provides guidance in doing so.

Pole-mounted ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT or an ME SYSTEM that is pole-mounted should be tested as table-top equipment or mounted to a pole, whichever is worst case. For ME EQUIPMENT for which there is a particular (Part 2) standard, this could be addressed in the Part 2 standard.

Dwell time

The dwell time should be at least 1 s and should be no less than the response time of the slowest responding function plus the settling time of the IMMUNITY test system. For ME EQUIPMENT and ME SYSTEMS for which faster-responding signals can be used to determine the effect of the test signal on the ME EQUIPMENT or ME SYSTEM, the dwell time can be reduced if the faster-responding signals are monitored. In this case, the dwell time should be no less than the response time of the signal or of the monitoring system, whichever is greater, plus the response time of the radiated RF IMMUNITY test system, but in no case less than 1 s. For ME EQUIPMENT and ME SYSTEMS that have multiple individual parameters or subsystems, each of which would yield a different dwell time, the value used should be the maximum of the individually-determined dwell times.

The minimum dwell time of 1 s is recommended so that performance DEGRADATION that might occur in response to the IMMUNITY TEST LEVEL can be observed by test engineers.

The use of adequate dwell time (or a correspondingly slow sweep rate) can be particularly important to IMMUNITY testing of ME EQUIPMENT and ME SYSTEMS. While interference with a video display unit can be perceived instantly, ME EQUIPMENT and ME SYSTEMS can have a very slow response time and can require a long dwell time in order to assess performance during the test. For example:

– A pulse oximeter might display a value averaged over several cardiac cycles.
– It might take several minutes to determine that the flow rate of an infusion pump has remained within an acceptable range.
– A ventilator might require several breath cycles to respond to a test signal.

NOTE Some slow sensors, e.g. chemical/biochemical sensors, can have response times of several minutes but are not susceptible to RF fields. In such instances the response of the electronics, including filtering or averaging in hardware or software, would be the appropriate response time to consider in the determination of the dwell time.

Subclause 8.5 – Subsystems

Care needs to be taken that testing on a subsystem basis is appropriate and that subsystems absent from the system are adequately simulated. If, for example, MANUFACTURERS of connected subsystems have different specifications for the interconnecting cables or if subsystems cannot be adequately simulated, it might be more appropriate to test the equipment as a system.

Subclause 8.6 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for IMMUNITY testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;
– on a test site on a subsystem basis;
– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For certain ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation or of equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT and ME SYSTEMS that cannot fit within a 2 m × 2 m × 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration.

In situ testing – testing at the place of installation – as a system at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility.

The ME SYSTEM might be in use and might not present the maximum configuration. To operate the device in the modes and settings that are most likely to result in an unacceptable RISK might not be allowed by the RESPONSIBLE ORGANIZATION due to the potential for damage to the ME SYSTEM.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the EUT is likely to be fully available and testing in representative configurations is usually

possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement needs to be maintained, and if the applicable basic EMC standards allow in situ testing, the requirements in the basic EMC standards will take precedence. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report.

Subclause 8.7 – Operating modes

For example, a ventilator might have a paediatric mode and an adult mode. ULTRASONIC DIAGNOSTIC EQUIPMENT might have a 2D, a colour and a Doppler mode.

Subclause 8.8 – Non-ME EQUIPMENT

If non-ME EQUIPMENT is used in an ME SYSTEM and the non-ME EQUIPMENT is determined not to affect BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, the non-ME EQUIPMENT still could experience the same reasonably foreseeable ELECTROMAGNETIC DISTURBANCES in use as the rest of the ME SYSTEM. Therefore, any decoupling used during the test should be considered for incorporation into the ME SYSTEM.

Subclause 8.9 – IMMUNITY TEST LEVELS

a) General

Figure 3 shows examples of locations and EM ENVIRONMENTS of INTENDED USE that are found in healthcare, grouped according to professional healthcare facility environment, HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENT. Not all possible locations and EM ENVIRONMENTS are listed. Locations not shown should be assigned to the applicable similar environment.

Locations that are shown to be in the professional healthcare facility environment have expected levels of EM DISTURBANCES that are in the same general range. Similarly, locations that are shown to be in the HOME HEALTHCARE ENVIRONMENT have expected levels of EM DISTURBANCES that are in the same general range.

While the IMMUNITY TEST LEVELS are specified according to the EM ENVIRONMENT of INTENDED USE, 8.1 requires that if the INTENDED USE of the ME EQUIPMENT or ME SYSTEM includes multiple environments, the ME EQUIPMENT or ME SYSTEM is required to comply with the most stringent of the applicable IMMUNITY TEST LEVELS. The ME EQUIPMENT or ME SYSTEM would then be assumed to be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE in all of the environments of INTENDED USE.

The information in IEC/TR 61000-2-5 regarding expected levels of EM DISTURBANCES was taken into consideration in specifying the IMMUNITY TEST LEVELS. Table A.1 lists the tables of IEC/TR 61000-2-5 that were considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY test.

Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST

Phenomenon	Basic EMC standard or test method	IEC/TR 61000-2-5:2011 table number
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	37, 38
Radiated RF EM fields	IEC 61000-4-3	15, 16, 19, 21, 22, 23, 24, 25, 26
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	20, 27, 28, 30, 31, 32, 33, 34
RATED power frequency magnetic fields	IEC 61000-4-8	9
Electrical fast transients / bursts	IEC 61000-4-4	12
Surges	IEC 61000-4-5	12
Conducted disturbances induced by RF fields	IEC 61000-4-6	11,16, 25
Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	None [a)]

[a)] While there is no guidance in IEC 61000-2-5 on voltage dips and interruptions, guidance in IEC 61000-4-11 was used in selecting these IMMUNITY TEST LEVELS.

b) Environments

The names of the ELECTROMAGNETIC ENVIRONMENTS designated in this collateral standard are harmonized with IEC 60601-1-11. It is important to reference Figure 3 to understand what each environment includes and what it does not include.

There are several different locations in each environment. In general, similar levels of EM DISTURBANCES can be expected in locations assigned to the same environment. The IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11 for BASIC SAFETY and ESSENTIAL PERFORMANCE for ME EQUIPMENT and ME SYSTEMS intended for use in the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT are not the theoretical maximums for the respective environments, but are the reasonably foreseeable maximum levels. These levels might not be adequate for all types of ME EQUIPMENT and ME SYSTEMS. Part 2 standards or the MANUFACTURER should address such cases, where appropriate. Additional rationale for the IMMUNITY TEST LEVELS is presented below.

– **Professional healthcare facility environment**

Examples of locations in the professional healthcare facility environment are different settings where medical personnel often are nearby (doctors' offices, clinics, surgery rooms, intensive care, PATIENT rooms, emergency rooms, and clinics). Note however that the professional healthcare facility environment does not include all hospital locations. For example, it does not include areas of the hospital where there is sensitive equipment or sources of intense ELECTROMAGNETIC DISTURBANCES, such as the RF shielded room of an ME SYSTEM for magnetic resonance imaging, in operating rooms near active HF SURGICAL EQUIPMENT, electrophysiology laboratories, shielded rooms, or areas where SHORT-WAVE THERAPY EQUIPMENT is used. The IMMUNITY TEST LEVELS specified for the professional healthcare facility environment are likely not to be appropriate for these areas of the hospital. (See SPECIAL ENVIRONMENTS, below.)

Most environments and locations in the professional healthcare facility environment are considered to have a controlled EM ENVIRONMENT with regard to FIXED electromagnetic sources. Mobile communication devices are widely used by healthcare professionals in providing efficient PATIENT care. For this reason it is more difficult to control the environment for close proximity ELECTROMAGNETIC DISTURBANCES.

Examples of electromagnetic sources that might be used adjacent to ME EQUIPMENT and ME SYSTEMS in hospital environments are:

– HF SURGICAL EQUIPMENT;
– RFID systems;
– wireless local area networks (WLAN);
– mobile phones;
– handheld mobile radios (e.g. TETRA, two-way radio);
– paging systems.

It is assumed that ME EQUIPMENT and ME SYSTEMS used in hospitals (and large clinics) are not connected to the PUBLIC MAINS NETWORK.

LARGE ME EQUIPMENT and LARGE ME SYSTEMS that are PERMANENTLY INSTALLED in a trailer should be categorized according to the INTENDED USE. For example, if it is intended to be connected to hospital power, then the professional healthcare facility environment should be used. For radiated DISTURBANCES, the requirements for ME EQUIPMENT and ME SYSTEMS intended for use only in a shielded location might be applicable, depending on the shielding effectiveness and the filter attenuation.

– **HOME HEALTHCARE ENVIRONMENT**

Locations in the HOME HEALTHCARE ENVIRONMENT have much more diverse EM ENVIRONMENTS, with ELECTROMAGNETIC DISTURBANCES that might be less well-controlled and less well-characterized in terms of amplitude and probability of occurrence than for the professional healthcare facility environment. Except in transportation, ME EQUIPMENT and ME SYSTEMS are usually connected to the PUBLIC MAINS NETWORK. These reasons justify higher IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE.

Examples of electromagnetic sources that might be used near ME EQUIPMENT and ME SYSTEMS in these environments or otherwise expose the ME EQUIPMENT or ME SYSTEM to intense EM DISTURBANCES are:

– small mains frequency transformers (50 Hz and 60 Hz), e.g. in a clock radio on a bedside table;
– mains disturbances;
– mobile phones (often several);
– FIXED radio broadcast stations;
– TV transmitting equipment;
– amateur radio equipment (radio amateurs) operating from 136 kHz to microwave;
– mobile radio transmitters (e.g. taxi, police).

The HOME HEALTHCARE ENVIRONMENT includes transportation and locations that can be accessed by walking, shops and libraries, where electronic anti-theft equipment and metal detectors are used, cars, ambulatory (walking), bike and motorbike, trains, airplanes, and ships. The IMMUNITY TEST LEVELS specified for the HOME HEALTHCARE ENVIRONMENT might not be appropriate for helicopters, spacecraft, or submarines. Equipment intended for transportation applications might or might not be intended for permanent installation in a vehicle. If the ME EQUIPMENT or ME SYSTEM is intended to be connected to vehicle d.c. power, the applicable vehicle EMC standards should apply.

– **SPECIAL ENVIRONMENTS**

“Special” is used in EMC standards, e.g. the IEC 61000-4 Basic EMC IMMUNITY standards, for test levels that are outside or other than the standard test levels. For this reason, “special” is appropriate for the environments listed as such in Figure 3. This is not to say that these environments are unusual, only that the EM ENVIRONMENTS differ significantly from those of the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT, or the

EM ENVIRONMENT is not well-characterized. SPECIAL ENVIRONMENTS can also be justified for locations in the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT as specified in Annex E, e.g. due to special mitigations.

The vicinity of active HF SURGICAL EQUIPMENT is an example of a SPECIAL ENVIRONMENT because the EMISSIONS are broadband and consensus IMMUNITY TEST LEVELS and test methods have not yet been specified. Similarly, consensus IMMUNITY TEST LEVELS and test methods have not yet been specified for the RF shielded room of an ME SYSTEM for magnetic resonance imaging.

As special medical environments are characterized and requirements are developed, the intent is to add these requirements to this collateral standard. Meanwhile, MANUFACTURERS should use Annex E to determine IMMUNITY TEST LEVELS for locations of INTENDED USE that are in SPECIAL ENVIRONMENTS.

c) IMMUNITY TEST LEVEL determination

The IMMUNITY TEST LEVELS used in this collateral standard were based on the work of IEC Technical Committee 77. The characterization of each EM phenomenon can be found in Technical Report IEC/TR 61000-2-5:2011.

Not all EM phenomena have IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11. This does not imply that the phenomena do not exist, but rather that there is a practicality involved in determining which EM phenomena should be considered. The EM phenomena were chosen according to RISK and represent the most likely phenomena to occur in the environments specified. Users of this collateral standard are encouraged to consider all EM phenomena during the RISK MANAGEMENT PROCESS to determine if their ME EQUIPMENT or ME SYSTEM might have an unacceptable RISK as a result of the EM phenomena listed in IEC/TR 61000-2-5 or other foreseeable ELECTROMAGNETIC DISTURBANCES, or if higher levels of IMMUNITY are required based on the ME EQUIPMENT or ME SYSTEM'S INTENDED USE (see Annex E and Annex F).

NOTE 1 IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE were selected based on the reasonably foreseeable maximum DISTURBANCE levels found in the respective environments. Foreseeable maximum levels are expected to ensure that the ESSENTIAL PERFORMANCE AND BASIC SAFETY of the ME EQUIPMENT or ME SYSTEM will be maintained in its environments of INTENDED USE.

Compromises have been made to reduce the number of specified environments, making it easier for users of this collateral standard. For example, doctors' offices and hospital have been grouped together in one environment. Also, various types of transportation have been grouped together in the HOME HEALTHCARE ENVIRONMENT. The IMMUNITY TEST LEVELS listed for each environment are a compromise and should be considered as such during the RISK MANAGEMENT PROCESS.

NOTE 2 The higher IMMUNITY TEST LEVELS specified for the HOME HEALTHCARE ENVIRONMENT are necessary due to the closer distances to certain electromagnetic sources than found in the professional healthcare facility environment. Examples include PORTABLE RF communications equipment such as mobile phones and amateur radio equipment.

NOTE 3 Some transportation environments have high-power mobile transmitters that are normally not found in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. For this reason, a higher level of reasonably foreseeable maximum EM DISTURBANCE is expected.

NOTE 4 Some of the IMMUNITY TEST LEVELS in Clause 8 of this standard are based on the assumption of a controlled environment, meaning that a minimum separation distance between radiated electromagnetic sources and the ME EQUIPMENT or ME SYSTEM is required to ensure that the IMMUNITY TEST LEVELS in Clause 8 are effective in reducing the RISK to an acceptable level.

Table 4 – ENCLOSURE PORT

ELECTROSTATIC DISCHARGE

Appropriate ESD IMMUNITY TEST LEVELS for a given environment can be estimated using Figure A.1 of IEC 61000-4-2 (see Figure A.2). While some areas of some hospitals are controlled regarding relative humidity and use of anti-static (or low static) flooring and material, others are not. The HOME HEALTHCARE ENVIRONMENT can be assumed to be uncontrolled with respect to these parameters. It is well-known that the relative humidity can be quite low in some locations, as low as 5 %. As can be seen in Figure A.2, when the relative humidity is approximately 5 % and there are synthetic materials present, static charges approaching 15 kV can be generated. This is the reasonably foreseeable maximum level on which the IMMUNITY TEST LEVELS in Table 4 were based.

Even so, there are circumstances under which ME EQUIPMENT that was tested to an IMMUNITY TEST LEVEL of 15 kV air discharge failed in use and put PATIENTS at RISK. In two such case studies, ME EQUIPMENT that was tested to 15 kV failed in the field. The first was a body-worn, ambulatory insulin infusion pump. Pumps that had passed testing at 15 kV air discharge stopped pumping without alarm during use, and diabetic PATIENTS were injured. Making the pumps immune to 30 kV air discharge prevented further field failures due to ESD. In another case study, the “gas gauge” chips in the rechargeable batteries of an external defibrillator that had passed testing at 15 kV were shorting when the PATIENT was transferring them between the ME EQUIPMENT and the charger. The short-circuit completely discharged the battery and prevented recharging, potentially leaving the PATIENT unprotected.

Thus, while the 15 kV ESD air discharge IMMNITY TEST LEVEL specified in this collateral standard for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT is higher than the ESD air discharge IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, MANUFACTURERS should determine if even 15 kV is adequate for the environments of INTENDED USE.

Table 5 – Input a.c. power PORT

Conducted disturbances

The following examples provide rationale for the 6 V r.m.s. IMMUNITY TEST LEVEL in the amateur radio and ISM bands.

This is an example of a DISTURBANCE induced on the cables of an ME EQUIPMENT or ME SYSTEM due to amateur radio transmissions. The field strength can be calculated from the equation in 8.10. It is assumed that the conducted RF voltage is induced by a field strength of 10 V/m and the transmitter RF output power is assumed to be 1 500 W. The calculation shows that this could be produced by an amateur radio transmitter at a distance of 23 m. Furthermore, calculations have shown that the voltage induced on a cable in the frequency range 150 kHz to 80 MHz from a field strength of 10 V/m is unlikely to exceed 6 V r.m.s. However, once modulation is applied, the peak voltage induced on the cable under test will be greater than 10 V.

Similarly, SHORT-WAVE THERAPY EQUIPMENT operating at 100 W at an ISM frequency would also induce approximately 10 V r.m.s. in a cable of an ME EQUIPMENT or ME SYSTEM at a distance of approximately 6 m. In addition to SHORT-WAVE THERAPY EQUIPMENT intended for the professional healthcare facility environment, SHORT-WAVE THERAPY EQUIPMENT is also available by prescription for use in the HOME HEALTHCARE ENVIRONMENT and thus could expose an ME EQUIPMENT or ME SYSTEM to an EM DISTURBANCE that, when coupled to a cable, would result in an induced voltage of approximately 6 V r.m.s.

These are only examples; however, they show that the test level of 6 V r.m.s. is appropriate for amateur radio bands in the HOME HEALTHCARE ENVIRONMENT and the ISM bands in the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

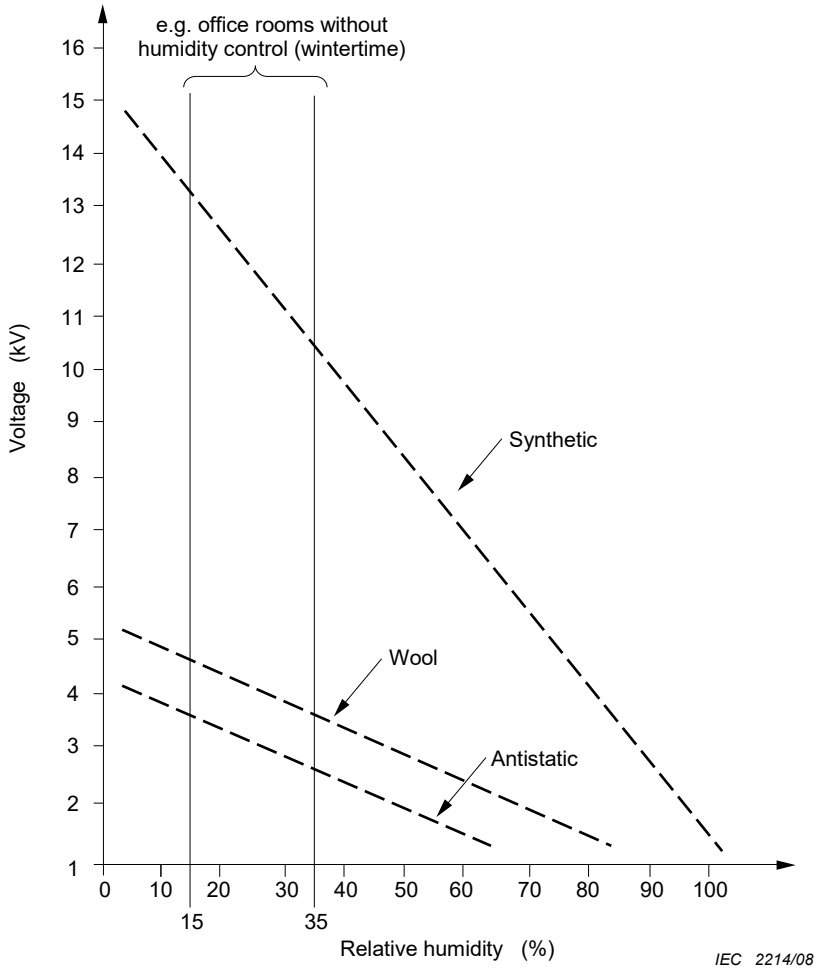


Figure A.2 – IEC 61000-4-2 Figure A.1 – Maximum values of electrostatic voltages to which OPERATORS can be charged while in contact with the materials mentioned in A.2

Voltage dips

The 40 % U_T test level that appeared in earlier editions of this collateral standard has been deleted because it was deleted from IEC 61000-4-11.

Table 7 – * Patient COUPLING PORT

Examples of PATIENT COUPLING PORTS include ECG cables, EEG cables, pulse oximeter PATIENT cables, and infusion pump saline lines.

The ESD IMMUNITY test specified in Table 7 is intended to verify BASIC SAFETY and ESSENTIAL PERFORMANCE after handling of PATIENT-COUPLED cables by the OPERATOR, e.g. after application of electrodes, application to the PATIENT. For this reason, the test is performed with no connection to an artificial hand and no connection to PATIENT simulation.

Only one end of a transmission line need be terminated to produce the source signal voltage at the far end of the line. The artificial hand, 510 Ω in series with 220 pF and usually connected to aluminium foil that is applied to the ME EQUIPMENT or ME SYSTEM, presents a relatively high impedance across the test spectrum. However, it is very important that the PATIENT cable look like a 150 Ω transmission line. This is not a trivial task above 30 MHz. Bundling of the PATIENT cable should be avoided. Bundling makes it very difficult to maintain the 150 Ω transmission line impedance above 30 MHz. For the tests for which it is specified, the use of the artificial hand helps to simulate the electromagnetic conditions of actual use.

Type-F PATIENT circuits are not properly terminated in the 150 Ω impedance when testing to IEC 61000-4-6 with the current injection method. However, when a product is used as intended, the cables are not terminated and resonant effects can occur. If this presents a problem, cables and circuits should be designed to be immune to such effects. If a cable length approaches ¼ wavelength, it might be necessary to move the clamp to inject at both ends of the cable. In the rare case that the cable length is ½ wavelength, injection should be done at both ends and the centre.

Subclause 8.10 – IMMUNITY to proximity fields from RF wireless communications equipment

Since IEC 60601-1-2 Edition 2.1 and Edition 3 were developed, new digital wireless technologies have been introduced not only to hospitals, but are also in widespread use by the general public. In addition, existing technologies are being used in ways that they were not used before.

Examples of RF wireless technologies and their use in healthcare and in various locations where ME EQUIPMENT and ME SYSTEMS are used:

– TETRA, LTE
– wireless local area network (WLAN) equipment in hospitals, including the use of mobile phones and personal digital assistants (PDAs) during rounds to access PATIENT data and images, sound ALARM SIGNALS and issue orders for PATIENT care and medication;
– use of mobile phones by healthcare professionals for instant communication;
– use of wireless communication in ME EQUIPMENT and ME SYSTEMS;
– installation and use of RFID tags and readers in hospitals, including in ME EQUIPMENT and ME SYSTEMS and in systems to scan for sponges left in PATIENTS after surgery;
– electronic article surveillance (EAS) systems based on RFID technology and magnetic field technology;
– use of wireless technologies like Bluetooth for controlling ME EQUIPMENT and ME SYSTEMS (e.g. footswitches) and for transmitting voice and other data;
– use of RFID to track the location of ME EQUIPMENT and ME SYSTEMS in the hospital;
– use of machine-to-machine (M2M) communications.

In addition, healthcare providers have specifically requested that requirements be developed so that wireless communications equipment can be used closer to medical equipment than is recommended based on compliance with e.g. IEC 60601-1-2:2007.

~~Today, wireless communications equipment is used in close proximity to ME EQUIPMENT and ME SYSTEMS. The IEC 61000-4-3 test method is not optimum for testing the effects of RF wireless communications equipment close to ME EQUIPMENT and ME SYSTEMS. A new test method for testing wireless communications equipment in close proximity to ME EQUIPMENT and ME SYSTEMS has been developed but has not yet been validated. However, SC 77B has started to draft a test method for IMMUNITY of electronic equipment to nearby wireless communications equipment.~~

~~Until SC 77B has developed such a test method, a modified test method from the existing IEC 61000-4-3 must be used as an interim solution. This test method and the associated test requirements are specified in 8.10.~~

For some services, only the uplink frequencies are included. Due to local circumstances and technical developments, the listed frequencies are only examples and are not claimed to be exhaustive. The services and frequencies listed were chosen to be reasonably representative and comprehensive for RF wireless communications equipment.

Test frequencies were chosen based on the following criteria:

If the band is greater than 10 % of the centre frequency, three frequencies are used. Otherwise only the centre frequency is used.

Modulation specifications were chosen to simplify the test based on relevant characteristics of frequency bands of RF wireless communications equipment. In most cases, the carrier is modulated using a square wave signal.

By experience, the duty cycle of 50 % appears to be worst-case for different modulation characteristics of RF wireless communications equipment.

In bands in which services use both 18 Hz and 217 Hz modulations, 18 Hz is specified for the test because it is worst case.

The IMMUNITY TEST LEVELS specified in ~~the table~~ Table 9 were calculated using the maximum power shown in Table A.3, an assumed separation distance of 0,3 m, and the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. The factor of 6 is a compromise for a range of antenna factors, to simplify the test.

Table A.3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency MHz	Band [a)] MHz	Service [a)]	Maximum power W	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	1,8	27
450	430 to 470	GMRS 460, FRS 460	2	28
710	704 to 787	LTE Band 13, 17	0,2	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	2	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	0,2	9
5 500				
5 785				

[a)] For some services, only the uplink frequencies are included.

Subclause 8.11 – IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

This requirement was added due to concerns about the RISKS associated with fields radiated by a wide variety of sources in both the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. ME EQUIPMENT can contain electronic components and circuitry that are sensitive to radiated magnetic fields from these sources.

The procedure for determining the applicability of the proximity magnetic fields IMMUNITY test and the testing required are shown in Figure A.3. In general, this subclause applies to all ME EQUIPMENT and ME SYSTEMS. However, due to the fact that the sources of magnetic fields considered for this subclause are proximity sources, appropriate exemptions from testing are specified. Even if this test is not performed, there are requirements for documentation of the choices/decisions made. It should be noted that MANUFACTURERS are permitted to bypass these exemptions and conduct the tests if they so choose.

Exemptions

The first of three exemptions (see 8.11 a)) is where the ME EQUIPMENT or ME SYSTEM does not contain (i.e. within the ENCLOSURE or as part of an attached ACCESSORY) magnetically sensitive components or circuitry.

For the purposes of this subclause, magnetically sensitive components are those components that are either designed to sense magnetic fields or are likely to be influenced as a result of the fields specified in this subclause while in close proximity to the sources. Examples include but are not limited to coils, signal transformers, and hall-effect sensors.

Magnetically sensitive circuitry includes but is not limited to those circuits where voltages induced into wiring or the interconnect structure might alter the intended function of the circuit. Examples of such circuits are:

– an analogue signal processing circuit whose passband is within the frequency range specified in this subclause and where the area enclosed by any interconnecting pathways is such that the induced voltage can interfere with signals of interest.

– digital circuits where the induced voltage in an interconnect pathway approaches the logic threshold of the devices.

– an external pacemaker system, where the leads attached to temporarily implanted heart wires form a loop whose area is sufficient to result in an induced voltage comparable to the ECG signals being sensed from the heart.

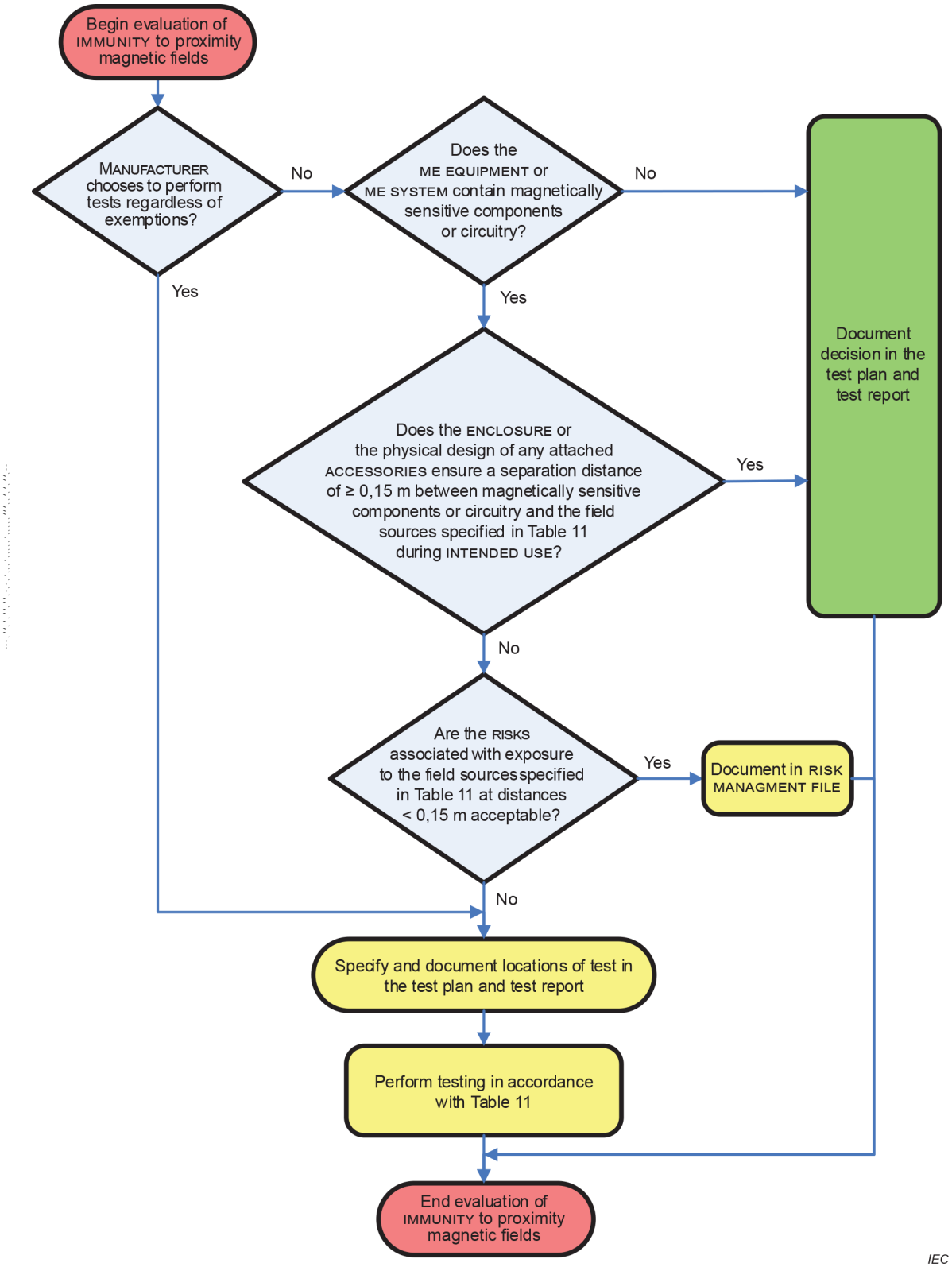


Figure A.3 – Steps for evaluation of IMMUNITY to proximity magnetic fields

The second exemption (see 8.11 b)) specified by this subclause is allowed when the ME EQUIPMENT or ME SYSTEM or an attached ACCESSORY does contain magnetically sensitive components or circuitry but these components or circuits are mounted behind the surface of the equipment ENCLOSURE (or the ENCLOSURE or other physical barrier associated with an attached ACCESSORY) such that during INTENDED USE a minimum separation distance from the sources of proximity magnetic fields specified in Table 11 is ensured. For the purposes of this collateral standard, this minimum separation distance is considered to be a “proximity threshold”, and a value of 0,15 m was assigned to it. To establish the “proximity threshold”, SC 62A considered the types of proximity magnetic field DISTURBANCE sources expected:

– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134,2 kHz and 13,56 MHz;
– electronic article surveillance (EAS) systems;
– sponge detection systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.

These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of this collateral standard. All of these sources (with the exception of wireless charging for electric vehicles) generally use coils that are small in diameter. RFID readers operating at 134,2 kHz use coils with a radius of about 0,06 m, and those operating at 13,56 MHz use coils with a radius of about 0,02 m.

The magnetic field along the axis of a “thin” coil relative to the maximum field at its centre is approximated by:

$$\frac{B(x)}{B(0)} = \frac{1}{(1+a^2)^{1,5}}$$

where

$a = \frac{x}{r}$;

x is the distance from the centre of the coil along the coil axis;

r is the radius of the coil.

Figure A.4 illustrates the field decay characteristics of coils having radii up to 0,06 m.

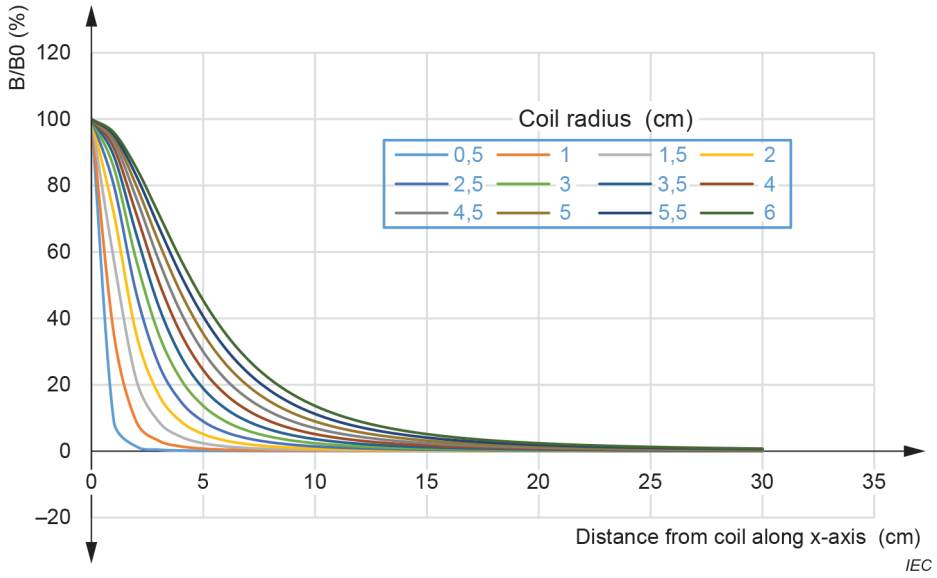


Figure A.4 – Magnetic field roll-off characteristics along the x-axis for a thin planar coil and various coil radii

This shows that at a distance of 0,15 m, the magnetic field for all coil radii up to 0,06 m has decayed to 5 % or less of the maximum field. In order to assess the impact of these reductions in field amplitude upon a receiving circuit, analysis of the field characteristics and coupling coefficients between two coils according to [50] was undertaken. The induced voltage in a single-turn coil of the same radius as the transmit coil was then estimated using Faraday's law and the coupling coefficients. The results of this analysis are shown in Figure A.5 and Figure A.6. It can be seen from these results that at a separation distance of 0,15 m, the induced voltage from an RFID reader operating at 134,2 kHz in a loop of wire with diameter of 0,12 m is approximately 45 mV peak-to-peak. Similarly, a 13,56 MHz RFID reader will induce approximately 300 µV peak-to-peak in a loop of diameter 0,04 m. The low levels determined by these calculations provide adequate justification for a "proximity threshold" of 0,15 m.

The coil sizes associated with wireless electric vehicle charging, while larger than analysed above, are not of concern because these systems employ protection mechanisms that prohibit approach closer than distances of the order of 1 m.

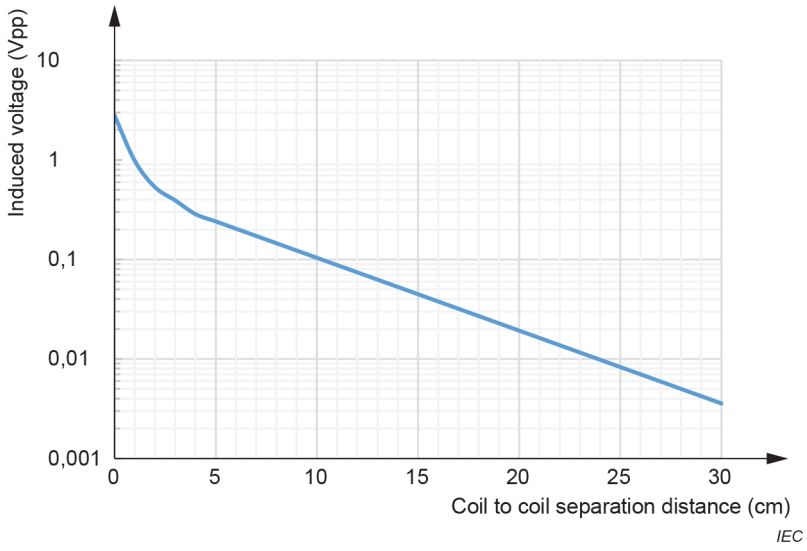


Figure A.5 – Voltage induced in a 1-turn, 6 cm radius coil by a 6 cm radiating coil operating at 134,2 kHz and H_0 of 82,65 A/m (r.m.s.)

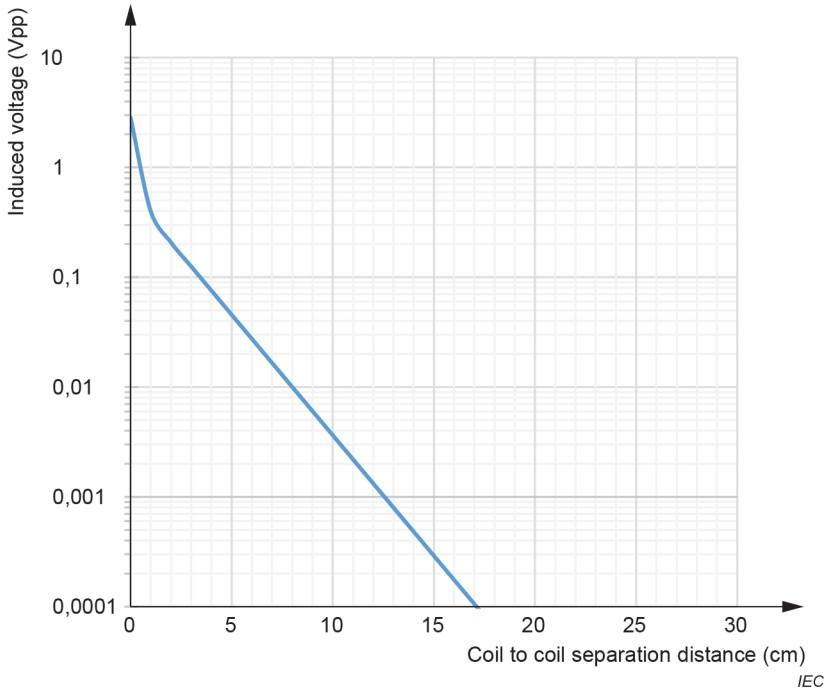


Figure A.6 – Voltage induced in a 1-turn, 2 cm radius coil by a 2 cm radiating coil operating at 13,56 MHz and H_0 of 7,5 A/m (r.m.s.)

Where neither of the exemptions specified in a) or b) are applicable, 8.11 introduces an option (see 8.11 c)) for the MANUFACTURER to perform a RISK ANALYSIS when it is known that exposure of magnetically sensitive components or circuitry with separation distances less than 0,15 m during INTENDED USE might be possible. Where the RISKS are determined to be acceptable, following documentation of the assessment in the RISK MANAGEMENT FILE, further testing for IMMUNITY to proximity magnetic fields at the frequencies specified is not necessary. If the RISKS are found to be unacceptable, or if the MANUFACTURER chooses to perform testing regardless of the exemptions or RISK ANALYSIS option, then testing proceeds according to 8.11 d).

Test levels, frequencies, and modulations

The test specifications are not intended to cover every frequency and application used in every country. The concept of testing at just a few frequencies as opposed to sweeping over a range of frequencies is predicated on the assumption that the inductive coupling into the ME EQUIPMENT within the scope of this subclause is non-resonant. Under this assumption, it only becomes necessary to test using the highest known frequency of the known emitter types. SC 62A intentionally limited the scope of frequencies for this subclause to align with the minimum test frequency of IEC 61000-4-39. For this reason, emitters operating below 9 kHz are not considered.

In the frequency range 9 kHz to 150 kHz, SC 62A considered the RISKS primarily from induction cooking appliances and the emerging sources of wireless power transfer used to charge electric vehicles. There are many operating frequencies for induction cooking appliances, but SC 62A chose the single, highest known operating frequency (30 kHz) to simplify the testing. The test level for this frequency was chosen based upon reference [45]. This test is applicable to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT, as exposure to the noted sources is not expected in the professional healthcare facility environment.

With respect to electric vehicle charging, SC 62A considered emerging standards for these systems from the Society of Automotive Engineers (SAE) and the IEC. The operating frequencies range from approximately 50 kHz to over 100 kHz and the magnetic fields are CW. The field strengths outside of the vehicles are not expected to exceed 12 A/m. This exposure level is less than that expected from pulsed magnetic sources such as electronic article surveillance (EAS) and RFID systems. Therefore, until further information becomes available, no emitter-specific test for electric vehicle charging at frequencies below 100 kHz is specified. Instead, the test at 134,2 kHz is used as a surrogate test for disturbances associated with electric vehicle charging.

SC 62A recognizes that other forms of wireless power transfer have recently been deployed or are in development (e.g. for charging of portable electronic devices (PEDs)). However, the HAZARDS associated with the potential DISTURBANCES due to this type of equipment have not yet been evaluated at the time of publication.

The HAZARDS associated with exposure to EAS and RFID equipment at 134,2 kHz and 13,56 MHz are addressed in 8.11. The IMMUNITY TEST LEVELS specified for these technologies were based upon reference [44]. For RFID equipment operating at 134,2 kHz, the test level in [44] was established by measurement of magnetic field EMISSIONS from RFID readers at a distance of 0,025 m. The analysis of induced voltage in Figure A.5 uses a field strength of 82,6 A/m as the maximum, which is the 65 A/m IMMUNITY TEST LEVEL specified in Table 11, extrapolated to a distance of 0 m. For similar equipment operating at 13,56 MHz, the test level was measured in contact with the equipment (no separation). These test levels are considered adequate to cover any other known sources in the frequency range 134 kHz to 13,56 MHz.

All test levels specified in this subclause are based on equipment standards or other source-based references. Levels associated with human exposure standards such as those published by ICNIRP or IEEE are not used because they were not developed with regard to IMMUNITY of ME EQUIPMENT or ME SYSTEMS.

The modulation type and rates shown in Table 11 for 134,2 kHz and 13,56 MHz were chosen as surrogates for the multiplicity of actual modulations associated with commercial RFID equipment. The test modulations are considered to be an adequate challenge to the ME EQUIPMENT within the scope of the tests, while at the same time avoiding the need for complex signal generation equipment.

Clause 9 – Test report / Table 10 – Minimum test report contents

ISO 17025 [25] is cited because it is a good reference for the minimum content of a test report. A similar format can be found in Table F.1 of CISPR 32.

Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT or their parts are found in 7.2 and Table C.1 of the general standard. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts are found in the subclauses listed in Table B.1.

Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Description	Clause or subclause
ME EQUIPMENT or ME SYSTEMS specified for use only in a shielded location: marking of	5.1

B.2 ACCOMPANYING DOCUMENTS, instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses of this collateral standard listed in Table B.2.

Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use

Description	Clause or subclause
Environments for which the ME EQUIPMENT or ME SYSTEM is suitable: statement of	5.2.1.1 a)
Performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES	5.2.1.1 b)
Use of ME EQUIPMENT or ME SYSTEM adjacent to or stacked with other equipment: warning of	5.2.1.1 c)
Cables, transducers and other ACCESSORIES that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 and Clause 8: list of	5.2.1.1 d)
Use of ACCESSORIES, transducers and cables other than those specified or provided by the MANUFACTURER: warning about	5.2.1.1 e)
Minimum separation from RF communication equipment: warning of	5.2.1.1 f)
CISPR 11 class A ME EQUIPMENT and ME SYSTEMS used in a residential area, warning about	5.2.1.2

B.3 ACCOMPANYING DOCUMENTS, technical description

The requirements for general information to be included in the technical description are found in Subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for general information to be included in the technical description are found in the subclauses listed in Table B.3.

Table B.3 – ACCOMPANYING DOCUMENTS, technical description

Description	Clause or subclause
Precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES: description of	5.2.2.1
Compliance for each EMISSIONS and IMMUNITY standard or test specified	5.2.2.1 a)
Deviations from this collateral standard and allowances used	5.2.2.1 b)
Maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the ELECTROMAGNETIC DISTURBANCES: instructions for	5.2.2.1 c)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: warning to use only in a shielded location	5.2.2.2 a)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: shielded location specifications	5.2.2.2 b)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: test methods for measurement of RF shielding effectiveness and RF filter attenuation, recommendation for	5.2.2.2 c)
EMISSIONS characteristics of other equipment allowed inside the shielded location: specification of	5.2.2.2 d)
ME EQUIPMENT that intentionally receives RF electromagnetic energy: frequency or frequency band of reception, preferred frequency or frequency band and bandwidth	5.2.2.3
ME EQUIPMENT that includes RF transmitters: frequency or frequency band of transmission, modulation and EFFECTIVE RADIATED POWER	5.2.2.4
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: statement that an exemption has been used	5.2.2.5 a)
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: warning that testing for radiated RF IMMUNITY was done only at selected frequencies	5.2.2.5 b)
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: list of the frequencies and modulations used for IMMUNITY testing	5.2.2.5 c)
Statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery, if applicable	5.2.2.6

Annex C
(informative)

Guidance in classification according to CISPR 11

C.1 General

Rules for classification and separation into groups of equipment are specified in CISPR 11 and apply for this collateral standard. The purpose of this annex is to provide additional guidance in the assignment of ME EQUIPMENT or an ME SYSTEM to the appropriate CISPR 11 group and class.

Annex A of CISPR 11 gives examples of equipment classification. "Medical electrical equipment" is listed as an example of group 1 equipment, whereas "medical apparatus" is listed as an example of group 2 equipment. Only short-wave diathermy equipment and microwave therapy equipment are mentioned explicitly. No other type of ME EQUIPMENT or ME SYSTEM is listed.

C.2 Separation into groups

Most types of ME EQUIPMENT and ME SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to group 1.

Examples of group 1 ME EQUIPMENT and ME SYSTEMS are as follows:

Group 1 also includes ME EQUIPMENT and ME SYSTEMS intended to deliver energy to the PATIENT, but in a form that is other than RF electromagnetic. Examples are as follows:

– Medical imaging ME EQUIPMENT and ME SYSTEMS:
  - diagnostic X-ray systems for radiography and fluoroscopy (including cinefluoroscopy) for general purpose but also for special purposes, e.g. angiography, mammography, therapy planning, dentistry
  - computed tomography ME SYSTEMS
  - ME SYSTEMS for nuclear medicine
  - diagnostic ultrasound ME EQUIPMENT
– Therapy ME EQUIPMENT and ME SYSTEMS:
  - therapeutic x-ray ME EQUIPMENT
  - dental ME EQUIPMENT
  - electron beam accelerators
  - ultrasound ME EQUIPMENT for therapy
  - ME EQUIPMENT for extracorporeal lithotripsy
  - infusion pumps
  - radiant warmers
  - infant incubators
  - ventilators
  - anaesthesia machines
– Monitoring ME EQUIPMENT and ME SYSTEMS:
  - impedance plethysmography monitors
  - pulse oximeters

- PATIENT monitors
- electro- and magneto-cardiography ME EQUIPMENT and ME SYSTEMS
- electro- and magneto-encephalography ME EQUIPMENT and ME SYSTEMS
- electro- and magneto-myography ME EQUIPMENT and ME SYSTEMS

Only a few ME EQUIPMENT and ME SYSTEMS apply RF energy to material (in this case to PATIENTS) and are therefore members of group 2.

Examples are as follows:

– Medical imaging ME EQUIPMENT:
  - ME SYSTEMS for magnetic resonance imaging

– Therapy ME EQUIPMENT:
  - diathermy ME EQUIPMENT (short wave, ultra-short wave, microwave therapy ME EQUIPMENT)
  - hyperthermy ME EQUIPMENT

Additionally, HF SURGICAL EQUIPMENT, when active, should be classified as group 2 equipment (similar to spark erosion equipment), because it applies RF energy to the PATIENT.

C.3 Division into classes

ME EQUIPMENT and ME SYSTEMS predominantly intended for use in domestic establishments and connected to the PUBLIC MAINS NETWORK (e.g. home care ME EQUIPMENT and ME EQUIPMENT for doctors' offices in residential areas) should meet the requirements for CISPR 11 class B.

Special provisions cover professional medical electrical equipment. This means only equipment/systems for use by healthcare professionals and that are not intended for sale to the general public. These professional ME EQUIPMENT and ME SYSTEMS are allowed to meet either the requirements for CISPR 11 class A or class B under the following conditions:

– they are predominantly intended to be connected (e.g. in hospitals or doctor's offices) to dedicated supply systems (normally fed by separation transformers), or

– they have a RATED input power > 20 kVA and are intended to be powered by a dedicated power transformer and connected to it solely by a clearly identifiable power line path.

Annex D
(informative)

Guidance in the application of IEC 60601-1-2 to particular standards

D.1 General

This annex contains recommendations to standards committees and working groups writing requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for particular standards ("Part 2" standards and ISO standards) to help ensure consistency in the application of this collateral standard. Such committees are encouraged to contact subcommittee 62A with questions that arise in doing so.

This annex identifies the requirements that should be amended when this standard is applied to particular standards and provides guidance in doing so. It also identifies the requirements that should not be modified. In addition to this annex, the rationale in Annex A should be consulted for additional information and guidance in the application of this collateral standard.

Writers of particular standards are encouraged to specify the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and ME SYSTEMS within the scope of their standards.

D.2 Recommended modifications

D.2.1 Testing requirements

Writers of particular standards are encouraged to make amendments to the testing requirements as follows.

a) If the particular ME EQUIPMENT or ME SYSTEM is intended to be used in a SPECIAL ENVIRONMENT and the electromagnetic characteristics of that environment are known, appropriate IMMUNITY TEST LEVELS should be specified, using the procedure in Annex E.

b) Subclause 4.3.1, Configurations; 8.2, PATIENT physiological simulation and 8.7, Operating modes should be amended to be more specific for the particular ME EQUIPMENT or ME SYSTEM, while maintaining the intent of this collateral standard.

c) Amend the IMMUNITY pass/fail criteria paragraph in 8.1. to provide specific criteria for the particular ME EQUIPMENT or ME SYSTEM that follow the intent of that subclause.

D.2.2 ACCOMPANYING DOCUMENTS

If writers of particular standards make amendments to the testing requirements of this collateral standard, it should be determined if corresponding modifications to the ACCOMPANYING DOCUMENTS requirements are needed.

D.3 Cautions

Writers of particular standards are cautioned against making other modifications, particularly those listed below.

a) Subclause 7.1 should not be modified, except for specification of group 1 or 2, using the guidance in Annex C, and classification to class B, if the specific ME EQUIPMENT and ME SYSTEMS should only be classified as class B. Particular standards are not free to modify the EMISSIONS requirements or the test methods specified in CISPR 11 without the consent of CISPR subcommittee B.

b) Subclauses 7.1.9, PATIENT physiological simulation; 8.2, PATIENT physiological simulation; 8.3, Termination of PATIENT-COUPLED parts; 7.1.10, Artificial hand, 7.1.11, PATIENT-

COUPLED cables; and 8.4, HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD while providing its INTENDED USE should not be modified. The PATIENT cables are treated differently in different tests. The default termination requirements specify that no intentional conductive or capacitive connection be made to earth because either the termination is not considered relevant (i.e. in the surge IMMUNITY test) or the prohibited termination is considered less stringent (i.e. in the ESD and radiated RF tests). In specific tests, the artificial hand and RC element specified in 8.3 of CISPR 16-1-2 have been specified because for these tests, either it is necessary for the artificial hand and RC element to be in place to properly perform the test or the use of the artificial hand and RC element was considered to be the worst case. The general standard treats the conditions in which the PATIENT is floating and in which the PATIENT is earthed as NORMAL CONDITIONS. However, from a RF perspective, it is unlikely that a PATIENT in a medical environment would ever be as effectively earthed as in an EMC test environment in which a direct earth reference is used. As a result, the artificial hand and RC element specified in 8.3 of CISPR 16-1-2 are used to represent the earthed condition. The treatment of PATIENT cables in this collateral standard has been chosen to represent a condition of use that is worst case for each IMMUNITY test.

c) Do not exempt PATIENT cables or SIP/SOPS from the IEC 61000-4-6 test unless the effective length of the ME EQUIPMENT or ME SYSTEM plus its cables is less than 0,4 m. Otherwise, the ME EQUIPMENT or ME SYSTEM should be tested using the IEC 61000-4-3 (radiated RF IMMUNITY) test method down to the start frequency specified by IEC 61000-4-6 for the effective length. In the frequency range 0,15 MHz to 80 MHz, the IEC 61000-4-6 “conducted RF IMMUNITY” standard is actually a test for IMMUNITY to conducted DISTURBANCES that are induced by radiated RF fields. It is used as a substitute for the IEC 61000-4-3 “radiated RF IMMUNITY” standard because below 80 MHz in a moderately-sized test facility, it is difficult to achieve the EM field uniformity required by IEC 61000-4-3. IEC 61000-4-6 uses conducted methods to test equipment for IMMUNITY to the radiated RF that could occur in this frequency range. Therefore, PATIENT cables and SIP/SOPS should not be exempted from this test unless the effective length (ENCLOSURE plus cables, extended in opposite directions) will always be less than 0,4 m.

Annex E
(informative)

Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS

E.1 General

This annex specifies a procedure for determining IMMUNITY TEST LEVELS for ME EQUIPMENT and ME SYSTEMS for which the environments of INTENDED USE include one or more SPECIAL ENVIRONMENTS. The recommended determination PROCESS is shown in Figure E.1 and Figure E.2.

NOTE 1 Examples of when this might be appropriate include ME EQUIPMENT and ME SYSTEMS in the vicinity of SHORT-WAVE THERAPY EQUIPMENT (diathermy) and PERMANENTLY INSTALLED computed tomography ME SYSTEMS within an X-ray shielded room with air conditioning (controlled temperature and humidity).

NOTE 2 The following documents were used in the preparation of this annex: ISO 14971, IEC/TS 61000-1-2 [8], and IEC/TR 61000-2-5 [9] . Please refer to them for additional information.

The existing IMMUNITY TEST LEVELS of Clause 8 are based on reasonably foreseeable maximum EM DISTURBANCES related to (a set of) electromagnetic phenomena that are characteristic of the specified EM ENVIRONMENTS, i.e. the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT.

The situations that could justify new IMMUNITY TEST LEVELS or an increase or decrease in the existing IMMUNITY TEST LEVELS are as follows:

a) mitigations that might reduce exposure to EM DISTURBANCE levels resulting from the phenomena listed in Clause 8;
b) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have lower EM DISTURBANCE levels;
c) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have higher EM DISTURBANCE levels (e.g. shorter minimum separation distances for RF wireless equipment);
d) the presence of an EM DISTURBANCE from an EM phenomenon that is not listed in Clause 8.

The difference between a mitigation and a special condition might not always be obvious. In general, mitigation involves an active defence of the ME EQUIPMENT or ME SYSTEM against the EM ENVIRONMENT. An example would be the use of an uninterruptible power supply to limit the exposure to voltage dips and interruptions. Note that in this case, the EM ENVIRONMENT, per se, hasn't changed or been altered.

An example of a special condition would be a SPECIAL ENVIRONMENT where the relative humidity levels are always above 35 %. In this situation, it could be expected that the ESD DISTURBANCE levels would be lower than those specified in the tables in Clause 8. This is an example of a situation where the environment of INTENDED USE would have lower EM DISTURBANCE levels for ESD than the specifications in Clause 8, so an additional active defence of the ME EQUIPMENT or ME SYSTEM would not be necessary.

On the other hand, if an environmental chamber is used to control the relative humidity to a level above 50% and the ME EQUIPMENT or ME SYSTEM is specified and labelled to always and only be used within this chamber, then this is an example of mitigation.

In the end, it doesn't matter whether it's called mitigation or a special condition, as long as the new or adjusted IMMUNITY TEST LEVELS are appropriate for the EM DISTURBANCE levels to which the ME EQUIPMENT or ME SYSTEM will be exposed.

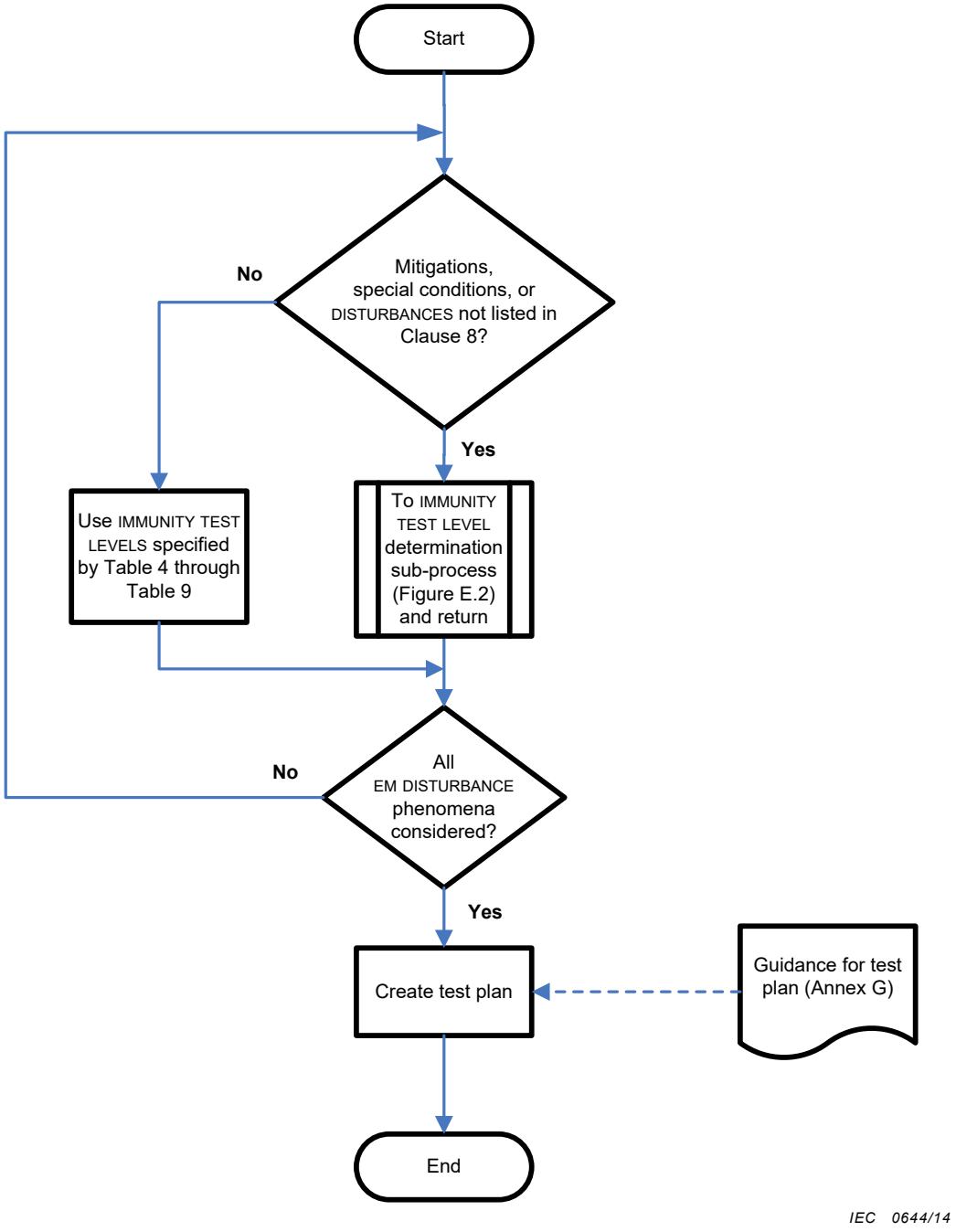


Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known

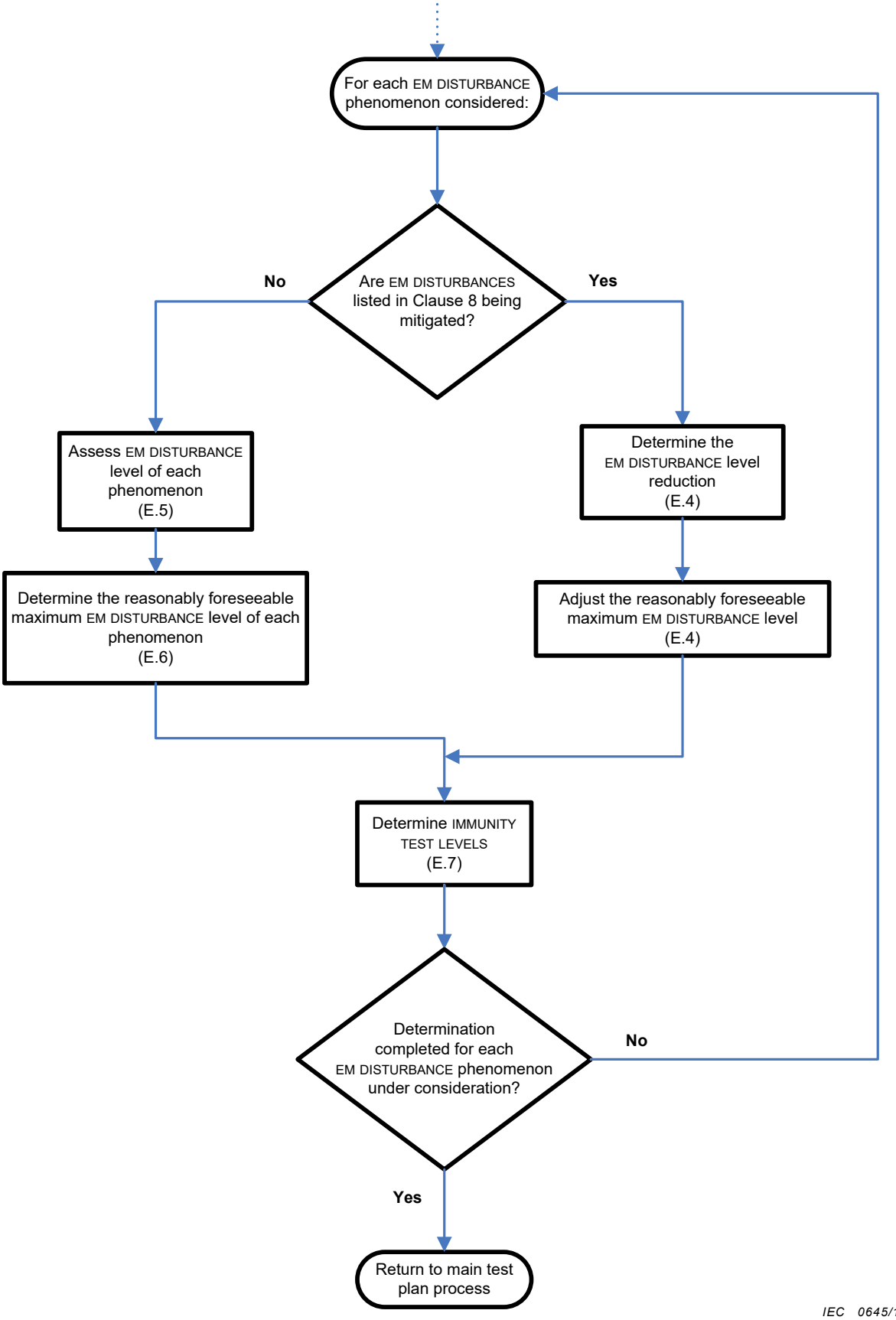


Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS

E.2 Summary of method for E.1 a)

For mitigations (E.1 a)), the following steps should be followed to determine an adjusted IMMUNITY TEST LEVEL for each phenomenon for which this is necessary:

– determination of EM DISTURBANCE level reduction (E.4);
– determination of IMMUNITY TEST LEVELS (E.7).

E.3 Summary of method for E.1 b), c) and d)

For special conditions (E.1 b) and c) and for the presence of EM phenomena described in E.1 d), the following steps should be followed to determine a new IMMUNITY TEST LEVEL for each phenomenon for which this is necessary:

– assessment of EM DISTURBANCE sources (E.5);
– determination of reasonably foreseeable maximum EM DISTURBANCE levels (E.6);
– determination of IMMUNITY TEST LEVELS (E.7).

An example of mitigations (special conditions) for two different phenomena offered by one INTENDED USE is an oncology system with an electron accelerator. The shielding effectiveness of the bunker provides mitigation for radiated RF and the limited movement of the PATIENT during treatment would be an INTENDED USE consideration for ESD.

E.4 Determination of EM DISTURBANCE level reduction

Once the MANUFACTURER of an ME EQUIPMENT or ME SYSTEM has decided to mitigate exposure to the EM DISTURBANCES caused by an EM phenomenon listed in Clause 8, a determination of mitigation reduction is needed in order to adjust the reasonably foreseeable maximum EM DISTURBANCE level of that phenomenon. Once the new level of EM DISTURBANCE has been determined, this new level can then be used to determine the IMMUNITY TEST LEVEL for that phenomenon. Each phenomenon that is mitigated, and for which the MANUFACTURER would like to adjust the IMMUNITY TEST LEVEL, will need its own assessment.

E.5 Assessment of EM DISTURBANCE sources

Once the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM has determined that in the INTENDED USE environment there might be special conditions associated with certain sources of EM DISTURBANCE (E.1 b) or c)) or there might be EM phenomena that are not listed in Clause 8 (E.1 b)), the next step is to perform an assessment of each source. The assessment will result in determination of reasonably foreseeable maximum EM DISTURBANCE levels.

Methods of making an assessment include, but are not limited to, the following:

– use of applicable standards representing the generally accepted state-of-the-art;
– comparing levels evident from medical devices already in use, being considered state-of-the-art;
– use of expert opinion;
– use of scientific research results, including clinical data;
– use of measured data, including field survey results.

The IET *Guide on EMC for Functional Safety* [36] has useful information applicable to field survey measurements.

For the case of a single source, EM DISTURBANCE levels can be obtained from direct measurement or by obtaining MANUFACTURER'S data or other published information. Other

references exist that describe methods for assessing the EM ENVIRONMENT. One such reference is IEC/TS 61000-1-2 [8], Subclauses 6.1 to 6.3. IEC/TR 61000-2-5 [9] can be used as a basis for understanding compatibility levels, from which safety levels can be evaluated.

A single source (e.g. emitter) can generate multiple EM phenomena or a single phenomenon consisting of multiple EM DISTURBANCE levels at multiple frequencies, such as RF transmitters. Such factors that are determined for the same source of EM DISTURBANCE but are based on different characteristics can be combined.

E.6 Reasonably foreseeable maximum EM DISTURBANCE levels

"Reasonably foreseeable" is generally accepted to mean the consequences that a reasonable person could expect from his or her actions. This applies to ME EQUIPMENT and ME SYSTEMS as follows: if you are aiming for a high probability of safety and bring a device into a particular EM ENVIRONMENT where it does not have sufficient IMMUNITY, it is not reasonable to expect that the device will operate safely. The consequences of this decision would be expected to be foreseeable to a reasonable person.

"Reasonably foreseeable maximum" is not the everyday (typical) exposure level expected. Neither does it mean whatever level someone can imagine. The everyday expected level would be considered to be appropriate for performance. A higher level would therefore be expected for safety because it covers a wider range of possibilities, but not higher than what is reasonably foreseeable. The current thinking is that testing to levels greater than the reasonably foreseeable maximum is not likely to result in increased safety of the ME EQUIPMENT or ME SYSTEM.

In determining these levels, one needs to consider uncertainties such as the quality of the assessment data and the effects of other EM phenomena that could be present at the same time. The PROCESS should be performed for each EM phenomenon for which this determination is necessary.

E.7 Determination of IMMUNITY TEST LEVELS

The IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE should be chosen based on a high probability of maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE. It should not be confused with RISK ASSESSMENT. The IMMUNITY TEST LEVEL should be chosen at a point that represents exposure to the reasonably foreseeable maximum EM DISTURBANCE level. This is independent from RISK mitigation following a RISK ASSESSMENT. Reducing the IMMUNITY TEST LEVEL because the probability of occurrence of HARM or the SEVERITY of that HARM is low is not appropriate.

For E.1 d), special test methods might be necessary.

See 8.9 for requirements for rounding of final IMMUNITY TEST LEVELS.

E.8 RF radiators in SPECIAL ENVIRONMENTS

One type of intentional RF radiator that is well-known is RF wireless communication services equipment. Because of the prevalence of this equipment, this collateral standard explicitly specifies requirements for IMMUNITY to EMISSIONS from this equipment in 8.10. There are also sources of RF EMISSIONS that transmit unintentionally. Examples of RF radiators the vicinity of which could be SPECIAL ENVIRONMENTS, depending on e.g. the minimum separation distance during the INTENDED USE of the ME EQUIPMENT or ME SYSTEM, include near-field communication (NFC) equipment, electronic article surveillance (EAS) (anti-theft) equipment, HF SURGICAL EQUIPMENT, and SHORT-WAVE THERAPY EQUIPMENT.

E.9 Examples of mitigations and special conditions

Example mitigations and special conditions are shown in Table E.1, listed by EM phenomenon.

Mitigations and special conditions and resulting IMMUNITY TEST LEVELS are unique to each ME EQUIPMENT and situation. These are examples only and should not be misinterpreted as recommendations or requirements.

Table E.1 – Examples of specific mitigations / environmental conditions

Phenomenon / Basic standard	Example mitigation or special condition	Example adjusted IMMUNITY TEST LEVEL	Remarks
ESD IEC 61000-4-2	Actual (not just specified) relative humidity >50 % and conductive floor	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	See IEC 61000-4-2 Table A.1 and IEC 61340 series
ESD IEC 61000-4-2	INTENDED USE for X-ray imaging: during the exposure time, no one is close to the ME EQUIPMENT except the PATIENT	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	Movements of PATIENT are very small and will not generate high electrostatic charges
Radiated RF EM fields IEC 61000-4-3	RF shielded environment, including filtering of all cables passing through the shielding (e.g. room, housing, bunker), with a minimum shielding effectiveness and filter attenuation of 20 dB	1 V/m	VG 95376-4 MIL Std 285D EN 61587-3 Example: bunker for electron accelerator
Fields from radio and TV transmitters IEC 61000-4-3	RF shielded room of an ME SYSTEM for magnetic resonance imaging	3 V/m	
Electrical fast transients / bursts IEC 61000-4-4	Signal line separation by a minimum of 30 cm required by installation guide and verified by acceptance testing.	500 V	IEC 61000-4-4 Annex B
Surges IEC 61000-4-5	Internal / external lightning protection with periodic maintenance throughout the EXPECTED SERVICE LIFE as shown in the circuit diagram / critical components list	500 V	IEC 61000-4-5, Article B.3
Conducted disturbances induced by RF fields IEC 61000-4-6	RF shielded environment including filtering of all cables passing through the shielding, with a minimum shielding effectiveness and filter attenuation of 20 dB	1 V	
RATED power frequency magnetic fields IEC 61000-4-8	PERMANENTLY INSTALLED in a controlled location ensures that no extra equipment / cables using high currents with RATED power frequency will be brought in close proximity; verified during acceptance testing and in periodic inspections throughout the EXPECTED SERVICE LIFE	No testing	
Voltage dips and interruptions IEC 61000-4-11	Uninterruptible power supply (UPS) sufficiently fast and powerful to provide the energy needed	No testing	Test applicable only to UPS

Annex F
(informative)

RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES

F.1 General

ISO 14971:2007 includes the following requirements:

- general requirements for RISK MANAGEMENT (in Clause 3);
- RISK ANALYSIS (in Clause 4);
- RISK evaluation (in Clause 5);
- RISK control (in Clause 6);
- evaluation of overall RESIDUAL RISK acceptability (in Clause 7);
- RISK MANAGEMENT report (in Clause 8);
- production and post-production information (in Clause 9).

Each of these is discussed in turn below regarding issues related to the effects of ELECTROMAGNETIC DISTURBANCES on ME EQUIPMENT or ME SYSTEMS. References are given, where more information could be helpful. Figure F.1 summarizes the function of this collateral standard in the RISK MANAGEMENT PROCESS.

NOTE Within this annex the term safety will be used to mean freedom from unacceptable RISK as defined in ISO 14971. BASIC SAFETY and ESSENTIAL PERFORMANCE are included within this definition of safety.

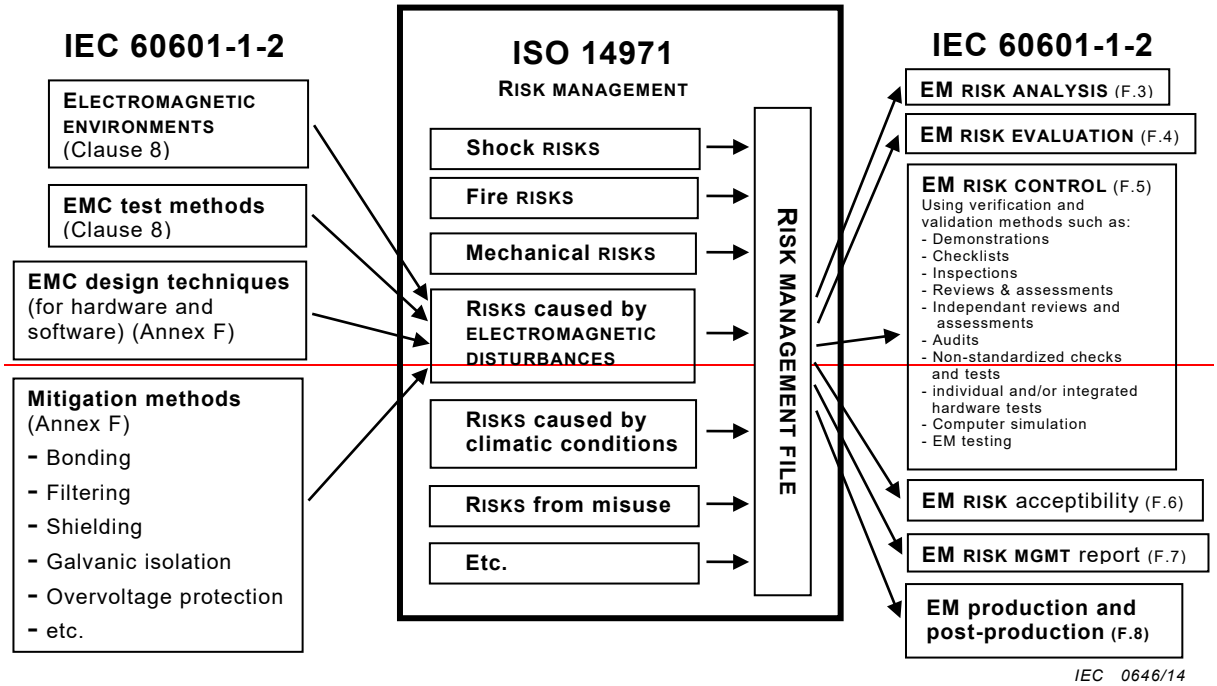


Figure F.1 – Function of this collateral standard in the RISK MANAGEMENT PROCESS

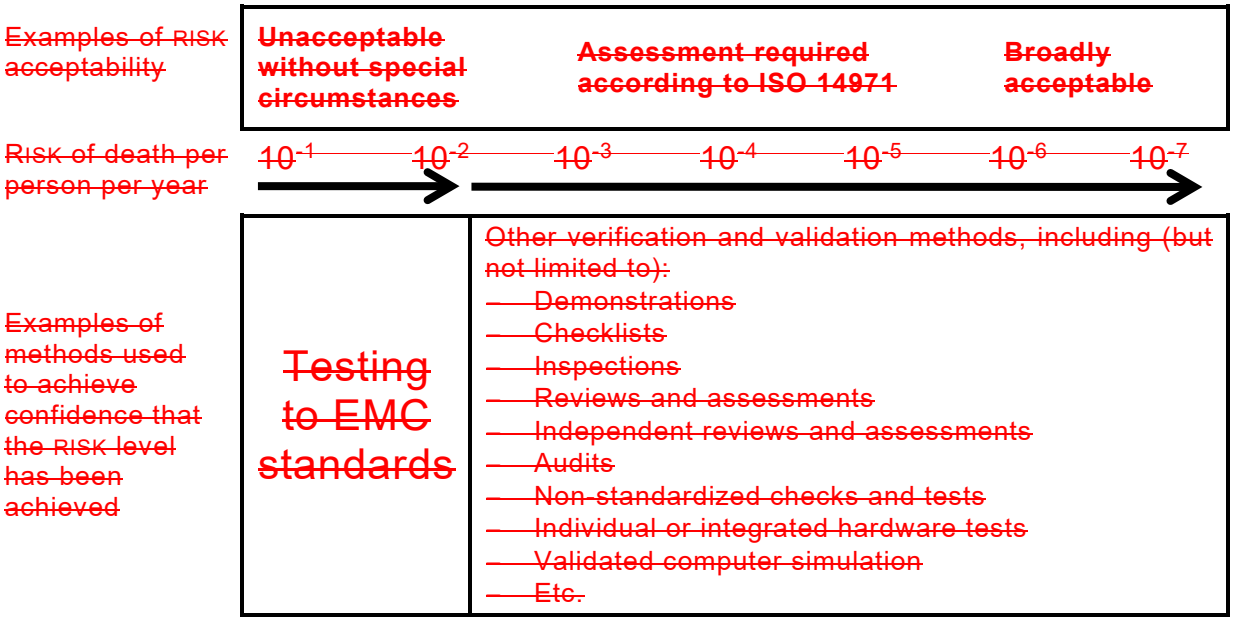


Figure F.2 – Examples of multiple VERIFICATION methods for improving confidence in RISK levels

The RISK MANAGEMENT FILE might include or reference technical arguments, calculations, simulations, VERIFICATION/validation plans (including test plans), and VERIFICATION/validation results (including test results). Note that simply testing at higher IMMUNITY TEST LEVELS is not sufficient to achieve safety.

Figure F.1 illustrates how this collateral standard fits into the RISK MANAGEMENT PROCESS.

Figure F.2 shows how the use of additional VERIFICATION methods can improve confidence in RISK levels. The numbers in Figure F.2 are speculative; however, they are used here to illustrate the fact that acceptable levels of RISK cannot be demonstrated by any practicable amount of EMC testing alone.

Other design and manufacturing VERIFICATION and validation methods (other than EMC testing) are required, except where special circumstances make very high RISK levels acceptable.

The correct application of the RISK MANAGEMENT PROCESS is not likely to result in a significant financial or testing burden. In fact, the cost of correcting problems that occur in the field is likely to be significant compared to the cost of designing and producing a safe product.

F.2 General requirements for RISK MANAGEMENT

Subclause 3.1 and Figure 1 of ISO 14971:2007 summarize the main steps of the RISK MANAGEMENT PROCESS. Other subclauses in that standard cover:

– management responsibilities;

– qualification of personnel;

– RISK MANAGEMENT plan;

– RISK MANAGEMENT.

All of these requirements apply fully to issues related to the effects of EM DISTURBANCES on both the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS.

See sections 0.8 – 0.10, 3.2 and 5.2 of the IET 2008, *Guide on EMC for Functional Safety* [36] and 5.4, 5.5 and Annex F of IEC/TS 61000-1-2:2008 [8] for more information.

F.3 RISK ANALYSIS

Subclause 4.1 of ISO 14971:2007 describes the RISK ANALYSIS PROCESS and refers to its Annex G for details of some RISK ANALYSIS techniques.

No single RISK ANALYSIS technique is considered adequate on its own. A thorough RISK ANALYSIS should include at least one 'deductive' or 'top-down' method (e.g. fault tree), and at least one 'inductive' or 'bottom-up' method (e.g. failure modes and effects analysis (FMEA)). It should also include "brainstorming" involving a wide range of people, including field service engineers, potential OPERATORS, etc.—not just designers—using one of the many proven methods (e.g. DELPHI). Human task analysis methods and similar should be used where OPERATOR interactions are concerned.

Mechanical or 'rote' application of RISK ANALYSIS methods should be avoided – it is widely accepted by RISK experts that good RISK ANALYSIS always requires the application of experience and imagination.

None of the RISK ANALYSIS methods available have been written to include the possible effects of ELECTROMAGNETIC DISTURBANCES, so EMC experience is always required when applying them for the purpose of this annex.

Sections 3 and 4 of IET 2008 [36] provide additional guidance and many useful references to RISK ANALYSIS techniques.

When applying any RISK ANALYSIS methods to comply with this collateral standard, these methods should take into account the possible effects of the EM ENVIRONMENT to which the ME EQUIPMENT or ME SYSTEM could reasonably foreseeably be exposed over its EXPECTED SERVICE LIFE. While this collateral standard specifies a set of tests for IMMUNITY to ELECTROMAGNETIC DISTURBANCES, the RISK ANALYSIS should consider additional electromagnetic phenomena, tests and standards than might be applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM over its EXPECTED SERVICE LIFE in its EM ENVIRONMENTS of INTENDED USE. The examples of additional phenomena in Table F.1 should be taken into account.

The following are examples of additional standards and tests that should be considered:

- IEC 61000-3-11 [10];
- IEC 61000-3-12 [11];
- IEC 61000-4-13 [12];
- MIL_STD-461G [38];
- EUROCAE ED-14G [39] or RTCA DO-160G [40];
- PATIENT-COUPLED cables EMISSIONS, as specified in Annex H;
- low-frequency magnetic field EMISSIONS;
- proximity magnetic field IMMUNITY, e.g. ISO 11452-8 [21];
- proximity electromagnetic field IMMUNITY, e.g. ISO 11452-9.2 [22];
- frequency bands of new RF communications equipment technologies that are not listed in Table 9.

Clause 6 of IEC/TS 61000-1-2:2008 [8], sections 1 and 2 of IET 2008 [36] and TGN 47 [33] provide additional information.

Table F.1 – Examples of EM phenomena that should be considered in a RISK ANALYSIS

EM Phenomenon	Consider in a RISK ANALYSIS
Conducted low frequency phenomena	Harmonics, interharmonics Signalling voltages Voltage fluctuations Voltage dips and interruptions Voltage unbalance Power frequency variations Induced low frequency voltages d.c. in a.c. networks
Radiated low frequency field phenomena	Magnetic fields [a)] Electric fields
Conducted HIGH FREQUENCY phenomena	Directly coupled or induced continuous voltages or currents Unidirectional transients [b)] Oscillatory transients [b)]
Radiated HIGH FREQUENCY field phenomena	Magnetic fields Electric fields Electromagnetic fields – continuous waves – transients [c)]
ELECTROSTATIC DISCHARGE phenomena (ESD)	Human and machine
Intentional EMI [d)]	

[a)] Continuous or transient.

[b)] Single or repetitive (bursts).

[c)] Single or repetitive.

[d)] To be considered in case of special conditions.

For ME EQUIPMENT and ME SYSTEMS intended to be used near active HF SURGICAL EQUIPMENT, it is particularly important to consider conducted and radiated EMISSIONS from HF SURGICAL EQUIPMENT, specifically:

a) energy conducted through the PATIENT, and

b) radiated EMISSIONS from HF SURGICAL ACCESSORY cables.

In general these EMISSIONS have high field strength and are broadband. As a result, IEC 61000-4-3 is not adequate for assuring IMMUNITY to these EMISSIONS.

Item a) is an issue for ME EQUIPMENT and ME SYSTEMS intended to have a direct connection to PATIENTS who will undergo treatment with HF SURGICAL EQUIPMENT. Item b) is an issue when HF SURGICAL ACCESSORY cables are near other ME EQUIPMENT or ME SYSTEMS. HF SURGICAL ACCESSORY cables are either 3 m or 4,6 m long, with the majority being 3 m. These cables are sterile and need to span the distance between the HF generator and the sterile operative field. It takes 1 m to 2 m for an HF SURGICAL ACCESSORY cable to exit the sterile field, leaving approximately 1 m to 2 m where this cable could interact with other ME EQUIPMENT or ME SYSTEMS.

The effects of HF SURGICAL EQUIPMENT EMISSIONS can be mitigated by testing. Test methods are specified in Annex BB of IEC 60601-2-2 and in IEC 60601-2-27 [3].

The RISK ANALYSIS methods used should also take into account the physical, climatic and use environments to which the ME EQUIPMENT or ME SYSTEM could reasonably foreseeably be exposed over its EXPECTED SERVICE LIFE.

This is because the ability of an ME EQUIPMENT or ME SYSTEM to function as intended in the presence of ELECTROMAGNETIC DISTURBANCES can be degraded by its exposure to its physical and climatic environments and by the actions of OPERATORS and third parties.

Extremes of temperature, supply voltage, shock, vibration, loading, physical forces, etc. can reduce IMMUNITY by degrading filtering, shielding and other EMI mitigation measures. For example, the paper by Beck *et. al.* [35] reports on a test that shows that—under reasonably foreseeable real-life conditions of ambient temperature and load current within the ratings of the components—an EMI filter's attenuation could degrade by 20 dB.

Ageing can also degrade IMMUNITY, and can be caused by condensation, liquid spillages and sprays (including human body fluids), mould growth, particulate matter, dust, cleaning (e.g. wire-brushing, solvents) and maintenance - plus wear and tear caused by multiple operations of controls, opening and closing of doors and access panels, temperature cycling, etc. For example, a common ageing problem is corrosion at metal joints, which degrades EMI filtering and shielding and can also degrade earth connections and so cause a very wide range of problems.[9)]

Subclause 11.6 of the general standard gives some guidance on a number of exposure issues concerning liquids and particulate matter.

For further guidance in how to determine the reasonably foreseeable physical, climatic and use environments over the EXPECTED SERVICE LIFE (lifecycle), see Clause 5 and Annex B of IEC/TS 61000-1-2:2008 [8] and sections 1 and 2 of the *Guide on EMC for Functional Safety* [36].

Tests that simulate the reasonably foreseeable operational life of an ME EQUIPMENT or ME SYSTEM, for example accelerated life tests, are recommended to help verify that the design is adequate to maintain safety over the EXPECTED SERVICE LIFE. Where such tests are performed, it is also recommended that the EMC characteristics of the ME EQUIPMENT or ME SYSTEM are assessed before and after the tests, to verify that as a result of the tests they have not become degraded to the point where RISKS have risen to unacceptable levels. It could be appropriate to assess some EMC characteristics during some tests.

The effects of reasonably foreseeable faults and use/misuse on the EMISSIONS and IMMUNITY of the ME EQUIPMENT or ME SYSTEM should be taken into account during the RISK ANALYSIS, considering the fact that one or more faults could arise at the same time as use/misuse.

The RISK ANALYSIS should take into account reasonably foreseeable simultaneous events and phenomena including ELECTROMAGNETIC DISTURBANCES, physical and climatic phenomena, faults and OPERATOR actions.

Section 4.3.7 of the *Guide on EMC for Functional Safety* [36] provides more information.

Some examples of faults and use/misuse that can affect the ability of an ME EQUIPMENT or ME SYSTEM to function as required in the presence of ELECTROMAGNETIC DISTURBANCES include:

– dry joints or short circuits;

– intermittent contacts in connectors;

– incorrect/out-of-tolerance electronic components;

– incorrect, loose or missing fasteners associated with shielding or radio-frequency bonding;

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9) See Ageing of Shielding Joints, Shielding Performance and Corrosion, by Sjögren and Bäckström [31].

– damaged or missing conductive gaskets;

– failure of a surge protection device, for example by wear-out;

– shielding doors or covers left open;

– installation or modification using an incorrect type of cable.

The RISK ANALYSIS methods used should take into account the fact that ELECTROMAGNETIC DISTURBANCES can cause degraded, distorted or false signals that could affect BASIC SAFETY or ESSENTIAL PERFORMANCE, including:

– degraded, distorted or false signals to appear at each inadequately protected PORT of one subsystem of the ME EQUIPMENT or ME SYSTEM;

– similar or different degraded, distorted or false signals to appear at two or more, or all of one component's PORTS at the same time;

– similar or different degraded, distorted or false signals to appear at one or more inadequately protected PORTS of two or more different components of an ME EQUIPMENT or ME SYSTEM at the same time.

Other examples might apply. The appearance of such signals on multiple PORTS at the same time is a very important consideration where redundancy is used to improve reliability of safety-related electronic technologies. Intermittent contacts and intermittent short-circuits and open-circuits can also cause degraded, distorted, or false signals and are significantly affected by the physical environment over the EXPECTED SERVICE LIFE.

The RISK ANALYSIS should take into account reset, latch-up and looping, including:

– reset of programmable devices;

– 'latch-up' of semiconductor hardware devices (transistors, ICs, etc.);

– 'looping' or 'crashing' of software and firmware in programmable devices.

The following is an example of phenomena that could occur simultaneously: high ambient temperature, vibration, a distorted voltage waveform from the a.c. supply, an RF field, a corroded shielding gasket, the use of an incorrect cable, and an ESD event.

Sections 3 and 4 of the *Guide on EMC for Functional Safety* [36] provide additional information. It would normally be expected that these issues would be addressed by design, rather than by testing with simultaneous phenomena.

ELECTROMAGNETIC DISTURBANCES should be fully taken into account in the following subclauses in Clause 4 of ISO 14971:2007:

– INTENDED USE and identification of characteristics related to the safety of the medical device (in Subclause 4.2);

– Identification of HAZARDS (in Subclause 4.3);

– Estimation of the RISK(s) for each HAZARDOUS SITUATION (in Subclause 4.4).

Sections 3 and 4.1 – 4.2 of the *Guide on EMC for Functional Safety* [36] provide additional information.

F.4 RISK EVALUATION

Clause 5 of ISO 14971:2007 describes the RISK EVALUATION PROCESS.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.5 RISK CONTROL

F.5.1 RISK CONTROL option analysis

Subclause 6.2 of ISO 14971:2007 describes the RISK CONTROL option analysis PROCESS to be used when RISK reduction is required.

There are many ways in which the RISKS that can be caused by ELECTROMAGNETIC DISTURBANCES can be reduced. Sections 4.3 – 4.8 and 6 of the *Guide on EMC for Functional Safety* [36] and Clause 7 and Annex B of IEC/TS 61000-1-2:2008 [8] provide more information on some of them.

NOTE 1 In addition to mitigating electromagnetic interference by e.g. shielding, filtering, there are a number of error-recovery and fail-safe techniques, using hardware or software that can often be used to help reduce the RISKS due to ELECTROMAGNETIC DISTURBANCES. These techniques can be very powerful when it is difficult to foresee the maximum level of ELECTROMAGNETIC DISTURBANCES in the EM ENVIRONMENT, or to foresee the effects of faults in ELECTROMAGNETIC IMMUNITY or mitigation over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM.

NOTE 2 It is likely that the correct application of RISK REDUCTION will not significantly affect the overall cost of the ME EQUIPMENT or ME SYSTEM.

F.5.2 Implementation of RISK CONTROL measure(s)

Subclause 6.3 of ISO 14971:2007 describes the PROCESS for implementing RISK CONTROL measure(s), to be used when RISK REDUCTION is required.

There are many ways in which the RISK CONTROL measures of F.5.1 can be verified or validated, including, but not limited to:

- demonstrations;
- checklists;
- inspections;
- reviews and assessments;
- independent reviews;
- audits (part of quality control);
- non-standardized checks and tests;
- individual and/or integrated hardware tests;
- validated computer modelling;
- testing (e.g. laboratory, factory acceptance test or on-site testing).

Sections 5.3 – 5.13, 7 and 8 of the *Guide on EMC for Functional Safety* [36] and Clauses 8 and 9 of IEC/TS 61000-1-2:2008 [8] provide more information on these.

F.5.3 RESIDUAL RISK EVALUATION

Subclause 6.4 of ISO 14971:2007 describes the RESIDUAL RISK EVALUATION PROCESS to be followed when RISK reduction is required.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.5.4 RISK/benefit analysis

Subclause 6.5 of ISO 14971:2007 describes the RISK/benefit analysis PROCESS to be followed when RISK REDUCTION is required. No additional requirements with regard to ELECTROMAGNETIC DISTURBANCES apply.

Inputs to the RISK/benefit analysis are already covered in F.3.

F.5.5 RISKS arising from RISK CONTROL measures

Subclause 6.6 of ISO 14971:2007 describes the PROCESS for dealing with the RISKS arising from RISK CONTROL measures to be followed when RISK reduction is required.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.5.6 Completeness of RISK CONTROL

Subclause 6.7 of ISO 14971:2007 describes the PROCESS for ensuring completeness of RISK CONTROL to be followed when RISK REDUCTION is required.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.6 Evaluation of overall RESIDUAL RISK acceptability

Clause 7 of ISO 14971:2007 describes the PROCESS to be followed for evaluating the acceptability of the overall RESIDUAL RISK.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.7 RISK MANAGEMENT report

Clause 8 of ISO 14971:2007 describes the PROCESS to be followed for reviewing the RISK MANAGEMENT PROCESS and recording the results in a RISK MANAGEMENT report.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 3.4 – 3.8 and 4.2 of the *Guide on EMC for Functional Safety* [36] provide more information.

F.8 Production and post-production information

Clause 9 of ISO 14971:2007 describes the PROCESS to be followed for establishing, documenting and maintaining a system to collect and review information about the ME EQUIPMENT or ME SYSTEM in the production and post-production phases.

The special issues relating to ensuring that ELECTROMAGNETIC DISTURBANCES do not interfere with provision of safety over the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM that are discussed in F.3 should be taken into account during this PROCESS.

Sections 4.6, 4.7, 5.13 and 9.2 – 9.4 of the *Guide on EMC for Functional Safety* [36] provide more information.

Guidance on the application of RISK MANAGEMENT with regard to ELECTROMAGNETIC DISTURBANCES in this collateral standard

Annex F provides specific guidance for those subclauses of this collateral standard that involve aspects of RISK MANAGEMENT. In general, this collateral standard requires the MANUFACTURER to analyse, evaluate and apply RISK CONTROLS as part of an effort to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE. The tests in this collateral standard are only one form of RISK EVALUATION.

The users of this collateral standard are reminded that particular standards IEC 60601-2-xx and ISO/IEC 80601-2-xx can include RISK MANAGEMENT requirements that could supersede (replace) those provided in this collateral standard.

NOTE 1 This collateral standard does not address how to incorporate into the design of a product RISK CONTROLS for RISKS arising from ELECTROMAGNETIC DISTURBANCES. Reference [8] provides guidance on this topic. In addition, SC 62A is developing a technical report in the IEC 60601-4-x series on RISK CONTROL with regard to ELECTROMAGNETIC DISTURBANCES.

Table F.1 lists the subclauses in this collateral standard that include RISK MANAGEMENT as part of normative requirements. Guidance is provided for these subclauses when applying RISK MANAGEMENT activities while considering the RISKS related to ELECTROMAGNETIC DISTURBANCES.

A view of the relationship between this collateral standard and ISO 14971:2019 in the form of a flowchart is provided in Figure F.1. Another useful example of the relationship between the PROCESS described in ISO 14971 and HAZARDS/HAZARDOUS SITUATIONS identified in IEC 60601-1 is provided in Figure E.1 of ISO/TR 24971:2020 [48].

NOTE 2 Subclause 3.108 of IEC 60601-1:2005+A1:2012+A2:2020 specifies the contents of the RISK MANAGEMENT FILE.

Table F.1 – Specific guidance for subclauses of this collateral standard that reference RISK MANAGEMENT *(1 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS. NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS. NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities. *Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.*	This RISK MANAGEMENT PROCESS is intended to identify whether the normative requirements specified in this collateral standard address the RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES in the environments where the ME EQUIPMENT or ME SYSTEM is intended to be used. An example of reasonably foreseeable ELECTROMAGNETIC DISTURBANCES not covered by this collateral standard is EMISSIONS from 5G mobile phones. This equipment might affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of ME EQUIPMENT or ME SYSTEMS.

Table F.1 *(2 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.2 Non-ME EQUIPMENT used in an ME SYSTEM In addition to 16.1 of the general standard: – non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment; – non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard.*	The RISK MANAGEMENT FILE needs to show the results of RISK ANALYSIS that leads to a determination of whether the non-ME EQUIPMENT is involved in any way with the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. If the non-ME EQUIPMENT is not tested in accordance with this collateral standard, there needs to be OBJECTIVE EVIDENCE (i.e. an EMC test report) showing that the non-ME EQUIPMENT meets its applicable requirements. For example, ITE used in conjunction with the ME SYSTEM needs to conform with CISPR 32 and CISPR 35 [49].
4.3 General test conditions **4.3.1 Configurations** ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. (other text omitted) *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The RISK MANAGEMENT FILE needs to show how the configurations to be tested were determined (i.e. experience, engineering analysis, or pretesting). Where the ME EQUIPMENT or ME SYSTEM has only one configuration, there should be a comment in the RISK MANAGEMENT FILE stating this. An example is an ultrasound system designed to work with several families of probes. The MANUFACTURER could select one probe from each family of probes as individual configurations for test. In this case, the RISK MANAGEMENT FILE would include justification for why the selected probe was representative of all other probes in a given family.
5.2 ACCOMPANYING DOCUMENTS **5.2.1 Instructions for use** **5.2.1.1 General** In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following: a) a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF SHIELDED ROOM of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.	If there are excluded environments as determined by RISK ANALYSIS, they need to be stated in both the instructions for use and the RISK MANAGEMENT FILE. For example, a statement in instructions for use could exclude the use of the ME EQUIPMENT or ME SYSTEM in the presence of active HF SURGICAL EQUIPMENT.

Table F.1 *(3 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS **8.1 General** (other text omitted) **Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal** If any equipment is damaged, it can continue to be used for the IMMUNITY test for this specific phenomenon, as long as it can be proven (e.g. by RISK MANAGEMENT, engineering analysis, experience, redundancy) that the ability of the ME EQUIPMENT or ME SYSTEM to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE can still be determined while using the damaged equipment. (other text omitted) Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE. IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK. (other text omitted)	RISK MANAGEMENT is applied generally in this subclause in three areas: 1) As one of several optional means to determine whether or not equipment that is being tested and subsequently damaged can continue to be used for testing. 2) Determination of pass/fail criteria when the criteria have not been provided in an applicable part two standard. 3) Provision of feedback to the RISK MANAGEMENT PROCESS concerning any effects that might be observed during testing. When RISK MANAGEMENT is used to determine any of the pass/fail criteria, the RISK MANAGEMENT FILE needs to document that this was done. If justified, Annex E is used to determine the IMMUNITY TEST LEVELS. Also see 4.1 of this table. Upon completion of testing, the effects observed need to be evaluated to determine if there is a clinical impact that could lead to unacceptable RISK. Depending on the outcome of the review, additional RISK mitigations might be required for the ME EQUIPMENT or ME SYSTEM.
Following the tests, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the on-going RISK MANAGEMENT PROCESS. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by application of the tests specified in Table 4 through Table 9 and 8.11, as applicable. If the ME EQUIPMENT or ME SYSTEM meets its specified IMMUNITY pass/fail criteria before, during and after these tests and the compliance tests of the individual subclauses of this clause are met, then compliance with Clause 8 is verified.*	

Table F.1 *(4 of 6)*

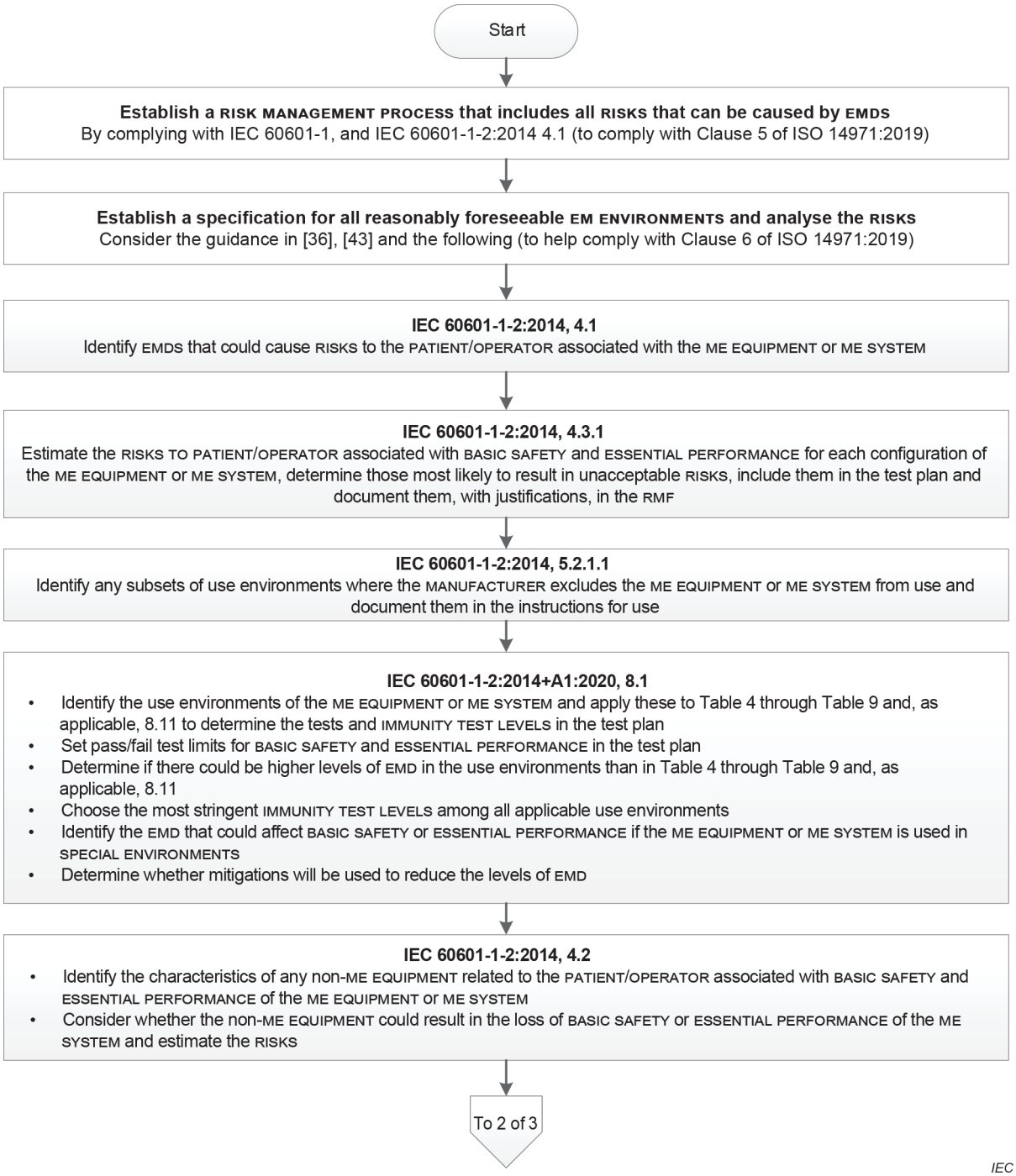
Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.5 Subsystems Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER'S knowledge of how the ME SYSTEM operates can be used to determine if normal operating conditions can be simulated. Note that normal operating conditions are, for the purposes of this subclause, defined as at least the simulation of representative electrical, mechanical, RF signals, impedances and cables and their configurations. See Annex A for further explanation regarding this subclause. The decision to perform subsystem-level testing should be documented in the RISK MANAGEMENT FILE.
8.7 Operating modes During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. If the ME EQUIPMENT or ME SYSTEM is not RATED for continuous duty, a duty cycle may be selected that is appropriate for the ME EQUIPMENT or ME SYSTEM under test. The standby mode should be considered for inclusion in IMMUNITY testing, particularly for ME EQUIPMENT and ME SYSTEMS that are in standby mode for long periods of time in the presence of PATIENTS or OPERATORS. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report.*	For ME EQUIPMENT and ME SYSTEMS that have multiple modes of operation or operational settings, the MANUFACTURER needs to first determine the specific set of modes and settings that will be used during testing. The choice of these modes and settings is made by identifying which are most likely to result in an unacceptable RISK (loss of BASIC SAFETY or ESSENTIAL PERFORMANCE) as a result of the applied ELECTROMAGNETIC DISTURBANCE. RISK ANALYSIS is one option to make the choice, but regardless, the choices made and rationale for them should be documented in the RISK MANAGEMENT FILE.
8.8 Non-ME EQUIPMENT Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER's knowledge of how the ME SYSTEM operates can be used to determine if testing of the non-ME EQUIPMENT is required according to 4.2.

Table F.1 *(5 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.9 IMMUNITY TEST LEVELS (other text omitted) When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS. Annex E may be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 4 through Table 9 and 8.11 and, when justified, to adjust the specified IMMUNITY TEST LEVELS based on e.g. mitigations or conditions of INTENDED USE. If this determination or adjustment is made, the following information should be documented in the test plan, as specified in Table G.1, and shall be documented in the RISK MANAGEMENT FILE and in the test report, as specified in Table 10: a) justification for any SPECIAL ENVIRONMENTS identified or adjustments made; b) the adjusted reasonably foreseeable maximum EM DISTURBANCE levels; c) the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit; d) details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS. If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include documentation explaining how it can be reasonably expected that the mitigations will continue to be effective over the EXPECTED SERVICE LIFE in all locations in which the ME EQUIPMENT or ME SYSTEM is expected to be used. In all cases, the IMMUNITY TEST LEVELS used should be documented in the test plan (see Annex G) and shall be documented in the test report (see Clause 9). *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	When the environment of INTENDED USE is known to alter the reasonably foreseeable EM DISTURBANCE levels specified in this collateral standard, this knowledge needs to be incorporated into the RISK MANAGEMENT PROCESS. Specifically, this information might affect the determination of IMMUNITY TEST LEVELS, which might be increased or decreased, according to Annex E. The MANUFACTURER needs to ensure that all choices and justifications for them are documented in the RISK MANAGEMENT FILE. Most importantly, it needs to explain how any mitigations applied or assumed can be reasonably expected to remain effective over the EXPECTED SERVICE LIFE, and in all locations of INTENDED USE, for the ME EQUIPMENT or ME SYSTEM. For example, if the MANUFACTURER assumes that the ME EQUIPMENT or ME SYSTEM will be used in a controlled humidity environment where the reasonably foreseeable ESD DISTURBANCE level (and the corresponding IMMUNITY TEST LEVEL) are reduced, then the RISK MANAGEMENT FILE needs to explain why the controlled humidity environment can be expected to be maintained and the ME EQUIPMENT or ME SYSTEM will only be used in that environment over its EXPECTED SERVICE LIFE.
Table 4 – ENCLOSURE PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Table 4, table footnote c), provides the option to perform the radiated RF swept test using modulations other than those given in the table. The alternative modulation frequencies would be determined by a RISK ANALYSIS. For example, if the MANUFACTURER knows that their ME EQUIPMENT or ME SYSTEM is particularly sensitive to a specific modulation frequency or range of frequencies, they might choose to use these instead of or in addition to those specified in Table 4 as they could be the highest RISK modulations.

Table F.1 *(6 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
Table 5 – Input a.c. power PORT *(1 of 2)* Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 6 – Input d.c. power PORT Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 7 – PATIENT coupling PORT Table footnotes: a), fourth indent Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 8 – SIP/SOP PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
8.10 IMMUNITY to proximity fields from RF wireless communications equipment (other text omitted) The frequencies and services listed in Table 9 are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9. (other text omitted) The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance.	For this subclause, RISK MANAGEMENT is used in two ways: 1) To identify communications services that might be encountered in the environment of INTENDED USE and that are not listed in Table 9. The RISK ANALYSIS needs to consider whether these services present a RISK, and if so, they should be documented in the RISK MANAGEMENT FILE and incorporated into the test plan. An example of this would be services for 5G mobile phones. 2) To identify whether the environment(s) of INTENDED USE for the ME EQUIPMENT or ME SYSTEM will routinely allow for exposure to RF wireless communications equipment at separation distances less than 0,3 m. The RISK ANALYSIS would determine a different reasonably foreseeable minimum separation distance and adjust the IMMUNITY TEST LEVELS (higher) to account for this scenario.
8.11 IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz (other text omitted) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, the tests of Table 11 need not be performed.	For this subclause, if the exemptions of 8.11 a) and b) do not apply, then a RISK ANALYSIS can be performed to determine if this test is necessary.



Key

EM = ELECTROMAGNETIC	EMD = EM DISTURBANCE
RMP = RISK MANAGEMENT PROCESS	RMF = RISK MANAGEMENT FILE

Figure F.1 – RISK MANAGEMENT flow in IEC 60601-1-2 *(1 of 3)*

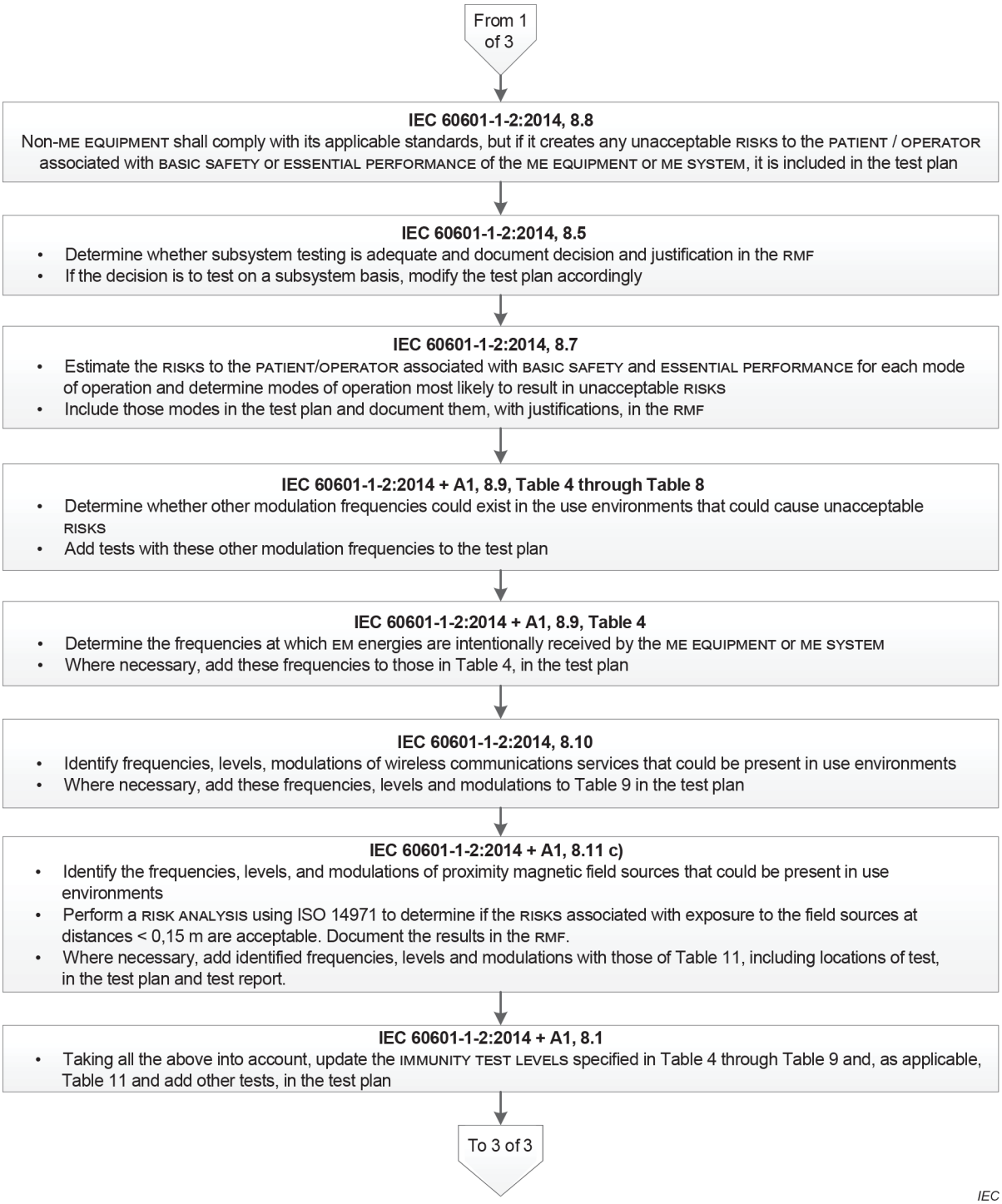


Figure F.1 *(2 of 3)*

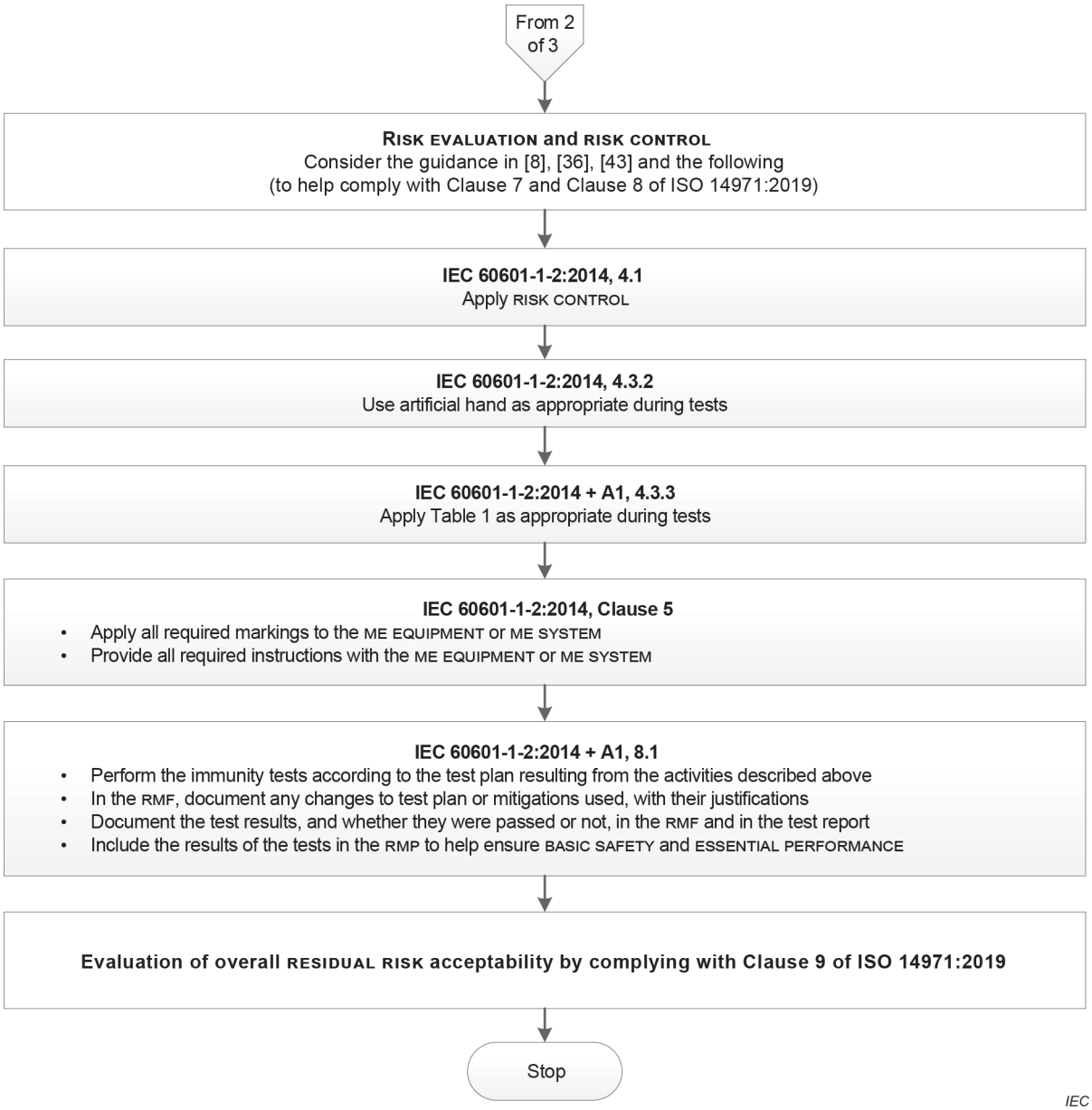


Figure F.1 *(3 of 3)*

Annex G
(informative)

Guidance: Test plan

G.1 Test plan contents

Table G.1 shows the suggested contents of a test plan.

Table G.1 – Recommended minimum test plan contents *(1 of 2)*

No.	Item	Additional detail
1	Name and address of the test facility	
2	Description of the ME EQUIPMENT or ME SYSTEM	Describe all devices, racks, modules, boards, cables, etc. belonging to the ME EQUIPMENT or ME SYSTEM.
3	Description of the BASIC SAFETY and ESSENTIAL PERFORMANCE including a description how the BASIC SAFETY and ESSENTIAL PERFORMANCE will be monitored against the pass/fail criteria during each test	
4	Identification of the ME EQUIPMENT or ME SYSTEM	Include device name and model number.
5	ME EQUIPMENT or ME SYSTEM software / firmware version of the sample to be tested	
6	Number of samples to be tested	The number of samples for each EMC test
7	INTENDED USE and intended environments	
8	Applicable standards and test methods	A list of the standards (with dates) and EMISSIONS limits or IMMUNITY TEST LEVELS
9	Deviations from the Basic EMC standards or from this collateral standard	Include any instructions needed
10	Applicability / tests that will not be performed	The decision and justification not to perform a measurement or test shall be documented.
11	If the procedure specified by Annex E or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made – the adjusted reasonably foreseeable maximum EM DISTURBANCE levels – the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit – details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS	
12	IMMUNITY TEST LEVELS for each IMMUNITY test and EMISSIONS compliance class and group	
13	IMMUNITY pass/fail criteria	Specific IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as per the RISK ANALYSIS (see Annex I)
14	ME EQUIPMENT or ME SYSTEM configurations, settings and operating modes	List by test.
15	Test setup electrical and physical diagrams	Show how the ME EQUIPMENT OR ME SYSTEM hardware will be configured and connected to the test systems, how cables will be routed and bundled, and disposition of excess cable.
16	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	List by test.

Table G.1 *(2 of 2)*

No.	Item	Additional detail
17	Earthing configuration	Describe how the ME EQUIPMENT OR ME SYSTEM connects to protective earth.
18	Whether the ME EQUIPMENT or ME SYSTEM will be tested as table-top or floor-standing equipment, or a combination of the two	
19	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or LARGE ME SYSTEM	If on-site testing is required, diagram the equipment or system in the location in which it will be installed and describe how testing will be performed.
20	Exercising of SIP/SOPS	Describe how each SIP/SOP PORT is to be exercised.
21	For floor-standing ME EQUIPMENT or ME SYSTEMS, the height of the support	
22	Description of any PATIENT-COUPLED cable terminations to be used	
23	Simulators, accessories and auxiliary equipment	Describe simulators, ACCESSORIES and auxiliary equipment used, including PATIENT physiological and subsystem simulation
24	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
25	ALARM LIMIT settings	If applicable, provide rationale for the settings chosen.
26	Planned ESD test points.	If possible, include a drawing or annotated photo showing the ESD test points.
27	Dwell time for each IMMUNITY test requiring a dwell time	
28	The locations of application of proximity magnetic fields	If the testing according to 8.11 step d) is performed.

Annex H
(informative)

PATIENT-coupled cables EMISSIONS

H.1 * Protection of other equipment from PATIENT cable conducted EMISSIONS

Conducted EMISSIONS from PATIENT-COUPLED cables should comply with the limit in Table H.1, measured using the common-mode clamp method specified in H.2. ME EQUIPMENT and ME SYSTEMS that deliver RF electromagnetic energy for diagnosis, treatment or monitoring of PATIENTS may be tested in standby mode. All other ME EQUIPMENT and ME SYSTEMS should be tested in both standby and active modes.

Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit

Frequency	Peak current
MHz	dBμA
1-30	24

H.2 Test method

For each PATIENT-COUPLED cable, the peak conducted EMISSION should be determined using a current probe having a frequency range of at least 1 MHz to 30 MHz as specified in Annex B of CISPR 16-1-2. For ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27 [3], the probe should initially be placed close to the ME EQUIPMENT or ME SYSTEM as shown in Figure H.1 and then moved to the point that maximizes the measured EMISSIONS. All other PATIENT-COUPLED cables should be non-inductively bundled and the probe should be placed at the point that maximizes the measured EMISSIONS. EMISSION measurements should be performed in accordance with the requirements in CISPR 16-1-1 [16] and should comply with the limit specified in Table H.1.

PATIENT-COUPLED cables are considered interconnecting cables in accordance with the requirements of CISPR 11. Any PATIENT-COUPLED cable termination used should be described in the documentation of the test. If simulated PATIENT physiological signals are required to simulate normal operation of the ME EQUIPMENT or ME SYSTEM, they should be provided. The PATIENT COUPLING POINT should not have an intentional conductive or capacitive connection to earth during testing.

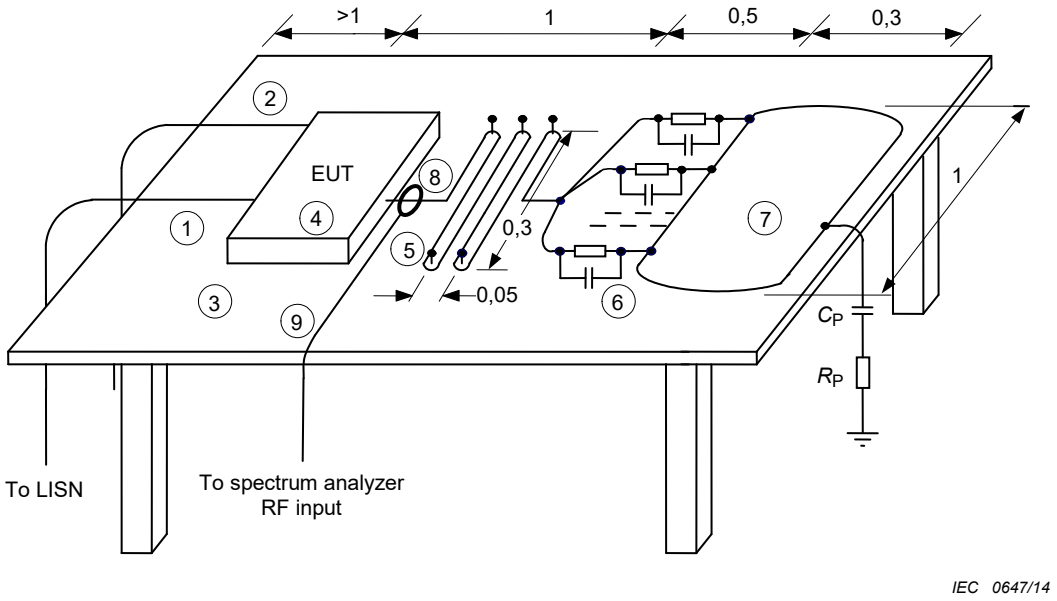
The test setup is shown in Figure H.1.

H.3 Rationale

In modern medical practice there is more and more ME EQUIPMENT coupled concurrently to the PATIENT. Often a PATIENT monitor is coupled to the same PATIENT as ULTRASOUND DIAGNOSTIC EQUIPMENT. In the electrophysiology lab there can be several separate devices coupled to the same PATIENT simultaneously. This is also true for the operating room. In fact, there is considerable evidence in medical practice that these EMISSIONS have caused image artefact in ULTRASOUND DIAGNOSTIC EQUIPMENT that was coupled to the same PATIENT as monitoring equipment. This often results from excessive coupling to the PATIENT of noise from switching power supplies.

Previously there was no specification for the amount of RF noise that PATIENT-COUPLED ME EQUIPMENT or ME SYSTEMS could couple onto the PATIENT. When there is multiple PATIENT-COUPLED ME EQUIPMENT, there can be interference from one ME EQUIPMENT to another. This

test sets a limit on the RF noise coupled to the PATIENT. It is intended to be a simple measurement that can be made quickly using the conducted EMISSIONS test setup. The RF EMISSIONS limit was set based on the susceptibility of sensitive PATIENT-COUPLED ME EQUIPMENT and ME SYSTEMS, yet accommodating the reasonably foreseeable level of RF conducted EMISSIONS from PATIENT-COUPLED APPLIED PARTS.



Components

1	Mains cable
2	Signal cable
3	Table made of insulating material
4	EQUIPMENT under test
5	PATIENT CABLE
6	Load simulating the PATIENT (51 kΩ in parallel with 47 nF)
7	Metal plate
8	Current clamp
9	Current clamp cable to spectrum analyzer RF input
C_P	220 pF
R_P	510 Ω

C_P in series with R_P simulates the body of the PATIENT.

NOTE This figure is derived from Figure 202.101 of IEC 60601-2-27:2011.

Figure H.1 – Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27

Annex I
(informative)

Identification of IMMUNITY pass/fail criteria

I.1 General

Clause 8 of this collateral standard specifies IMMUNITY TEST LEVELS. Annex E specifies methods for determining IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS. This annex provides guidance and examples to aid in the required determination of specific, detailed IMMUNITY pass/fail criteria.

I.2 IMMUNITY pass/fail criteria principles

I.2.1 General

It is necessary to identify the specific hardware, firmware, and software functions that need to be verified during IMMUNITY tests. These functions should be derived from one or more sources, including the RISK ANALYSIS. The response of these functions should be monitored, with sufficient accuracy and resolution, before, during and after IMMUNITY testing.

The IMMUNITY pass/fail criteria should be specified using quantitative values when possible. An example starting point to quantify the pass/fail criteria might be the MANUFACTURER'S accuracy specification in the ACCOMPANYING DOCUMENTS.

The selection of pass/fail criteria should include consultations with clinicians whose experience and area of expertise include the use of the particular ME EQUIPMENT or ME SYSTEM.

I.2.2 IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM

An ME SYSTEM that includes non-ME EQUIPMENT requires a determination whether additional IMMUNITY tests and pass/fail criteria are necessary.

I.2.3 IMMUNITY pass/fail criteria determination

The functions to be tested and the specific, detailed IMMUNITY pass/fail criteria should be derived from one or more sources. This includes identification of:

– the HAZARDS;
– the functions to be tested for IMMUNITY to verify freedom from unacceptable RISK;
– the criteria on which to base the pass/fail decision;
– operating modes;
– characteristics of simulated PATIENT physiological signals;
– specification of locations of INTENDED USE;
– the characteristics of the test, where these are at the discretion of the MANUFACTURER.

Part 2 standards in the IEC 60601 family can specify particular ESSENTIAL PERFORMANCE and IMMUNITY pass/fail criteria.

IMMUNITY pass/fail criteria can specify degradations that are acceptable because they do not result in unacceptable RISK.

I.3 IMMUNITY pass/fail criteria examples

I.3.1 General examples

The following are examples that can be used to develop pass/fail criteria. For ME EQUIPMENT and ME SYSTEMS with multiple functions, the pass/fail criteria should be applied to each function, parameter and channel.

Examples of test failures:

– malfunction;
– non-operation when operation is required;
– unwanted operation when no operation is required;
– deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR;
– component failures;
– change in programmable parameters;
– reset to factory defaults (MANUFACTURER's presets);
– change of operating mode;
– a FALSE POSITIVE ALARM CONDITION;
– a FALSE NEGATIVE ALARM CONDITION (failure to alarm);
– cessation or interruption of any intended operation, even if accompanied by an ALARM SIGNAL;
– initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL;
– error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
– noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring;
– artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
– failure of automatic diagnosis or treatment ME EQUIPMENT or ME SYSTEM to diagnose or treat, even if accompanied by an ALARM SIGNAL.

Example of performance during and after the applied testing stimulus required to pass the test:

– for a mammography system, the compression full release and associated command remains fully operational;
– for ULTRASOUND DIAGNOSTIC EQUIPMENT, the probe heating, dissipative power and temperature shall remain within specifications;
– safety-related functions perform as intended;
– false operation of alarms, "fail safe" modes and similar functions do not occur.

NOTE This might require performing the test twice – once to ensure the functions occur as expected and again to ensure they do not occur falsely.

Examples of acceptable degradation:

– an imaging system displays an image that could be altered, but in a way that would not affect the diagnosis or treatment;
– a heart rate monitor displays a heart rate that could be in error, but by an amount that is not clinically significant;
– a PATIENT monitor exhibits a small amount of noise or a transient on a waveform and the noise or transient would not affect diagnosis, treatment or monitoring.

Examples of ME EQUIPMENT and ME SYSTEMS with multiple functions:

– multi-parameter monitors;
– anaesthesia system with monitors;
– ventilators with monitors;
– multiple instances of the same function (e.g. multiple invasive blood pressure sensors).

Failure of therapy equipment to terminate a treatment at the intended time can be considered cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE. If the effect of the test signal on an ME EQUIPMENT or ME SYSTEM is so brief as to be transparent to the PATIENT or OPERATOR and does not affect diagnosis, monitoring or treatment of the PATIENT, this can be considered not to be cessation or interruption of an intended operation. For example, if in response to the IMMUNITY TEST LEVEL a ventilator stops pumping for 50 ms and then resumes operation such that accuracy is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

Note that it might be necessary to test the ME EQUIPMENT or ME SYSTEM multiple times, e.g. under one set of conditions to assure that it sounds an ALARM SIGNAL when it should, within the MANUFACTURER's specifications for sensitivity and response time, and under another set of conditions to assure that it does not sound an ALARM SIGNAL when it should not.

I.3.2 Example of IMMUNITY pass/fail criteria for a radiological table system

Before, during, and after the IMMUNITY tests, the radiological table system provides freedom from unacceptable RISK (see Table I.1).

This IMMUNITY pass/fail criteria determination example is an output of the RISK ANALYSIS (see).

Table I.1 – Example of IMMUNITY pass criteria for a radiological table system

No.	Function to verify for freedom from unacceptable RISK	IMMUNITY pass criteria
1	System initialization at power ON is operating correctly	No system failure able to prevent a new examination.
2	System stop and turn OFF is operating correctly	The system initialization operates correctly and the system is effective in less than xx minutes (see NOTE 1).
3	Display the PATIENT image during the X-ray acquisition	Image noise or artifact is distinguishable from physiologically-produced signals.
4	X-ray acquisition images and sequence are saved. Saved recorded images can be displayed.	PATIENT data is not lost.
5	X-ray acquisition start is under control	No uncontrolled start.
6	X-ray acquisition stop is under control	No uncontrolled stop or lock-out.
7	The positioner (table and gantry) is operating correctly.	No uncontrolled movements (see NOTE 4). The stop of the table shall be effective in yy mm maximum distance (see NOTE 1).
8	PATIENT information can be displayed.	PATIENT data is not lost.

NOTE 1 The RISK ANALYSIS and RESIDUAL RISK determination are used to determine xx, yy, and zz.

NOTE 2 During the 5 s power supply network interrupt test (IEC61000-4-11), only N images from the last acquisition sequence can be lost. The system recovers full performance in zz s maximum after the initialization sequence.

NOTE 3 More specific IMMUNITY criteria for particular subtests might be defined, depending on the RISK MANAGEMENT and RISK ANALYSIS inputs (see Annex F).

NOTE 4 While this performance could be identified to be ESSENTIAL PERFORMANCE, some standards have requirements to control unintended motion but do not identify this as ESSENTIAL PERFORMANCE (for example IEC 60601-2-44 [4]. Thus, such standards consider prevention of unintended motion to be BASIC SAFETY. The result, however, would be the same in either case. The RISK from uncontrolled movements would be unacceptable.

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Index of defined terms used in this collateral standard

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IEC 60601-1-2

Edition 4.1 2020-09
CONSOLIDATED VERSION

FINAL VERSION

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral Standard: Electromagnetic disturbances – Requirements and tests

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-2 edition 4.1 contains the fourth edition (2014-04) [documents 62A/916/FDIS and 62A/924/RVD] and its amendment 1 (2020-09) [documents 62A/1390/FDIS and 62A/1405/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-1-2 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition constitutes a technical revision.

This fourth edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

The most significant changes with respect to the previous edition include the following modifications:

– specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;
– specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT than was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;
– specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;
– specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and
– better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term “life-supporting”;

and the following additions:

– guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;
– guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;
– guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and
– guidance on identification of IMMUNITY pass/fail criteria.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this collateral standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 1 includes 1.1, 1.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 1.1, 1.2 and 1.3.1 are all subclauses of Clause 1).

References to clauses within this collateral standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this collateral standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this collateral standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this collateral standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this collateral standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this collateral standard;

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

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

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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

INTRODUCTION

The need for establishing specific standards for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

The requirements and tests specified by this collateral standard are generally applicable to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS as defined in 3.63 and 3.64 in the general standard. For certain types of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, these requirements might need to be modified by the special requirements of a particular standard. Writers of particular standards are encouraged to refer to Annex D for guidance in the application of this collateral standard.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE without interfering with other equipment and systems in the ELECTROMAGNETIC ENVIRONMENTS in which they are intended by their MANUFACTURER to be used. The application of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

– safety services;
– other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;
– non-ME EQUIPMENT (e.g. computers);
– telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the application of ELECTROMAGNETIC IMMUNITY standards is essential to ensure safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. To ensure safety, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE in the ELECTROMAGNETIC ENVIRONMENTS of INTENDED USE throughout their EXPECTED SERVICE LIFE.

This collateral standard specifies IMMUNITY TEST LEVELS for safety for ME EQUIPMENT and ME SYSTEMS intended by their MANUFACTURER for use in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. It recognizes that RF wireless communications equipment can no longer be prohibited from most PATIENT ENVIRONMENTS because in many cases it has become essential to the efficient provision of healthcare. This collateral standard also recognizes that, for certain SPECIAL ENVIRONMENTS, higher or lower IMMUNITY TEST LEVELS than those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT might be appropriate. This collateral standard provides guidance in determining appropriate IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.

The IMMUNITY TEST LEVELS specified for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on the reasonably foreseeable maximum of the ELECTROMAGNETIC DISTURBANCE phenomena in the applicable environments of INTENDED USE.

Not all ELECTROMAGNETIC DISTURBANCE phenomena are covered by this collateral standard, as it is not practical to do so. MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS need to address this during their RISK ASSESSMENT and evaluate if other ELECTROMAGNETIC DISTURBANCE phenomena could make their product unsafe. This evaluation should be based on the environments of INTENDED USE and the reasonably foreseeable maximum levels of ELECTROMAGNETIC DISTURBANCES expected throughout the EXPECTED SERVICE LIFE.

This collateral standard recognizes that the MANUFACTURER has the responsibility to design and perform VERIFICATION of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS to meet the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will remain safe throughout its EXPECTED SERVICE LIFE.

This collateral standard provides guidance in incorporating considerations regarding ELECTROMAGNETIC DISTURBANCES into the RISK MANAGEMENT PROCESS.

This collateral standard is based on existing IEC standards prepared by subcommittee 62A, technical committee 77 (ELECTROMAGNETIC COMPATIBILITY between electrical equipment including networks), ISO (International standards organization), and CISPR (International special committee on radio interference).

INTRODUCTION to Amendment 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS in the presence of ELECTROMAGNETIC DISTURBANCES and to ELECTROMAGNETIC DISTURBANCES emitted by ME EQUIPMENT and ME SYSTEMS.

BASIC SAFETY with regard to ELECTROMAGNETIC DISTURBANCES is applicable to all ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES and for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone, including any amendments;
– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;
– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
Amendment 1:2020

IEC 60601-1-12:2014 *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-3:2012, *Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment*

IEC 61000-3-2:2005[2)], *Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
Amendment 1:2008
Amendment 2:2009

IEC 61000-3-3:2013, *Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3:2006[3)], *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*
Amendment 1:2007
Amendment 2:2010

IEC 61000-4-4:2012, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

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2) There exists a consolidated edition 3.2, including IEC 61000-3-2:2005 and its Amendment 1:2008 and Amendment 2:2009.

3) There exists a consolidated edition 3.2, including IEC 61000-4-3:2006 and its Amendment 1:2007 and Amendment 2:2010.

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017

IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8:2009, *Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test*

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques –Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

IEC 61000-4-39:2017, *Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test*

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
Amendment 1:2016
Amendment 2:2019

CISPR 14-1:2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*
Amendment 1:2017

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*

ISO 7637-2:2011, *Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only*

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012+A2:2020, IEC 60601-1-8:2006+A1:2012+A2:2020, IEC 60601-1-11:2015+A1:2020, IEC 60601-1-12:2014+A1:2020, IEC 60601-2-2:2009, IEC 60601-2-3:2012 and the following definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

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

NOTE 3 An index of defined terms is found beginning on page 101.

3.1
*** EFFECTIVE RADIATED POWER** (of any device in a given direction)
ERP
the power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

Note 1 to entry: As used by the ITU and as used in Chapter 712 of the International Electrotechnical Vocabulary, the term "EFFECTIVE RADIATED POWER" appears without qualification only when the reference antenna is a half-wave dipole.

[SOURCE: IEC 60050-161:1990, 161-04-16, modified — Note 1 has been made clearer.]

3.2
ELECTROMAGNETIC COMPATIBILITY
EMC
ability of ME EQUIPMENT or an ME SYSTEM to function satisfactorily in its EM ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment

[SOURCE: IEC 60050-161:1990, 161-01-07, modified — "an equipment or system" has been changed to "ME EQUIPMENT or an ME SYSTEM".]

3.3
ELECTROMAGNETIC DISTURBANCE
EM DISTURBANCE
any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

Note 1 to entry: An ELECTROMAGNETIC DISTURBANCE can be ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

[SOURCE: IEC 60050-161:1990,161-01-05, modified — "which" has been changed to "that" and "may" has been changed to "could" and "can", respectively, and the phrase "or adversely affect living or inert matter" has been deleted.]

3.4
(ELECTROMAGNETIC) EMISSION
the phenomenon by which electromagnetic energy emanates from a source

[SOURCE: IEC 60050-161:1990, 161-01-08]

3.5
ELECTROMAGNETIC ENVIRONMENT
EM ENVIRONMENT
the totality of electromagnetic phenomena existing at a given location

Note 1 to entry: In general, the EM ENVIRONMENT is time dependent and its description might need a statistical approach.

[SOURCE: IEC 60050-161:1990, 161-01-01, modified — "may" has been changed to "might" in the note.]

3.6
ELECTROSTATIC DISCHARGE
ESD
a transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact

[SOURCE: IEC 60050-161:1990, 161-01-22]

3.7
ENCLOSURE PORT
physical boundary of the ME EQUIPMENT or ME SYSTEM that electromagnetic fields can radiate through or impinge on

Note 1 to entry: According to Annex A of the general standard, the ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.

[SOURCE: IEC 61000-6-1:2005, 3.2, modified — clarification added, “apparatus” changed to “ME EQUIPMENT or ME SYSTEM”, “may” changed to “can”, “which” changed to “that” and rationale from IEC 60601-1 for the definition of ENCLOSURE added in the form of a note to entry.]

3.8
*** IMMUNITY (TO A DISTURBANCE)**
the ability of ME EQUIPMENT or an ME SYSTEM to perform without degradation in the presence of an ELECTROMAGNETIC DISTURBANCE

[SOURCE: IEC 60050-161:1990, 161-01-20, modified — “a device, equipment or system” has been changed to “ME EQUIPMENT or an ME SYSTEM”.]

3.9
IMMUNITY TEST LEVEL
the level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test

[SOURCE: IEC 60050-161:1990, 161-04-41]

3.10
INFORMATION TECHNOLOGY EQUIPMENT
ITE
equipment designed for the purpose of

a) receiving data from an external source (such as a data input line or via a keyboard);
b) performing some processing functions on the received data (such as computation, data transformation or recording, filing, sorting, storage, transfer of data);
c) providing a data output (either to other equipment or by the reproduction of data or images)

Note 1 to entry: This definition includes electrical or electronic units or systems that predominantly generate a multiplicity of periodic binary pulsed electrical or electronic waveforms and are designed to perform data processing functions such as word processing, electronic computation, data transformation, recording, filing, sorting, storage, retrieval and transfer, and reproduction of data as images.

[SOURCE: IEC 60050-161:1990, 161-05-04]

3.11
INTERMITTENT MODE
for an X-ray generator, mode of loading an X-ray tube where the electric energy is supplied to the tube in single, intermittent or pulsed loadings, as for example in radiography, cineradiography

[SOURCE: IEC/TR 60788:2004, rm-36-41]

3.12
LARGE ME EQUIPMENT
ME EQUIPMENT that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables

3.13
LARGE ME SYSTEM
ME SYSTEM that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables; this includes distributed ME SYSTEMS

3.14
LOW VOLTAGE
line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V a.c. or 1 500 V d.c.

3.15
PATIENT-COUPLED
term referring to the presence of a path for the transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

3.16
PATIENT COUPLING POINT
a sensing or treatment point of ME EQUIPMENT that is necessary to achieve the INTENDED USE of the ME EQUIPMENT or an ME SYSTEM and that provides a path for transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

3.17
PORT
access to a device or network where electromagnetic energy or signals can be supplied or received or where the device or network variables can be observed or measured

Note 1 to entry: Examples of PORTS include terminal pairs, PATIENT cables (PATIENT CONNECTIONS), SIGNAL INPUT/OUTPUT PARTS such as data ports and USB connections, battery charger connections, and the ENCLOSURE itself (i.e. ENCLOSURE PORT).

[SOURCE: IEC 60050-131:2002, 131-12-60, modified — “may” has been changed to “can” and more examples have been added to the note to entry.]

3.18
*** PUBLIC MAINS NETWORK**
LOW VOLTAGE electricity power lines to which all categories of consumers have access

3.19
RADIO FREQUENCY
RF
a frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission

[SOURCE: ANSI C63.14 4.313, modified — the note regarding the practical limits of RADIO FREQUENCY has been omitted.]

3.20
SPECIAL ENVIRONMENT
ELECTROMAGNETIC ENVIRONMENT with electromagnetic characteristics different from those specified in this collateral standard in Table 2 through Table 9 and Table 11 or that requires EMISSIONS limits, IMMUNITY TEST LEVELS or test methods that are different from those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT

4 General requirements

4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS

RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS.

NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS.

NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities.

Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.

4.2 * Non-ME EQUIPMENT used in an ME SYSTEM

In addition to 16.1 of the general standard:

– non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment;

– non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard.

4.3 General test conditions

4.3.1 * Configurations

ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK. as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting.

These configurations shall include:

– attachment of cables to all PORTS as necessary to achieve the INTENDED USE (including SIP/SOPs and, if applicable, the POTENTIAL EQUALIZATION CONDUCTOR);

– attachment of all tubing and filling of all fluid containers;

– termination of the cables with the intended equipment, subsystem simulators as specified in 7.1.4 and 8.5, PATIENT physiological simulators as specified in 7.1.9 and 8.2 or artificial hands as specified in 7.1.10 and 8.4;

– earthing on the ENCLOSURE PORT, if applicable, including connections to the terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR;

– use of cables and connectors that meet the specifications of the ME EQUIPMENT or ME SYSTEM MANUFACTURER.

Special ME EQUIPMENT or ME SYSTEM hardware or software might be needed to perform the tests specified in Clause 7 and Clause 8. If so, this should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

4.3.2 Artificial hand

Where an artificial hand is required by this collateral standard, it shall be connected as follows:

– For PATIENT COUPLING POINTS that do not have a conductive contact, the PATIENT COUPLING POINT is terminated with the artificial hand and (series) RC element shown in Figure 9a of 8.3 of CISPR 16-1-2 (see Figure 1). The metal foil of the artificial hand is sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of the RC element and the other terminal of the RC element is connected to the ground reference plane.

– For PATIENT COUPLING POINTS that have conductive contact to the PATIENT (PATIENT CONNECTION), terminal M of the RC element is connected directly to the PATIENT COUPLING POINT, and the other terminal of the RC element is connected to the ground reference plane. If normal operation of the ME EQUIPMENT or ME SYSTEM cannot be verified with terminal M connected to the PATIENT COUPLING POINT, an insulating material with a maximum thickness of 5 mm may be applied between the metal foil of the artificial hand and the PATIENT COUPLING POINT. In this case, the metal foil of the artificial hand is to be sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE, and terminal M of the RC element is to be connected to the metal foil but not to the PATIENT COUPLING POINT. The other terminal of the RC element is connected to the ground reference plane in all cases.

– For ME EQUIPMENT and ME SYSTEMS that have multiple PATIENT COUPLING POINTS intended to be connected to a single PATIENT, each PATIENT COUPLING POINT and each PATIENT-COUPLED part is to have an artificial hand applied as specified above. The artificial hands are connected to a single common connection and this common connection is connected to terminal M of the RC element, as specified in 8.3 of CISPR 16-1-2. For ME EQUIPMENT and ME SYSTEMS intended to be connected to multiple PATIENTS, artificial hands are to be applied as specified above and a separate common connection and RC element is to be used for each PATIENT for which the capacitive coupling effect and RF impedance is to be simulated. The other terminal of each RC element is connected to the ground reference plane in all cases.

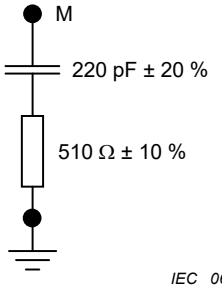


Figure 1 – RC element of the artificial hand

4.3.3 * Power input voltages and frequencies

If a test is applicable, it shall be performed using the power input voltages and frequencies specified in Table 1. The test report shall list the actual voltages and frequencies used during testing.

Compliance is checked by inspection of the test report.

Table 1 – Power input voltages and frequencies during the tests *(1 of 2)*

Test	Power input voltage	Power frequency
Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	Minimum and maximum RATED voltage [c) d)]	Any one frequency [b)]
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Any one voltage [a)]	Any one frequency [b)]
Harmonic current EMISSIONS IEC 61000-3-2	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 240 V or 380 V to 415 V: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz or 60 Hz
Voltage changes, voltage fluctuations and flicker EMISSIONS IEC 61000-3-3	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 250 V line to neutral: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz
ELECTROSTATIC DISCHARGE IMMUNITY IEC 61000-4-2	Any one voltage [a)]	Any one frequency [b)]
Radiated RF electromagnetic field IMMUNITY IEC 61000-4-3	Any one voltage [a)]	Any one frequency [b)]
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	Any one voltage [a)]	Any one frequency [b)]
Electrical fast transient/burst IMMUNITY – a.c. mains IEC 61000-4-4	Any one voltage [a)]	Any one frequency [b)]
Electrical fast transient/burst IMMUNITY – I/O SIP/SOP PORTS IEC 61000-4-4	Any one voltage [a)]	Any one frequency [b)]
Surge IMMUNITY IEC 61000-4-5	Any one voltage [a)]	Any one frequency [b)]
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) – a.c. mains IEC 61000-4-6	Any one voltage [a)]	Any one frequency [b)]
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted DISTURBANCE IMMUNITY) – SIP/SOP PORTS IEC 61000-4-6	Any one voltage [a)]	Any one frequency [b)]

Table 1 *(2 of 2)*

Test	Power input voltage	Power frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage [a)]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the power frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. [b)]
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage [c) d)]	Any one frequency [b)]
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage [a)]	Any one frequency [b)]
Proximity magnetic fields IEC 61000-4-39	Any one voltage [a)]	Any one frequency [b)]

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.

c) If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.

d) ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

5.1 Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT

In addition to the requirements of 7.2 of the general standard, ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT shall be labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location.

Compliance is checked by inspection of the ME EQUIPMENT or ME SYSTEM.

5.2 ACCOMPANYING DOCUMENTS

5.2.1 Instructions for use

5.2.1.1 * General

In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following:

a) * a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

b) * the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

c) * a warning statement to the effect that “WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.”

The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.

d) * a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE).

Transducers and cables specified by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components need not be listed.

e) * a warning statement to the effect that “WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”

f) * a warning statement to the effect that: “WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

In the above warning, “[ME EQUIPMENT or ME SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.

If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in 8.10.

5.2.1.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11

In addition to the requirements of 7.9.2 of the general standard, for ME EQUIPMENT and ME SYSTEMS that are classified class A according to CISPR 11, the instructions for use shall include the following note:

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

5.2.2 Technical description

5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

In addition to the requirements of 7.9.3 of the general standard, the technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES.

For all ME EQUIPMENT and ME SYSTEMS, the technical description shall include the following information:

a) the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL;

b) any deviations from this collateral standard and allowances used;

c) * all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

5.2.2.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location (see 7.1.5), the technical description shall include the following information:

a) a warning to the effect that: “WARNING: Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services”;

b) specifications for the shielded location, including:
   – minimum RF shielding effectiveness;
   – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and
   – the frequency range(s) over which the specifications apply;

c) recommended test methods for measurement of RF shielding effectiveness and RF filter attenuation;

d) one or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location:
   – a specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM;
   – a list of specific equipment allowed;
   – a list of types of equipment prohibited.

5.2.2.3 Requirements applicable to ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation (RF receivers), the technical description shall include the following information:

– each frequency or frequency band of reception;
– the preferred frequency or frequency band, if applicable; and
– the bandwidth of the receiving section of the ME EQUIPMENT in those bands.

5.2.2.4 Requirements applicable to ME EQUIPMENT that includes RF transmitters

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that includes RF transmitters, the technical description shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.

5.2.2.5 Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

In addition to the requirements of 7.9.3 of the general standard, for PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, the technical description shall include the following information:

a) a statement that an exemption has been used and that the equipment has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 000 MHz;

b) a warning to the effect that “WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation”; and

c) a list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

5.2.2.6 Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT

In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT, the technical description shall include a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery.

For all of 5.2, compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

6 Documentation of the tests

6.1 General

The documentation of the tests shall contain all the information necessary to facilitate adequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced.

Compliance is checked by inspection of the test report.

6.2 Test plan

Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory. Deviations from the test plan shall be documented in the test report. See Annex G for guidance on the recommended content of a test plan.

6.3 Test report

The test report shall meet the requirements of Clause 9.

7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

7.1 Protection of radio services and other equipment

7.1.1 * General

Unless otherwise specified herein, ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 11. See Annex C for guidance on classification according to CISPR 11.

NOTE For further guidance on test setups, see CISPR 16-2-3.

7.1.2 Operating modes

During EMISSIONS testing, the ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS. In addition to testing for EMISSIONS in active modes, inclusion of standby mode should be considered. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report.

7.1.3 Multimedia equipment

Multimedia equipment connected to ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 32. If CISPR 32 class A equipment is supplied as part of an ME SYSTEM, the ME SYSTEM shall be classified class A.

NOTE Multimedia equipment includes INFORMATION TECHNOLOGY EQUIPMENT (ITE).

7.1.4 * Subsystems

Compliance with CISPR 11 may be demonstrated by testing each subsystem of an ME SYSTEM on a subsystem basis, provided the requirements of CISPR 11 for evaluation of equipment that interacts with other equipment to form a system are met.

7.1.5 ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT

For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements specified below.

For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that enter or exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified below.

a) The specified RF shielding effectiveness and RF filter attenuation shall;
   - be expressed in dB;
   - be rounded to the nearest integer; and
   - be at least 20 dB.

b) The RF shielding effectiveness and RF filter attenuation specification shall include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range shall be at least one decade in width.

c) The specified value(s) for minimum RF filter attenuation shall be identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified.

d) In frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation shall be assumed to be 0 dB for the purpose of this collateral standard.

7.1.6 ME EQUIPMENT and ME SYSTEMS that include radio equipment

ME EQUIPMENT and ME SYSTEMS that include radio equipment (e.g. RF transmitters, receivers, transceivers) and have been tested together with the radio equipment and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this collateral standard in the dedicated transmission band of the transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this collateral standard shall apply.

7.1.7 * ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

The scope of this collateral standard includes ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices. Examples include motor-driven electromedical apparatus such as simple dental drills and simple operation tables. Unless the ME EQUIPMENT intentionally generates RF energy or is intended for illumination, it may be classified in accordance with CISPR 14-1. If so, the corresponding limits of CISPR 14-1 shall apply.

7.1.8 ME EQUIPMENT and ME SYSTEMS containing X-ray generators

For diagnostic X-ray generators and ME SYSTEMS that include X-ray generators operating in INTERMITTENT MODE, the quasi-peak limits to discontinuous radiated and conducted DISTURBANCES can be relaxed by 20 dB. This relaxation does not apply to average limits.

7.1.9 PATIENT physiological simulation

If PATIENT physiological simulation is required for normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during the test. PATIENT physiological simulation shall not provide, to PATIENT-COUPLED connections, an intentional conductive or capacitive connection to earth during testing except as specified in 4.3.2.

As an alternative to the termination methods specified in 4.3.2, if PATIENT physiological simulation is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulation shall provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified in 4.3.2.

Any PATIENT simulation used should be documented in the test plan and shall be documented in the test report.

7.1.10 Artificial hand

The artificial hand requirements of CISPR 11 apply to mains terminal disturbance EMISSIONS testing (see the NOTE in Table 1) with the additional requirement that PATIENT-COUPLED parts of ME EQUIPMENT and ME SYSTEMS and ME EQUIPMENT intended to be HAND-HELD shall be terminated during the test as specified in 4.3.2.

7.1.11 PATIENT-coupled cables

PATIENT-COUPLED cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11.

7.1.12 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:

– on a test site as a system;

– on a test site on a subsystem basis;

– *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS that comply with CISPR 11 group 1 class A or class B limits may be tested *in situ* and shall comply with the CISPR 11 limits for equipment measured on a test site.

Compliance with 7.1 is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.2 Protection of the PUBLIC MAINS NETWORK

7.2.1 * Harmonic distortion

ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that are intended to be connected to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-2. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-2.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.2.2 * Voltage fluctuations and flicker

ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that is intended for connection to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-3. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-3.

NOTE Subclause 6.1 of IEC 61000-3-3 begins as follows: "Tests need not be made on equipment which is unlikely to produce significant voltage fluctuations or flicker… It may be necessary to determine, by examination of the circuit diagram and specification of the equipment and by a short functional test, whether significant voltage fluctuations are likely to be produced".

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.

7.3 EMISSIONS requirements summary

The EMISSIONS requirements are summarized in Table 2.

Table 2 – EMISSION limits per environment

Phenomenon	Professional healthcare facility environment [a)]	HOME HEALTHCARE ENVIRONMENT [a)]
Conducted and radiated RF EMISSIONS	CISPR 11	CISPR 11 [c)]
Harmonic distortion	See IEC 61000-3-2 [b)]	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3 [b)]	See IEC 61000-3-3

[a)] See 8.9 for information about the environments of INTENDED USE.

[b)] This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

[c)] Standards applicable to modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

8.1 * General

The IMMUNITY test requirements for ME EQUIPMENT and ME SYSTEMS are specified by this collateral standard on a PORT-by-PORT basis. This follows the convention of the IEC 61000-6 series of Generic EMC standards. Figure 2 shows the PORTS of ME EQUIPMENT and ME SYSTEMS for the purpose of IMMUNITY testing.

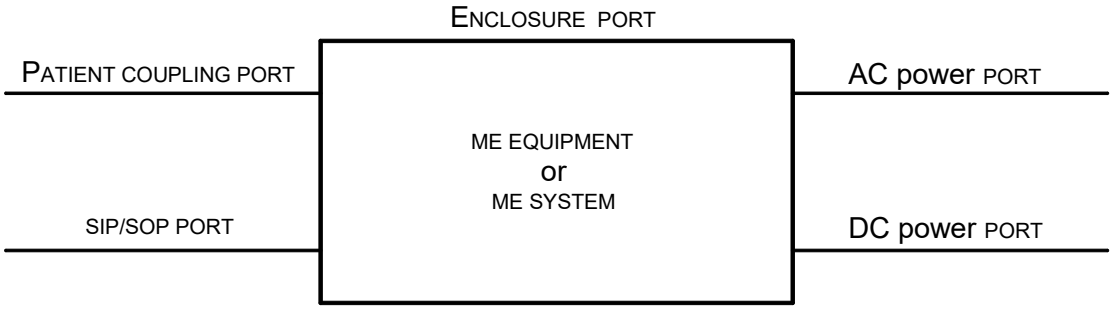


Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS

ELECTROMAGNETIC IMMUNITY tests:

– shall be performed in a well-defined and reproducible manner,
– shall be performed individually as single tests in sequence, and
– may be performed in any order.

At least one of each type of PORT (e.g. having the same input or output electronic circuits, loads, connected equipment) shall be connected during IMMUNITY testing. If the ME EQUIPMENT or ME SYSTEM has multiple identical PORTS, it is only necessary to test one of each type during IMMUNITY testing.

For the case in which the ME EQUIPMENT or ME SYSTEM is damaged by an IMMUNITY test signal, Table 3 specifies how to proceed with the remainder of the IMMUNITY test.

NOTE 1 For example, if an expensive ME SYSTEM is damaged by the first ESD discharge, it can be assumed that little useful information will be gained by making nine more identical discharges to the same test point to the same or to equivalent ME SYSTEMS.

Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal

Type of test	Reaction of ME EQUIPMENT or ME SYSTEM during test	How to continue with testing
Transient [a]	The ME EQUIPMENT or ME SYSTEM is permanently damaged. However, BASIC SAFETY and ESSENTIAL PERFORMANCE continue to be provided.	The test sequence shall be repeated two times with this IMMUNITY TEST LEVEL and polarity. The ME EQUIPMENT or ME SYSTEM passes the test if it continues to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE. If any equipment is damaged, it can continue to be used for the IMMUNITY test for this specific phenomenon, as long as it can be proven (e.g. by RISK MANAGEMENT, engineering analysis, experience, redundancy) that the ability of the ME EQUIPMENT or ME SYSTEM to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE can still be determined while using the damaged equipment. If a PORT of the ME EQUIPMENT or ME SYSTEM is damaged and the ME EQUIPMENT or ME SYSTEM has multiple identical ports, the test shall not be repeated on any of the identical ports. To test the next non-identical PORT, the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation. To continue with the IMMUNITY test of the next EM phenomenon, the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation.
	The ME EQUIPMENT or ME SYSTEM is permanently damaged. BASIC SAFETY or ESSENTIAL PERFORMANCE does not continue to be provided.	The ME EQUIPMENT or ME SYSTEM has failed the test.
Continuous [b]	The ME EQUIPMENT or ME SYSTEM is permanently damaged. However, BASIC SAFETY and ESSENTIAL PERFORMANCE continue to be provided.	The test sequence shall be repeated two times with this IMMUNITY TEST LEVEL and polarity or frequency. BASIC SAFETY and ESSENTIAL PERFORMANCE shall continue to be provided. To continue with the next frequency step the ME EQUIPMENT or ME SYSTEM shall be restored to normal operation.
	The ME EQUIPMENT or ME SYSTEM is permanently damaged. BASIC SAFETY or ESSENTIAL PERFORMANCE does not continue to be provided.	The ME EQUIPMENT or ME SYSTEM has failed the test.

[a] Tests according to IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5 and IEC 61000-4-11

[b] Tests according to IEC 61000-4-3, IEC 61000-4-6 and IEC 61000-4-8

The IMMUNITY test requirements shall be applied to the PORTS of the ME EQUIPMENT or ME SYSTEM as specified in Table 4 through Table 9 and 8.11 according to the environments (locations) of INTENDED USE (see Figure 3). Table 4 through Table 9 and 8.11 specify IMMUNITY requirements and test conditions for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. The procedure specified in Annex E can be used to determine IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS or, if justified, can be used to modify the IMMUNITY TEST LEVELS of Table 4 through Table 9 and 8.11 (higher or lower, as appropriate), based on specific EM characteristics of specific environments or specific mitigations that might be provided by the ME EQUIPMENT or ME SYSTEM or the conditions of INTENDED USE. If justified, higher or lower IMMUNITY TEST LEVELS determined using the procedure specified in Annex E may be used in place of those specified in Table 4 through Table 9 and 8.11.

NOTE 2 IMMUNITY TEST LEVELS are calculated individually for each phenomenon.

NOTE 3 Use of Annex E can permit more precise assessment of the EM phenomena and EM DISTURBANCES in the EM ENVIRONMENTS of INTENDED USE and these can be used to determine IMMUNITY TEST LEVELS that are more specific to the INTENDED USE of the ME EQUIPMENT or ME SYSTEM.

For ME EQUIPMENT and ME SYSTEMS for which the INTENDED USE includes types of transportation (e.g. land, sea and air vehicles) or other locations in the HOME HEALTHCARE ENVIRONMENT such as those that can be accessed by walking (e.g. near radiofrequency identification (RFID) systems, anti-theft systems), if additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher than those specified in Table 4 through Table 9 and 8.11 are appropriate or are specified by standards applicable to a mode or EM ENVIRONMENT of transportation, these additional tests and higher IMMUNITY TEST LEVELS shall apply.

NOTE 4 An example of a standard that might be applicable to ME EQUIPMENT and ME SYSTEMS with INTENDED USE that includes aircraft is EUROCAE ED-14G [39] or RTCA DO-160G [40].

ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT shall meet the requirements of Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT, and 8.11. If locations in the EMERGENCY MEDICAL SERVICES ENVIRONMENT are identified for which the specifications for the HOME HEALTHCARE ENVIRONMENT are not adequate, Annex E may be used to determine appropriate IMMUNITY TEST LEVELS.

Test methods and test equipment are specified in the test methods and Basic EMC standards referenced in Table 4 through Table 9 and 8.11. The entire contents of the Basic EMC standards are not repeated here; however, modifications or additional information needed for the practical application of the tests to ME EQUIPMENT and ME SYSTEMS are given in this collateral standard.

If the INTENDED USE of the ME EQUIPMENT or ME SYSTEM includes more than one environment, the most stringent IMMUNITY TEST LEVELS among all the applicable environments shall apply.

If testing is performed according to the requirements for the HOME HEALTHCARE ENVIRONMENT as specified in Table 4 through Table 8, additional testing according to the requirements of the professional healthcare environment as specified in Table 4 through Table 8 is not required.

The dwell time for IMMUNITY tests shall be based on the settling time of the test system and the time required for the ME EQUIPMENT or ME SYSTEM to be exercised (if applicable) and adequately respond to the test signal.

The power frequency for all IMMUNITY tests may be selected at any one of the NOMINAL power frequencies of the ME EQUIPMENT or ME SYSTEM, except as otherwise specified in Table 1.

Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE.

IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK.

NOTE 5 Guidance and examples for determining specific, detailed IMMUNITY pass/fail criteria are provided in Annex I.

ME EQUIPMENT and ME SYSTEMS shall meet the IMMUNITY pass/fail criteria during and after the IMMUNITY tests. For transient phenomena for which it might not be practical to assess performance during the application of the transient, assessing performance before and after the test is acceptable.

Table 10 requires that the effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES shall be documented in the test report (see Clause 9).

Following the tests, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the on-going RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by application of the tests specified in Table 4 through Table 9 and 8.11, as applicable. If the ME EQUIPMENT or ME SYSTEM meets its specified IMMUNITY pass/fail criteria before, during and after these tests and the compliance tests of the individual subclauses of this clause are met, then compliance with Clause 8 is verified.

8.2 PATIENT physiological simulation

If simulation of the PATIENT is required to verify normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during IMMUNITY testing. During testing according to IEC 61000-4-4 and IEC 61000-4-6, PATIENT physiological simulation shall not provide additional conductive or capacitive connection to earth (other than needed to simulate the PATIENT or OPERATOR) except as specified in 4.3.2.

As an alternative to the termination methods specified in 4.3.2, for the IMMUNITY tests for which they are required by 8.3 to be used, if PATIENT physiological simulation is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulation shall provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified in 4.3.2.

Prior to the beginning of the test, the amplitude of simulated PATIENT physiological signals shall be adjusted to be consistent with normal operation of the ME EQUIPMENT or ME SYSTEM, as specified by the MANUFACTURER, with the exception that if applicable, the amplitude of simulated PATIENT physiological signals shall be adjusted to approximately twice the detection threshold.

NOTE The signal is set close to the threshold but above it, so that the outcome of the test is not penalized by the statistics of detection and the noise floor of the detection circuitry. Setting the simulated signal at twice the threshold of detection (detection threshold plus 6 dB) puts the signal close to and above but not at the threshold of detection.

Compliance is checked by inspection of the test report.

8.3 Termination of PATIENT-COUPLED parts

For testing according to IEC 61000-4-4 and IEC 61000-4-6, the conditions specified in 4.3.2 apply. These conditions may also be used in other tests, as specified by the MANUFACTURER.

8.4 HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD

For testing according to IEC 61000-4-4 and IEC 61000-4-6 the following condition applies:

HAND-HELD ME EQUIPMENT and parts of ME EQUIPMENT intended to be HAND-HELD while providing its INTENDED USE shall be tested with an artificial hand applied as specified in 8.3 of CISPR 16-1-2, sized and placed to simulate the approximate area and location of OPERATOR coupling while providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of an RC element, as specified in 8.3 of CISPR 16-1-2 (see Figure 1), and the other terminal of the RC element shall be connected to the ground reference plane. These conditions may also be used in other tests, as specified by the MANUFACTURER. If HAND-HELD ME EQUIPMENT also has PATIENT-COUPLED parts, the PATIENT-COUPLED parts shall also have artificial hands applied as specified in 4.3.2, consistent with INTENDED USE.

8.5 * Subsystems

Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

8.6 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:

– on a test site as a system;

– on a test site on a subsystem basis;

– *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS that are constructed in such a way that simulated operation of subsystems is not feasible are exempt from the testing requirements of IEC 61000-4-3 specified in 8.9 and 8.10. If this exemption is used, such PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be tested for IMMUNITY to this phenomenon by TYPE TEST, either at one installation site or on an open area test site, using the RF sources (e.g. radio (mobile/cellular/cordless) telephones, walkie-talkies, radio-frequency identification (RFID) systems, other legal transmitters) that are expected to be operating in any of the locations of INTENDED USE. In addition, testing shall be performed in the range 80 MHz to 6 GHz at frequencies designated by the International Telecommunications Union (ITU) for ISM use. The power of, and distance from, any source used shall be adjusted to provide the applicable IMMUNITY TEST LEVELS of Table 4 according to the locations of INTENDED USE and the IMMUNITY TEST LEVELS of Table 9, with the exception that the actual modulations may be used (e.g. for radio (mobile/cellular/cordless) telephones, walkie-talkies).

The frequencies designated by the ITU for ISM use can be found in Volume I of the ITU Regulations ([31]) and in CISPR 11, Table 1.

NOTE Use of 1 kHz AM instead of actual modulation could be especially useful in the ISM bands.

This exemption applies only to the test methods specified by IEC 61000-4-3. Except as specified in this paragraph, the other requirements of 8.9, 8.10 and 8.11 apply to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS. The exception is that if the applicable Basic EMC standard allows *in situ* testing, the allowance in the Basic EMC standard shall take precedence.

Compliance is checked by inspection of the test report.

8.7 * Operating modes

During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. If the ME EQUIPMENT or ME SYSTEM is not RATED for continuous duty, a duty cycle may be selected that is appropriate for the ME EQUIPMENT or ME SYSTEM under test. The standby mode should be considered for inclusion in IMMUNITY testing, particularly for ME EQUIPMENT and ME SYSTEMS that are in standby mode for long periods of time in the presence of PATIENTS or OPERATORS. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report.

8.8 * Non-ME EQUIPMENT

Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.

8.9 * IMMUNITY TEST LEVELS

IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS shall be according to the professional healthcare facility environment, HOME HEALTHCARE ENVIRONMENT, and SPECIAL ENVIRONMENT, based on the locations of INTENDED USE as shown in Figure 3 and specified in Table 4 through Table 9 and 8.11. If applicable, an INTENDED USE location not shown in Figure 3 shall be assigned to an environment with a similar location, as determined by the MANUFACTURER.

When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS. Annex E may be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 4 through Table 9 and 8.11 and, when justified, to adjust the specified IMMUNITY TEST LEVELS based on e.g. mitigations or conditions of INTENDED USE. If this determination or adjustment is made, the following information should be documented in the test plan, as specified in Table G.1, and shall be documented in the RISK MANAGEMENT FILE and in the test report, as specified in Table 10:

a) justification for any SPECIAL ENVIRONMENTS identified or adjustments made;

b) the adjusted reasonably foreseeable maximum EM DISTURBANCE levels;

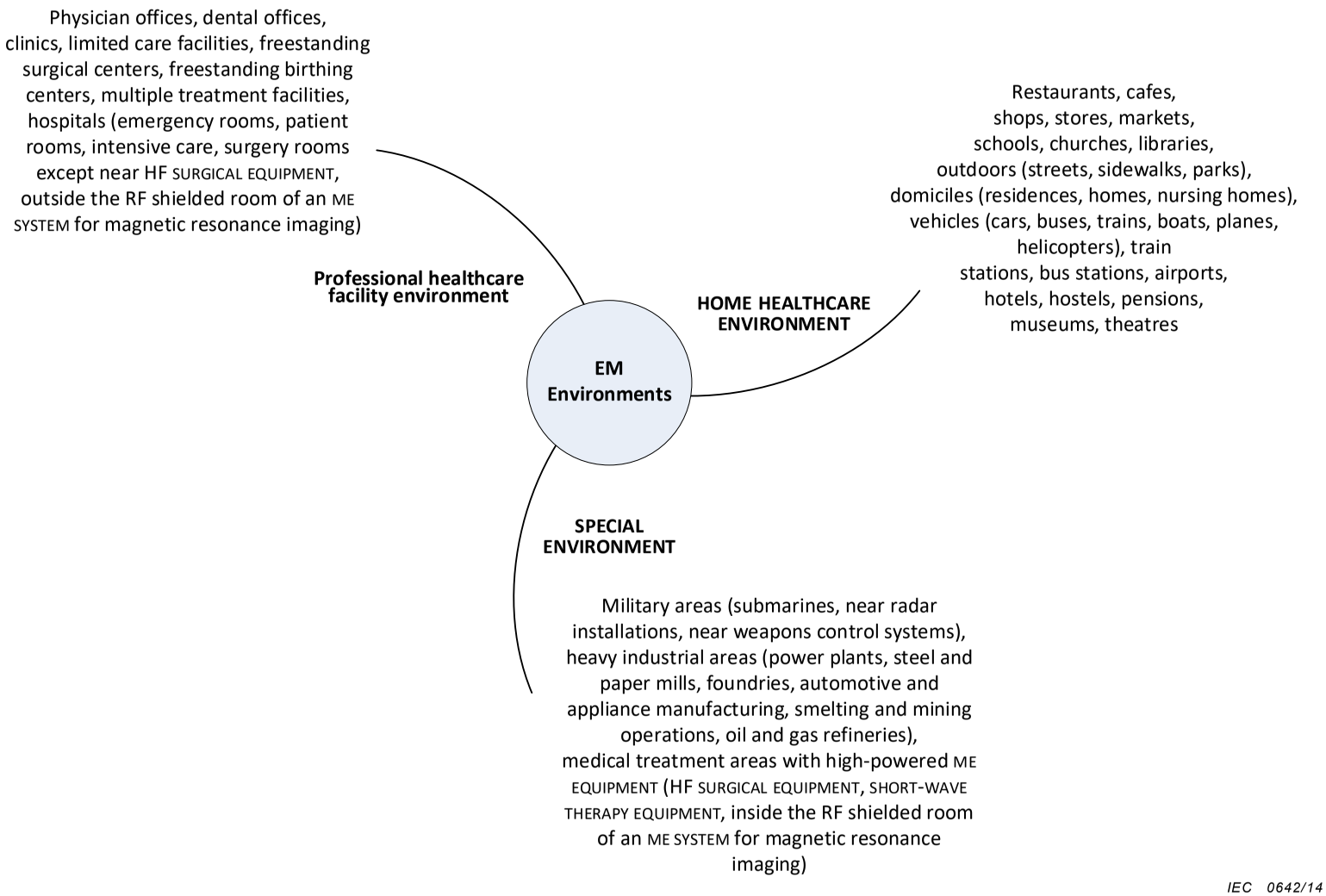
c) the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit;

d) details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS.

If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include documentation explaining how it can be reasonably expected that the mitigations will continue to be effective over the EXPECTED SERVICE LIFE in all locations in which the ME EQUIPMENT or ME SYSTEM is expected to be used.

In all cases, the IMMUNITY TEST LEVELS used should be documented in the test plan (see Annex G) and shall be documented in the test report (see Clause 9).

Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.



Although healthcare professionals are present in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, the ELECTROMAGNETIC ENVIRONMENT is similar to that of the HOME HEALTHCARE ENVIRONMENT. Therefore, for the purposes of this collateral standard, the EMISSIONS and IMMUNITY requirements of the HOME HEALTHCARE ENVIRONMENT apply to ME EQUIPMENT and ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT. An example of such a location is an ambulance.

Figure 3 – Examples of locations within EM ENVIRONMENTS

Table 4 – * ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]	10 V/m [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10.	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Proximity magnetic fields	IEC 61000-4-39	See 8.11.	

[a] The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

[b] ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

[c] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

[d] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

[e] Void

[f] Before modulation is applied.

Table 5 – * Input a.c. power PORT *(1 of 2)*

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts [l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % U_T; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o)]	IEC 61000-4-11	0 % U_T; 250/300 cycle [h)]	

a) Void

b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

Table 5 *(2 of 2)*

j)	ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
k)	Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
l)	Direct coupling shall be used.
m)	r.m.s., before modulation is applied.
n)	The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
o)	Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
p)	Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
q)	At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r)	For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1.

Table 6 – Input d.c. power PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts [a) g)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) g)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) g)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [a) c) d) i)]	IEC 61000-4-6	3 V [h)] 0,15 MHz – 80 MHz 6 V [h)] in ISM bands between 0,15 MHz and 80 MHz [j)] 80 % AM at 1 kHz [e)]	3 V [h)] 0,15 MHz – 80 MHz 6 V [h)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [j)] 80 % AM at 1 kHz [e)]
Electrical transient conduction along supply lines [f)]	ISO 7637-2	Not applicable	As specified in ISO 7637-2

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.

b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test

c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.

d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems

g) Direct coupling shall be used.

h) r.m.s., before modulation is applied.

i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

j) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 7 – * PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE [c]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0,15 MHz – 80 MHz 6 V [b] in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V [b] 0,15 MHz – 80 MHz 6 V [b] in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

[a] The following apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] r.m.s., before modulation is applied

[c] Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 8 – SIP/SOP PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE [e]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	
Surges Line-to-ground [a]	IEC 61000-4-5	± 2 kV	
Conducted disturbances induced by RF fields [d] [g] [j] [k]	IEC 61000-4-6	3 V [h] 0,15 MHz – 80 MHz 6 V [h] in ISM bands between 0,15 MHz and 80 MHz [i] 80 % AM at 1 kHz [c]	3 V [h] 0,15 MHz – 80 MHz 6 V [h] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [i] 80 % AM at 1 kHz [c]

[a] This test applies only to output lines intended to connect directly to outdoor cables.

[b] SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

[c] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

[d] Calibration for current injection clamps shall be performed in a 150 Ω system.

[e] Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

[f] Capacitive coupling shall be used.

[g] If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

[h] r.m.s., before modulation is applied.

[i] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[j] See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

[k] SIP/SOPS whose maximum cable length is less than 1 m are excluded.

8.10 * IMMUNITY to proximity fields from RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table 9 using the test methods specified in IEC 61000-4-3.

The frequencies and services listed in Table 9 are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.

8.11 * IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz shall be evaluated according to steps a) through d) below. MANUFACTURERS may proceed directly to step d). The result of the evaluation for each applicable step shall be documented in the test report or RISK MANAGEMENT FILE, as applicable. See also Figure A.3.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

a) ME EQUIPMENT and ME SYSTEMS that do not contain magnetically sensitive components or circuitry within the ENCLOSURE or as part of an attached ACCESSORY need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

b) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in Table 11 is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

c) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, then the tests of Table 11 need not be performed; otherwise,

d) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry not meeting the separation distance criteria in b) or the RISK acceptability criteria in c) shall be tested for IMMUNITY to magnetic fields as specified in Table 11 using the test methods specified in IEC 61000-4-39. The magnetic field shall be applied only to those surfaces of the ENCLOSURE or attached ACCESSORIES that are accessible during INTENDED USE. The test windows to be used with IEC 61000-4-39 may be selected to illuminate only the area of the magnetically sensitive components or circuitry. The location of application of the magnetic field should be specified in the test plan and shall be documented in the test report.

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

[b)] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c)] r.m.s., before modulation is applied.

9 * Test report

The test report shall include the items listed in Table 10. Additional information may be added to the test report as necessary.

Table 10 – * Minimum test report contents *(1 of 2)*

No.	Item	Additional detail
1	Name and location of the test facility	
2	Names and functions or equivalent identification of the persons authorizing the test report	
3	Description of the ME EQUIPMENT or ME SYSTEM	Include the device name, model number and MANUFACTURER.
4	Description of the BASIC SAFETY AND ESSENTIAL PERFORMANCE including a description how the BASIC SAFETY AND ESSENTIAL PERFORMANCE were monitored during each test	
5	ME EQUIPMENT or ME SYSTEM software / firmware version	
6	Prototype or production version of the ME EQUIPMENT or ME SYSTEM	Additionally, the relationship of the model tested to production models may be described.
7	Units tested and the rationale for the selected sample size.	Include serial numbers.
8	INTENDED USE and intended environments	
9	Applicable standards and test methods	A list of the standards (with dates) and EMISSIONS limits or IMMUNITY TEST LEVELS
10	Deviations from the Basic EMC standards or from this collateral standard	
11	Applicability / tests not performed	The decision and justification not to perform a measurement or test shall be documented.
12	If the procedure specified by Annex E or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made – the adjusted reasonably foreseeable maximum EM DISTURBANCE levels – the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit – details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS	
13	IMMUNITY TEST LEVEL for each IMMUNITY test and EMISSIONS compliance class and group	
14	IMMUNITY pass/fail criteria	Specific IMMUNITY criteria for BASIC SAFETY AND ESSENTIAL PERFORMANCE per the RISK ANALYSIS.
15	Environmental conditions as required by the relevant Basic EMC standards	
16	Compliance summary statement	Compliance of the ME EQUIPMENT or ME SYSTEM with each test.
17	Test data that support the compliance determination for each test performed	Include units of measurement
18	ME EQUIPMENT or ME SYSTEM configuration during the test, including a block diagram	Block diagram of the ME EQUIPMENT or ME SYSTEM and all peripherals and auxiliary equipment used.
19	ME EQUIPMENT or ME SYSTEM settings and operating modes	List by test.
20	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	Record the ME EQUIPMENT or ME SYSTEM power input voltages and frequencies for each test.

Table 10 *(2of 2)*

No.	Item	Additional detail
21	Any connections to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR, if used	Include information on connection to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR used during testing, if any.
22	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or LARGE ME SYSTEM: Frequencies, power and modulation of the RF test sources and test distances used.	
23	Use of SIP/SOPS, as applicable	
24	Description of any PATIENT-COUPLED cable termination used	
25	Description and position of interconnecting cables. The layout of excess cable shall be noted.	The length, shielding, ferrites and other construction details should be described. Photographs are also helpful.
26	Simulators, ACCESSORIES and auxiliary equipment	Describe simulators, accessories and auxiliary equipment used, including PATIENT physiological and subsystem simulation.
27	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
28	Test equipment used, including calibration or maintenance dates	
29	Test parameters used, e.g. frequencies, phase angles, as applicable	
30	Dwell time for each IMMUNITY test requiring a dwell time	
31	ESD test points	Photograph or drawing depicting the exact ESD test points with discharge method identified
32	Measured conducted and radiated EMISSIONS	Tabular data of at least the six highest EMISSIONS for each test shall be included.
33	The methods used to reduce the impact of ambients	
34	Measured harmonics and flicker EMISSIONS	
35	ME EQUIPMENT OR ME SYSTEM modifications	Describe ME EQUIPMENT or ME SYSTEM modifications needed in order to pass any of the EMISSIONS or IMMUNITY tests. A statement that they will all be incorporated into production units.
36	Effects on the ME EQUIPMENT or ME SYSTEM that were observed during or after the application of the test DISTURBANCES, and the duration for which these effects persisted	
37	Photographs of each test setup including the ME EQUIPMENT or ME SYSTEM and all peripherals and auxiliary equipment used.	
38	The locations of application of proximity magnetic fields.	If the testing according to 8.11 step d) is performed.
NOTE This table provides additional detail to 5.10 of ISO 17025:2005 [25].		

Annex A
(informative)

General guidance and rationale

A.1 Safety and performance

The scope of this collateral standard includes safety (BASIC SAFETY and ESSENTIAL PERFORMANCE) with regard to ELECTROMAGNETIC DISTURBANCES, which is also called EMC for safety.

The words “Electromagnetic compatibility” have been deleted from the title of this collateral standard based on the following text from IEC/TS 61000-1-2:2001 [7]:

Whether a test on the influence of an electromagnetic phenomenon on the behaviour of an equipment [sic] should be included in an EMC standard (or clause) or in a safety standard (or clause) is dependent on the approval criterion:

– If it is required that during or after the test the equipment continue to operate as intended, the test should be included in an EMC IMMUNITY standard (or clause) of a product (product family).
– If it is required that during or after the test no unsafe situation occurs (performance may be degraded incidentally or permanently, but not resulting in an unsafe situation), the test should be included in a safety standard (or clause). It is obvious that for products with safety functions the IMMUNITY levels may be chosen to be higher than in the generic standards for that environment.

NOTE The text above was removed from IEC/TS 61000-1-2:2008 in favour of “EMC for functional safety”.

Because this collateral standard is a safety standard, it is clear that the term “EMC” should not be used without qualification to refer to the requirements.

A.2 Testing of normally non-observable functions

If a function associated with ESSENTIAL PERFORMANCE (e.g. HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS) cannot normally be observed or verified during IMMUNITY testing, a method should be provided (e.g. display of internal parameters) for determining compliance. The use of special software or hardware might be needed.

A.3 Rationale for particular clauses and subclauses

Subclause 1.1 – Scope

Electrical/electronic infrastructure (e.g. existing local area networks, telecommunications networks, power networks) need not be tested in accordance with this collateral standard as part of an ME SYSTEM. However, the effects of such electrical/electronic infrastructure should be considered as part of RISK MANAGEMENT in accordance with ISO 14971, and electrical/electronic infrastructures intended to be used as part of an ME SYSTEM should be simulated during testing or assumed to fail. Equipment provided by the MANUFACTURER of the ME SYSTEM and intended to be connected to the ME SYSTEM by way of existing electrical/electronic infrastructure should meet the requirements of this collateral standard. If local area networks or telecommunications networks are supplied as part of an ME SYSTEM by the MANUFACTURER of the ME SYSTEM, they should be tested as specified in this collateral standard, as part of the ME SYSTEM.

Definition 3.1 – EFFECTIVE RADIATED POWER

The definition implies that the substitution method is used. Thus, to find the ERP, the power flux density is measured at a specified distance and direction. Then a lossless half-wave dipole is substituted for the equipment under test and the input power is adjusted to produce the same power flux density at the specified distance and direction. This input power is then the ERP.

If for example the reference antenna is isotropic instead of a half-wave dipole, then the term does receive qualification and becomes “effective isotropically radiated power” (EIRP).

Definition 3.8 – IMMUNITY (TO A DISTURBANCE)

IMMUNITY is the case in which there is no degradation. While the tests check for no degradation, some specified amount of degradation is usually considered a “pass” (acceptable) according to the pass/fail criteria and the RISK MANAGEMENT PROCESS.

Definition 3.18 – PUBLIC MAINS NETWORK

In CISPR 11, the PUBLIC MAINS NETWORK is called the “low-voltage power supply network which supplies buildings used for domestic purposes” and “domestic electricity power supplies”. In IEC 61000-3-2 and IEC 61000-3-3 it is called the “public supply system”, the “public low-voltage system”, and the “public low-voltage distribution system”.

ME EQUIPMENT and ME SYSTEMS are not connected to the PUBLIC MAINS NETWORK if they are used in locations, e.g. hospitals, in which the mains connection is isolated from the public LOW-VOLTAGE power supply network by transformers or substations.

Subclause 4.2 – Non-ME EQUIPMENT used in an ME SYSTEM

The purpose of this subclause is to limit additional (duplicative) testing of non-ME EQUIPMENT used in an ME SYSTEM to the non-ME EQUIPMENT that can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

The MANUFACTURER needs to perform an analysis on the ME SYSTEM to determine whether or not interference with the non-ME EQUIPMENT can result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. This analysis is part of the RISK MANAGEMENT PROCESS.

If the analysis shows that interference with the non-ME EQUIPMENT can result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, then the non-ME EQUIPMENT is required to be tested as part of the ME SYSTEM. If non-ME EQUIPMENT has previously been tested to its respective IEC or ISO EMC standards with equivalent test procedures and the same or higher IMMUNITY TEST LEVELS, the MANUFACTURER still needs to assess whether the acceptance (pass/fail) criteria were equivalent to those that would show that BASIC SAFETY and ESSENTIAL PERFORMANCE would not be affected.

For example:

EMISSIONS:

If non-ME EQUIPMENT is used in an ME SYSTEM, the non-ME EQUIPMENT should fulfil the same EMISSIONS requirements as the ME SYSTEM, proven by the applicable product standards of the non-ME EQUIPMENT.

IMMUNITY:

Consider if failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

– If failure or degradation of the non-ME EQUIPMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, apply to the non-ME EQUIPMENT the same IMMUNITY TEST LEVELS specified for the ME SYSTEM, based on the environments of INTENDED USE.

– If failure or degradation of the non-ME EQUIPMENT does not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, compliance with the product standard of the non-ME EQUIPMENT is sufficient.

When the non-ME EQUIPMENT only needs to meet its respective EMC standards, the appropriate documentation such as a declaration of conformity can be obtained from the original equipment MANUFACTURER and included in the design documentation.

Subclause 4.3.3 – Power input voltages and frequencies

The specifications for the IEC 61000-3-2 and IEC 61000-3-3 tests are copied directly from the Basic EMC standards.

IEC 61000-3-2:2005 Clause 6 states: “The requirements and limits specified in this clause are applicable to the power input terminals of equipment intended to be connected to 220/380 V, 230/400 V and 240/415 V systems operating at 50 Hz or 60 Hz. Requirements and limits for other cases are not yet considered.”

The Scope of IEC 61000-3-3:2013 states: “This part of IEC 61000 is applicable to electrical and electronic equipment having an input current equal to or less than 16 A per phase, intended to be connected to public low-voltage distribution systems of between 220 V and 250 V line to neutral at 50 Hz, and not subject to conditional connection.” In addition, subclause 6.3 states: “The test supply voltage (open-circuit voltage) shall be the RATED voltage of the equipment. If a voltage range is stipulated for the equipment, the test voltage shall be 230 V single-phase or 400 V three-phase.”

See also the rationale for 7.2.1 and 7.2.2.

Table 1, table footnote [c)], provides the MANUFACTURER with an allowance to perform testing at any one RATED input voltage when the difference between the maximum and minimum RATED input voltage is less than 25 % of the highest RATED input voltage. Table A.2 provides several examples of the calculation and associated conclusion for testing at a single RATED input voltage.

Table A.2 – Example calculations for applying the allowance to test at a single RATED power input voltage

Min. V	Max. V	Max. – Min. V	25 % of Max. V	(Max. – Min.) < 25 % of Max.?	Testing at one voltage allowed?
100	120	20	30	Yes	Yes
100	127	27	31,75	Yes	Yes
100	240	140	60	No	No
200	240	40	60	Yes	Yes
380	480	100	120	Yes	Yes

Subclause 5.2.1.1 – General

Additional requirements for the Instructions for use have been added in this edition of this collateral standard to help improve the safe use of ME EQUIPMENT and ME SYSTEMS with regard to EM DISTURBANCES.

NOTE Defined terms are not printed in SMALL CAPITALS in the sample text for warning statements that are required to appear in the instructions for use or the technical description because they are intended for the OPERATOR or RESPONSIBLE ORGANIZATION, who might not be familiar with the defined terms of IEC 60601 standards.

Subclause 5.2.1.1 a), Environments of INTENDED USE

Because some EMISSIONS and IMMUNITY requirements are different for the different EM ENVIRONMENTS of INTENDED USE, it is important that users have access to this information so that they can select ME EQUIPMENT and ME SYSTEMS appropriately and assure that they are used in the appropriate EM ENVIRONMENTS.

Subclause 5.2.1.1 b), ESSENTIAL PERFORMANCE

This information is required because different MANUFACTURERS might identify different ESSENTIAL PERFORMANCE for the same type of ME EQUIPMENT or ME SYSTEM, it is not possible to assure IMMUNITY under all possible conditions and because the MANUFACTURER might have observed performance degradation during the tests specified by this collateral standard, e.g. at an IMMUNITY TEST LEVEL that might have been higher than required. This requirement does not mention BASIC SAFETY and reminds the user of this collateral standard that the defined term "ESSENTIAL PERFORMANCE" need not be used in this statement, as does 5.2.2.1 c), because OPERATORS cannot be expected to know about the defined terms of IEC 60601 standards.

Subclause 5.2.1.1 c), Adjacent and stacked use warning

The adjacent and stacked use warning has been moved to the Instructions for use because the Instructions for use is the preferred location for warnings. This warning is needed because this collateral standard does not yet specify IMMUNITY tests for proximity magnetic or electric fields.

Subclause 5.2.1.1 d), List of cables, etc.

This list or specification is intended to be used with the ACCESSORY warning discussed below and it is important because ACCESSORIES, transducers and cables can affect the EMISSIONS and IMMUNITY of ME EQUIPMENT and ME SYSTEMS.

Subclause 5.2.1.1 e), ACCESSORY warning

This warning is intended to assure that for ACCESSORIES, transducers and cables that can affect the EMISSIONS or IMMUNITY of the ME EQUIPMENT or ME SYSTEM, ACCESSORIES, transducers and cables are chosen that will allow the ME EQUIPMENT or ME SYSTEM to continue to meet the EMISSIONS and IMMUNITY requirements of this collateral standard.

Subclause 5.2.1.1 f), PORTABLE RF communications equipment warning

This warning is intended to make PATIENTS and OPERATORS aware of the minimum separation distance that should be maintained between PORTABLE RF communications equipment and ME EQUIPMENT and ME SYSTEMS in order to avoid potential performance degradation and compromise of BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 5.2.2.1 a), Compliance for each EMISSIONS and IMMUNITY standard

This requirement replaces in part the requirements specified in Edition 3 to include tables of compliance levels and EMC guidance in the ACCOMPANYING DOCUMENTS. While a MANUFACTURER can choose to put the information in such a format, this collateral standard does not mandate the format for this information. This labelling requirement is particularly important because if the procedure in Annex E is used, IMMUNITY TEST LEVELS might be different from those expected, i.e. those specified in Table 4 through Table 9 and 8.11. Furthermore, RESPONSIBLE ORGANIZATIONS might not be familiar with this collateral standard and thus might not be aware of the IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11.

Subclause 5.2.2.1 c)

Providing the RESPONSIBLE ORGANIZATION with maintenance instructions with regard to EM DISTURBANCES is a good and practical way for the MANUFACTURER to assure that the ME EQUIPMENT or ME SYSTEM remains safe with regard to EM DISTURBANCES throughout the EXPECTED SERVICE LIFE.

For example, the technical description could include the following recommendations for actions that are known to affect the EMISSIONS and IMMUNITY of equipment throughout the EXPECTED SERVICE LIFE:

- recommendations for maintenance or service intervals;
- service procedures to maintain effectiveness of shields and grounds;
- precautions to take if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas.

NOTE AAMI TIR 18 [28] provides guidance in management of the EM ENVIRONMENT and management of medical devices for EMC, including assessment of the EM ENVIRONMENT, investigation and reporting of EMI problems and site selection, design, and construction of new healthcare facilities. Table A.3 of AAMI TIR 18:2010 shows field strengths at 1 km from FIXED transmitters such as AM, FM and TV broadcast antennas.

Subclause 7.1.1 – General

The EMISSIONS requirements have been simplified compared to those of IEC 60601-1-2:2007. As part of this simplification, references to CISPR 15 are not included in this collateral standard. These references sometimes caused confusion. In addition, CISPR 14-1 limits (other than for toys) on radiated disturbances only cover up to 1 GHz, which is not adequate for ME EQUIPMENT and ME SYSTEMS. The scope of CISPR 15 is limited to lighting equipment and does not include ME EQUIPMENT or ME SYSTEMS explicitly, thus causing confusion by being referenced from IEC 60601-1-2:2007. The scope of CISPR 15 excludes equipment for which the EMC requirements in the radio-frequency range are explicitly formulated in other IEC or CISPR standards. Therefore, this collateral standard specifies CISPR 11 for all ME EQUIPMENT and ME SYSTEMS except where indicated otherwise.

Subclause 7.1.4 – Subsystems

Care needs to be taken that testing on a subsystem basis is appropriate. For example, if EMISSION amplitudes add, because two or more subsystems have the same clock frequency, unless this is adequately simulated, it would be more appropriate to test the equipment as a system. This might also be the case if MANUFACTURERS of connected subsystems have different specifications for the interconnecting cables.

Subclause 7.1.7 – ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

According to CISPR 14-1, the scope includes such equipment as: household electrical appliances, electric tools, regulating controls using semiconductor devices, motor-driven electro-medical apparatus, electric/electronic toys, automatic dispensing machines as well as cine or slide projectors. Both mains powered appliances and battery powered appliances are included.

An example of ME EQUIPMENT that cannot be classified according to CISPR 14-1, because it intentionally generates RF energy, is SHORT-WAVE THERAPY EQUIPMENT. Examples of ME EQUIPMENT that cannot be classified according to CISPR 14-1 because they are intended for illumination are surgical lights and examination lights.

Subclause 7.1.12 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for EMISSION testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;

– on a test site on a subsystem basis;

– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For some ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation, or equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT or ME SYSTEMS that cannot fit within a 2 m x 2 m x 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration. Such a test would likely not fulfil the "worst case" or "modes that maximize EMISSIONS" approach of CISPR 11/IEC 60601-1-2 without several re-configurations and extensive test time.

In situ testing – testing at the place of installation – as a system, at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility. The ME SYSTEM might be in use and might not present the maximum configuration. Furthermore, it might not be possible to be tested in the modes that maximize EMISSIONS as required by this subclause because the available configuration for such testing is limited to what the customer/RESPONSIBLE ORGANIZATION has installed.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the equipment under test (EUT) is likely to be fully available and testing in representative configurations is usually possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement distance and positions should be achievable, and for EMISSION testing at the MANUFACTURER's premises, a measurement distance of at least 3 m should be maintained. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report. The measurement locations, including distance to the EUT, should be documented in the test report.

Subclause 7.2.1 – Harmonic distortion

Systems with RATED input voltage less than 220 V a.c. are exempt from this requirement because, according to the scope of IEC 61000-3-2, "the limits have not yet been considered."

See also the rationale for Subclause 4.3.3.

Subclause 7.2.2 – Voltage fluctuations and flicker

Systems with RATED input voltage less than 220 V a.c. are exempt from this requirement, as justified by the following note from the scope of IEC 61000-3-3:

NOTE 2 The limits in this standard are based mainly on the subjective SEVERITY of flicker imposed on the light from 230 V/60 W coiled-coil filament lamps by fluctuations of the supply voltage. For systems with NOMINAL voltage less than 220 V line to neutral and/or frequency of 60 Hz, the limits and reference circuit values are under consideration.

See also the rationale for Subclause 4.3.3.

Subclause 8.1 – General

PORTS

Figure A.1 below is Figure 1 from IEC 61000-6-1:2005.

NOTE 1 For the purposes of this collateral standard, the "Apparatus" is the ME EQUIPMENT or ME SYSTEM and the "Signal PORT" is the PATIENT COUPLING PORT or the SIP/SOPS PORT, as shown in Figure 2.

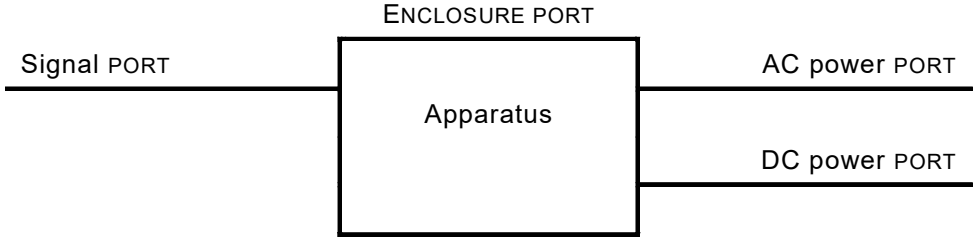


Figure A.1 – Examples of PORTS (from IEC 61000-6-1:2005)

NOTE 2 For ELECTROMAGNETIC IMMUNITY, the ENCLOSURE IS considered to be a PORT.

IMMUNITY pass/fail criteria

It should be noted that the IMMUNITY pass/fail criteria (formerly IMMUNITY compliance criteria) are specified differently in this edition than they were in previous editions. Previous editions specified a list of degradations that were not allowed with regard to the BASIC SAFETY and ESSENTIAL PERFORMANCE in response to the electromagnetic test signal. This edition includes a similar list (see I.3.1); however, the list is intended as general examples. The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM is required to specify specific IMMUNITY pass/fail criteria for the ME EQUIPMENT or ME SYSTEM under test before the test is performed. Annex I provides guidance in doing so.

Pole-mounted ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT or an ME SYSTEM that is pole-mounted should be tested as table-top equipment or mounted to a pole, whichever is worst case. For ME EQUIPMENT for which there is a particular (Part 2) standard, this could be addressed in the Part 2 standard.

Dwell time

The dwell time should be at least 1 s and should be no less than the response time of the slowest responding function plus the settling time of the IMMUNITY test system. For ME EQUIPMENT and ME SYSTEMS for which faster-responding signals can be used to determine the effect of the test signal on the ME EQUIPMENT or ME SYSTEM, the dwell time can be reduced if the faster-responding signals are monitored. In this case, the dwell time should be no less than the response time of the signal or of the monitoring system, whichever is greater, plus the response time of the radiated RF IMMUNITY test system, but in no case less than 1 s. For ME EQUIPMENT and ME SYSTEMS that have multiple individual parameters or subsystems, each of which would yield a different dwell time, the value used should be the maximum of the individually-determined dwell times.

The minimum dwell time of 1 s is recommended so that performance DEGRADATION that might occur in response to the IMMUNITY TEST LEVEL can be observed by test engineers.

The use of adequate dwell time (or a correspondingly slow sweep rate) can be particularly important to IMMUNITY testing of ME EQUIPMENT and ME SYSTEMS. While interference with a video display unit can be perceived instantly, ME EQUIPMENT and ME SYSTEMS can have a very slow response time and can require a long dwell time in order to assess performance during the test. For example:

– A pulse oximeter might display a value averaged over several cardiac cycles.
– It might take several minutes to determine that the flow rate of an infusion pump has remained within an acceptable range.
– A ventilator might require several breath cycles to respond to a test signal.

NOTE Some slow sensors, e.g. chemical/biochemical sensors, can have response times of several minutes but are not susceptible to RF fields. In such instances the response of the electronics, including filtering or averaging in hardware or software, would be the appropriate response time to consider in the determination of the dwell time.

Subclause 8.5 – Subsystems

Care needs to be taken that testing on a subsystem basis is appropriate and that subsystems absent from the system are adequately simulated. If, for example, MANUFACTURERS of connected subsystems have different specifications for the interconnecting cables or if subsystems cannot be adequately simulated, it might be more appropriate to test the equipment as a system.

Subclause 8.6 – PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

This subclause offers three methods for IMMUNITY testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS:

– on a test site as a system;
– on a test site on a subsystem basis;
– in situ as a system at the premises of a RESPONSIBLE ORGANIZATION.

For certain ME SYSTEMS, testing on a test site or on a subsystem basis is deemed to be very difficult. ME SYSTEMS (e.g. large X-ray equipment and particle therapy systems) requiring ceiling installation or of equipment that needs to be placed in different locations such as examination rooms, technical rooms and control rooms, cannot be installed in today's test sites due to the size or installation requirements. Note that "large" in this context is defined in this collateral standard to mean ME EQUIPMENT and ME SYSTEMS that cannot fit within a 2 m × 2 m × 2,5 m volume in any orientation (see 3.12 and 3.13).

Testing on a subsystem basis requires the simulation of physical behaviour of the replaced system, which is also deemed to be technically very difficult and sometimes impossible without a representative configuration.

In situ testing – testing at the place of installation – as a system at a RESPONSIBLE ORGANIZATION (i.e. a hospital or individual clinic) often requires a certification/approval before shipment to the facility.

The ME SYSTEM might be in use and might not present the maximum configuration. To operate the device in the modes and settings that are most likely to result in an unacceptable RISK might not be allowed by the RESPONSIBLE ORGANIZATION due to the potential for damage to the ME SYSTEM.

Moreover, BASIC SAFETY and ESSENTIAL PERFORMANCE needs to be verified according to the MANUFACTURER's specification and requires specific operating modes and auxiliary equipment that might not be available or authorized in situ.

At the MANUFACTURER's premises, the equipment used to provide input to, and monitoring of, the EUT is likely to be fully available and testing in representative configurations is usually

possible. Testing at the MANUFACTURER's premises could fulfil the operational mode requirements of this subclause.

Furthermore, at the MANUFACTURER's premises, all necessary components, service support and knowledge of maintenance is in place, as well as protection requirements (e.g. to protect the environment and personnel).

Comparing the limitations as described in this subclause against the advantages of testing at the MANUFACTURER's premises, the latter could be considered equal to in situ testing. In such cases, good EMC practice regarding the measurement needs to be maintained, and if the applicable basic EMC standards allow in situ testing, the requirements in the basic EMC standards will take precedence. Additionally, a rationale to explain why testing the ME EQUIPMENT or ME SYSTEM on the MANUFACTURER's premises is justified should be provided in the test plan and documented in the test report.

Subclause 8.7 – Operating modes

For example, a ventilator might have a paediatric mode and an adult mode. ULTRASONIC DIAGNOSTIC EQUIPMENT might have a 2D, a colour and a Doppler mode.

Subclause 8.8 – Non-ME EQUIPMENT

If non-ME EQUIPMENT is used in an ME SYSTEM and the non-ME EQUIPMENT is determined not to affect BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM, the non-ME EQUIPMENT still could experience the same reasonably foreseeable ELECTROMAGNETIC DISTURBANCES in use as the rest of the ME SYSTEM. Therefore, any decoupling used during the test should be considered for incorporation into the ME SYSTEM.

Subclause 8.9 – IMMUNITY TEST LEVELS

a) General

Figure 3 shows examples of locations and EM ENVIRONMENTS of INTENDED USE that are found in healthcare, grouped according to professional healthcare facility environment, HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENT. Not all possible locations and EM ENVIRONMENTS are listed. Locations not shown should be assigned to the applicable similar environment.

Locations that are shown to be in the professional healthcare facility environment have expected levels of EM DISTURBANCES that are in the same general range. Similarly, locations that are shown to be in the HOME HEALTHCARE ENVIRONMENT have expected levels of EM DISTURBANCES that are in the same general range.

While the IMMUNITY TEST LEVELS are specified according to the EM ENVIRONMENT of INTENDED USE, 8.1 requires that if the INTENDED USE of the ME EQUIPMENT or ME SYSTEM includes multiple environments, the ME EQUIPMENT or ME SYSTEM is required to comply with the most stringent of the applicable IMMUNITY TEST LEVELS. The ME EQUIPMENT or ME SYSTEM would then be assumed to be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE in all of the environments of INTENDED USE.

The information in IEC/TR 61000-2-5 regarding expected levels of EM DISTURBANCES was taken into consideration in specifying the IMMUNITY TEST LEVELS. Table A.1 lists the tables of IEC/TR 61000-2-5 that were considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY test.

Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST

Phenomenon	Basic EMC standard or test method	IEC/TR 61000-2-5:2011 table number
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	37, 38
Radiated RF EM fields	IEC 61000-4-3	15, 16, 19, 21, 22, 23, 24, 25, 26
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	20, 27, 28, 30, 31, 32, 33, 34
RATED power frequency magnetic fields	IEC 61000-4-8	9
Electrical fast transients / bursts	IEC 61000-4-4	12
Surges	IEC 61000-4-5	12
Conducted disturbances induced by RF fields	IEC 61000-4-6	11,16, 25
Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	None [a]

[a] While there is no guidance in IEC 61000-2-5 on voltage dips and interruptions, guidance in IEC 61000-4-11 was used in selecting these IMMUNITY TEST LEVELS.

b) Environments

The names of the ELECTROMAGNETIC ENVIRONMENTS designated in this collateral standard are harmonized with IEC 60601-1-11. It is important to reference Figure 3 to understand what each environment includes and what it does not include.

There are several different locations in each environment. In general, similar levels of EM DISTURBANCES can be expected in locations assigned to the same environment. The IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11 for BASIC SAFETY and ESSENTIAL PERFORMANCE for ME EQUIPMENT and ME SYSTEMS intended for use in the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT are not the theoretical maximums for the respective environments, but are the reasonably foreseeable maximum levels. These levels might not be adequate for all types of ME EQUIPMENT and ME SYSTEMS. Part 2 standards or the MANUFACTURER should address such cases, where appropriate. Additional rationale for the IMMUNITY TEST LEVELS is presented below.

– **Professional healthcare facility environment**

Examples of locations in the professional healthcare facility environment are different settings where medical personnel often are nearby (doctors' offices, clinics, surgery rooms, intensive care, PATIENT rooms, emergency rooms, and clinics). Note however that the professional healthcare facility environment does not include all hospital locations. For example, it does not include areas of the hospital where there is sensitive equipment or sources of intense ELECTROMAGNETIC DISTURBANCES, such as the RF shielded room of an ME SYSTEM for magnetic resonance imaging, in operating rooms near active HF SURGICAL EQUIPMENT, electrophysiology laboratories, shielded rooms, or areas where SHORT-WAVE THERAPY EQUIPMENT is used. The IMMUNITY TEST LEVELS specified for the professional healthcare facility environment are likely not to be appropriate for these areas of the hospital. (See SPECIAL ENVIRONMENTS, below.)

Most environments and locations in the professional healthcare facility environment are considered to have a controlled EM ENVIRONMENT with regard to FIXED electromagnetic sources. Mobile communication devices are widely used by healthcare professionals in providing efficient PATIENT care. For this reason it is more difficult to control the environment for close proximity ELECTROMAGNETIC DISTURBANCES.

Examples of electromagnetic sources that might be used adjacent to ME EQUIPMENT and ME SYSTEMS in hospital environments are:

– HF SURGICAL EQUIPMENT;
– RFID systems;
– wireless local area networks (WLAN);
– mobile phones;
– handheld mobile radios (e.g. TETRA, two-way radio);
– paging systems.

It is assumed that ME EQUIPMENT and ME SYSTEMS used in hospitals (and large clinics) are not connected to the PUBLIC MAINS NETWORK.

LARGE ME EQUIPMENT and LARGE ME SYSTEMS that are PERMANENTLY INSTALLED in a trailer should be categorized according to the INTENDED USE. For example, if it is intended to be connected to hospital power, then the professional healthcare facility environment should be used. For radiated DISTURBANCES, the requirements for ME EQUIPMENT and ME SYSTEMS intended for use only in a shielded location might be applicable, depending on the shielding effectiveness and the filter attenuation.

– **HOME HEALTHCARE ENVIRONMENT**

Locations in the HOME HEALTHCARE ENVIRONMENT have much more diverse EM ENVIRONMENTS, with ELECTROMAGNETIC DISTURBANCES that might be less well-controlled and less well-characterized in terms of amplitude and probability of occurrence than for the professional healthcare facility environment. Except in transportation, ME EQUIPMENT and ME SYSTEMS are usually connected to the PUBLIC MAINS NETWORK. These reasons justify higher IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE.

Examples of electromagnetic sources that might be used near ME EQUIPMENT and ME SYSTEMS in these environments or otherwise expose the ME EQUIPMENT or ME SYSTEM to intense EM DISTURBANCES are:

– small mains frequency transformers (50 Hz and 60 Hz), e.g. in a clock radio on a bedside table;
– mains disturbances;
– mobile phones (often several);
– FIXED radio broadcast stations;
– TV transmitting equipment;
– amateur radio equipment (radio amateurs) operating from 136 kHz to microwave;
– mobile radio transmitters (e.g. taxi, police).

The HOME HEALTHCARE ENVIRONMENT includes transportation and locations that can be accessed by walking, shops and libraries, where electronic anti-theft equipment and metal detectors are used, cars, ambulatory (walking), bike and motorbike, trains, airplanes, and ships. The IMMUNITY TEST LEVELS specified for the HOME HEALTHCARE ENVIRONMENT might not be appropriate for helicopters, spacecraft, or submarines. Equipment intended for transportation applications might or might not be intended for permanent installation in a vehicle. If the ME EQUIPMENT or ME SYSTEM is intended to be connected to vehicle d.c. power, the applicable vehicle EMC standards should apply.

– **SPECIAL ENVIRONMENTS**

“Special” is used in EMC standards, e.g. the IEC 61000-4 Basic EMC IMMUNITY standards, for test levels that are outside or other than the standard test levels. For this reason, “special” is appropriate for the environments listed as such in Figure 3. This is not to say that these environments are unusual, only that the EM ENVIRONMENTS differ significantly from those of the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT, or the

EM ENVIRONMENT is not well-characterized. SPECIAL ENVIRONMENTS can also be justified for locations in the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT as specified in Annex E, e.g. due to special mitigations.

The vicinity of active HF SURGICAL EQUIPMENT is an example of a SPECIAL ENVIRONMENT because the EMISSIONS are broadband and consensus IMMUNITY TEST LEVELS and test methods have not yet been specified. Similarly, consensus IMMUNITY TEST LEVELS and test methods have not yet been specified for the RF shielded room of an ME SYSTEM for magnetic resonance imaging.

As special medical environments are characterized and requirements are developed, the intent is to add these requirements to this collateral standard. Meanwhile, MANUFACTURERS should use Annex E to determine IMMUNITY TEST LEVELS for locations of INTENDED USE that are in SPECIAL ENVIRONMENTS.

c) IMMUNITY TEST LEVEL determination

The IMMUNITY TEST LEVELS used in this collateral standard were based on the work of IEC Technical Committee 77. The characterization of each EM phenomenon can be found in Technical Report IEC/TR 61000-2-5:2011.

Not all EM phenomena have IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11. This does not imply that the phenomena do not exist, but rather that there is a practicality involved in determining which EM phenomena should be considered. The EM phenomena were chosen according to RISK and represent the most likely phenomena to occur in the environments specified. Users of this collateral standard are encouraged to consider all EM phenomena during the RISK MANAGEMENT PROCESS to determine if their ME EQUIPMENT or ME SYSTEM might have an unacceptable RISK as a result of the EM phenomena listed in IEC/TR 61000-2-5 or other foreseeable ELECTROMAGNETIC DISTURBANCES, or if higher levels of IMMUNITY are required based on the ME EQUIPMENT or ME SYSTEM'S INTENDED USE (see Annex E and Annex F).

NOTE 1 IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE were selected based on the reasonably foreseeable maximum DISTURBANCE levels found in the respective environments. Foreseeable maximum levels are expected to ensure that the ESSENTIAL PERFORMANCE AND BASIC SAFETY of the ME EQUIPMENT or ME SYSTEM will be maintained in its environments of INTENDED USE.

Compromises have been made to reduce the number of specified environments, making it easier for users of this collateral standard. For example, doctors' offices and hospital have been grouped together in one environment. Also, various types of transportation have been grouped together in the HOME HEALTHCARE ENVIRONMENT. The IMMUNITY TEST LEVELS listed for each environment are a compromise and should be considered as such during the RISK MANAGEMENT PROCESS.

NOTE 2 The higher IMMUNITY TEST LEVELS specified for the HOME HEALTHCARE ENVIRONMENT are necessary due to the closer distances to certain electromagnetic sources than found in the professional healthcare facility environment. Examples include PORTABLE RF communications equipment such as mobile phones and amateur radio equipment.

NOTE 3 Some transportation environments have high-power mobile transmitters that are normally not found in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. For this reason, a higher level of reasonably foreseeable maximum EM DISTURBANCE is expected.

NOTE 4 Some of the IMMUNITY TEST LEVELS in Clause 8 of this standard are based on the assumption of a controlled environment, meaning that a minimum separation distance between radiated electromagnetic sources and the ME EQUIPMENT or ME SYSTEM is required to ensure that the IMMUNITY TEST LEVELS in Clause 8 are effective in reducing the RISK to an acceptable level.

Table 4 – ENCLOSURE PORT

ELECTROSTATIC DISCHARGE

Appropriate ESD IMMUNITY TEST LEVELS for a given environment can be estimated using Figure A.1 of IEC 61000-4-2 (see Figure A.2). While some areas of some hospitals are controlled regarding relative humidity and use of anti-static (or low static) flooring and material, others are not. The HOME HEALTHCARE ENVIRONMENT can be assumed to be uncontrolled with respect to these parameters. It is well-known that the relative humidity can be quite low in some locations, as low as 5 %. As can be seen in Figure A.2, when the relative humidity is approximately 5 % and there are synthetic materials present, static charges approaching 15 kV can be generated. This is the reasonably foreseeable maximum level on which the IMMUNITY TEST LEVELS in Table 4 were based.

Even so, there are circumstances under which ME EQUIPMENT that was tested to an IMMUNITY TEST LEVEL of 15 kV air discharge failed in use and put PATIENTS at RISK. In two such case studies, ME EQUIPMENT that was tested to 15 kV failed in the field. The first was a body-worn, ambulatory insulin infusion pump. Pumps that had passed testing at 15 kV air discharge stopped pumping without alarm during use, and diabetic PATIENTS were injured. Making the pumps immune to 30 kV air discharge prevented further field failures due to ESD. In another case study, the “gas gauge” chips in the rechargeable batteries of an external defibrillator that had passed testing at 15 kV were shorting when the PATIENT was transferring them between the ME EQUIPMENT and the charger. The short-circuit completely discharged the battery and prevented recharging, potentially leaving the PATIENT unprotected.

Thus, while the 15 kV ESD air discharge IMMNITY TEST LEVEL specified in this collateral standard for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT is higher than the ESD air discharge IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, MANUFACTURERS should determine if even 15 kV is adequate for the environments of INTENDED USE.

Table 5 – Input a.c. power PORT

Conducted disturbances

The following examples provide rationale for the 6 V r.m.s. IMMUNITY TEST LEVEL in the amateur radio and ISM bands.

This is an example of a DISTURBANCE induced on the cables of an ME EQUIPMENT or ME SYSTEM due to amateur radio transmissions. The field strength can be calculated from the equation in 8.10. It is assumed that the conducted RF voltage is induced by a field strength of 10 V/m and the transmitter RF output power is assumed to be 1 500 W. The calculation shows that this could be produced by an amateur radio transmitter at a distance of 23 m. Furthermore, calculations have shown that the voltage induced on a cable in the frequency range 150 kHz to 80 MHz from a field strength of 10 V/m is unlikely to exceed 6 V r.m.s. However, once modulation is applied, the peak voltage induced on the cable under test will be greater than 10 V.

Similarly, SHORT-WAVE THERAPY EQUIPMENT operating at 100 W at an ISM frequency would also induce approximately 10 V r.m.s. in a cable of an ME EQUIPMENT or ME SYSTEM at a distance of approximately 6 m. In addition to SHORT-WAVE THERAPY EQUIPMENT intended for the professional healthcare facility environment, SHORT-WAVE THERAPY EQUIPMENT is also available by prescription for use in the HOME HEALTHCARE ENVIRONMENT and thus could expose an ME EQUIPMENT or ME SYSTEM to an EM DISTURBANCE that, when coupled to a cable, would result in an induced voltage of approximately 6 V r.m.s.

These are only examples; however, they show that the test level of 6 V r.m.s. is appropriate for amateur radio bands in the HOME HEALTHCARE ENVIRONMENT and the ISM bands in the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

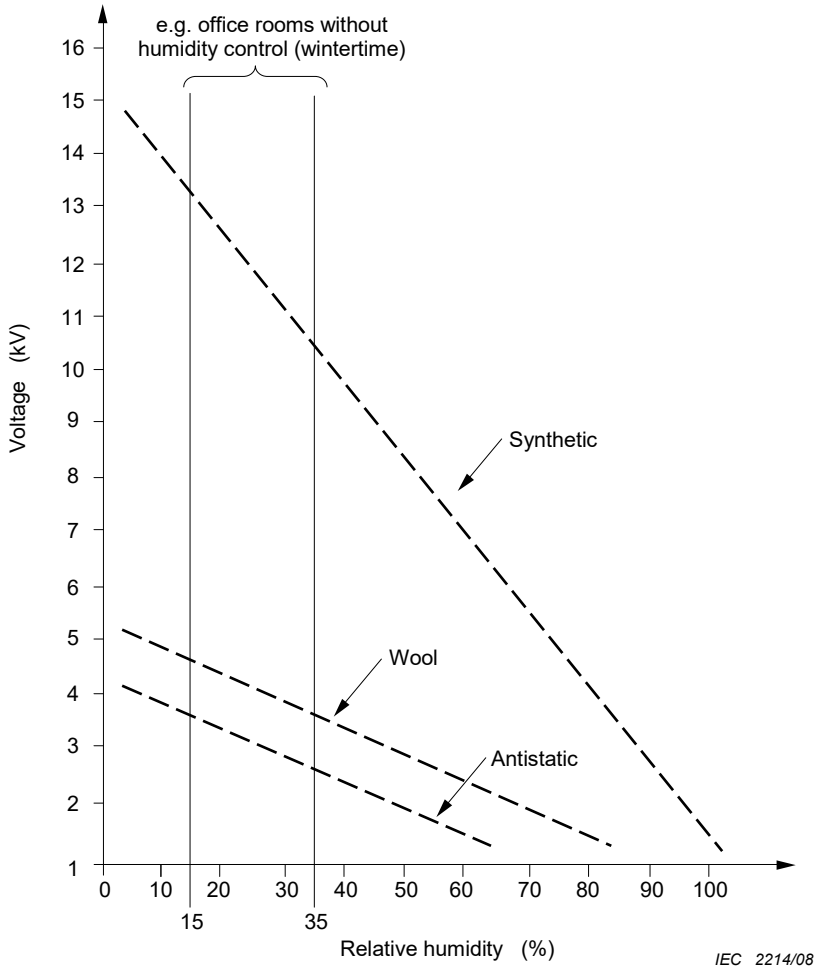


Figure A.2 – IEC 61000-4-2 Figure A.1 – Maximum values of electrostatic voltages to which OPERATORS can be charged while in contact with the materials mentioned in A.2

Voltage dips

The 40 % U_T test level that appeared in earlier editions of this collateral standard has been deleted because it was deleted from IEC 61000-4-11.

Table 7 – * Patient COUPLING PORT

Examples of PATIENT COUPLING PORTS include ECG cables, EEG cables, pulse oximeter PATIENT cables, and infusion pump saline lines.

The ESD IMMUNITY test specified in Table 7 is intended to verify BASIC SAFETY and ESSENTIAL PERFORMANCE after handling of PATIENT-COUPLED cables by the OPERATOR, e.g. after application of electrodes, application to the PATIENT. For this reason, the test is performed with no connection to an artificial hand and no connection to PATIENT simulation.

Only one end of a transmission line need be terminated to produce the source signal voltage at the far end of the line. The artificial hand, 510 Ω in series with 220 pF and usually connected to aluminium foil that is applied to the ME EQUIPMENT or ME SYSTEM, presents a relatively high impedance across the test spectrum. However, it is very important that the PATIENT cable look like a 150 Ω transmission line. This is not a trivial task above 30 MHz. Bundling of the PATIENT cable should be avoided. Bundling makes it very difficult to maintain the 150 Ω transmission line impedance above 30 MHz. For the tests for which it is specified, the use of the artificial hand helps to simulate the electromagnetic conditions of actual use.

Type-F PATIENT circuits are not properly terminated in the 150 Ω impedance when testing to IEC 61000-4-6 with the current injection method. However, when a product is used as intended, the cables are not terminated and resonant effects can occur. If this presents a problem, cables and circuits should be designed to be immune to such effects. If a cable length approaches ¼ wavelength, it might be necessary to move the clamp to inject at both ends of the cable. In the rare case that the cable length is ½ wavelength, injection should be done at both ends and the centre.

Subclause 8.10 – IMMUNITY to proximity fields from RF wireless communications equipment

Since IEC 60601-1-2 Edition 2.1 and Edition 3 were developed, new digital wireless technologies have been introduced not only to hospitals, but are also in widespread use by the general public. In addition, existing technologies are being used in ways that they were not used before.

Examples of RF wireless technologies and their use in healthcare and in various locations where ME EQUIPMENT and ME SYSTEMS are used:

– TETRA, LTE
– wireless local area network (WLAN) equipment in hospitals, including the use of mobile phones and personal digital assistants (PDAs) during rounds to access PATIENT data and images, sound ALARM SIGNALS and issue orders for PATIENT care and medication;
– use of mobile phones by healthcare professionals for instant communication;
– use of wireless communication in ME EQUIPMENT and ME SYSTEMS;
– installation and use of RFID tags and readers in hospitals, including in ME EQUIPMENT and ME SYSTEMS and in systems to scan for sponges left in PATIENTS after surgery;
– electronic article surveillance (EAS) systems based on RFID technology and magnetic field technology;
– use of wireless technologies like Bluetooth for controlling ME EQUIPMENT and ME SYSTEMS (e.g. footswitches) and for transmitting voice and other data;
– use of RFID to track the location of ME EQUIPMENT and ME SYSTEMS in the hospital;
– use of machine-to-machine (M2M) communications.

In addition, healthcare providers have specifically requested that requirements be developed so that wireless communications equipment can be used closer to medical equipment than is recommended based on compliance with e.g. IEC 60601-1-2:2007.

For some services, only the uplink frequencies are included. Due to local circumstances and technical developments, the listed frequencies are only examples and are not claimed to be exhaustive. The services and frequencies listed were chosen to be reasonably representative and comprehensive for RF wireless communications equipment.

Test frequencies were chosen based on the following criteria:

If the band is greater than 10 % of the centre frequency, three frequencies are used. Otherwise only the centre frequency is used.

Modulation specifications were chosen to simplify the test based on relevant characteristics of frequency bands of RF wireless communications equipment. In most cases, the carrier is modulated using a square wave signal.

By experience, the duty cycle of 50 % appears to be worst-case for different modulation characteristics of RF wireless communications equipment.

In bands in which services use both 18 Hz and 217 Hz modulations, 18 Hz is specified for the test because it is worst case.

The IMMUNITY TEST LEVELS specified in Table 9 were calculated using the maximum power shown in Table A.3, an assumed separation distance of 0,3 m, and the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. The factor of 6 is a compromise for a range of antenna factors, to simplify the test.

Table A.3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency MHz	Band [a)] MHz	Service [a)]	Maximum power W	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	1,8	27
450	430 to 470	GMRS 460, FRS 460	2	28
710	704 to 787	LTE Band 13, 17	0,2	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	2	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	0,2	9
5 500				
5 785				

[a)] For some services, only the uplink frequencies are included.

Subclause 8.11 – IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

This requirement was added due to concerns about the RISKS associated with fields radiated by a wide variety of sources in both the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. ME EQUIPMENT can contain electronic components and circuitry that are sensitive to radiated magnetic fields from these sources.

The procedure for determining the applicability of the proximity magnetic fields IMMUNITY test and the testing required are shown in Figure A.3. In general, this subclause applies to all ME EQUIPMENT and ME SYSTEMS. However, due to the fact that the sources of magnetic fields considered for this subclause are proximity sources, appropriate exemptions from testing are specified. Even if this test is not performed, there are requirements for documentation of the choices/decisions made. It should be noted that MANUFACTURERS are permitted to bypass these exemptions and conduct the tests if they so choose.

Exemptions

The first of three exemptions (see 8.11 a)) is where the ME EQUIPMENT or ME SYSTEM does not contain (i.e. within the ENCLOSURE or as part of an attached ACCESSORY) magnetically sensitive components or circuitry.

For the purposes of this subclause, magnetically sensitive components are those components that are either designed to sense magnetic fields or are likely to be influenced as a result of the fields specified in this subclause while in close proximity to the sources. Examples include but are not limited to coils, signal transformers, and hall-effect sensors.

Magnetically sensitive circuitry includes but is not limited to those circuits where voltages induced into wiring or the interconnect structure might alter the intended function of the circuit. Examples of such circuits are:

– an analogue signal processing circuit whose passband is within the frequency range specified in this subclause and where the area enclosed by any interconnecting pathways is such that the induced voltage can interfere with signals of interest.

– digital circuits where the induced voltage in an interconnect pathway approaches the logic threshold of the devices.

– an external pacemaker system, where the leads attached to temporarily implanted heart wires form a loop whose area is sufficient to result in an induced voltage comparable to the ECG signals being sensed from the heart.

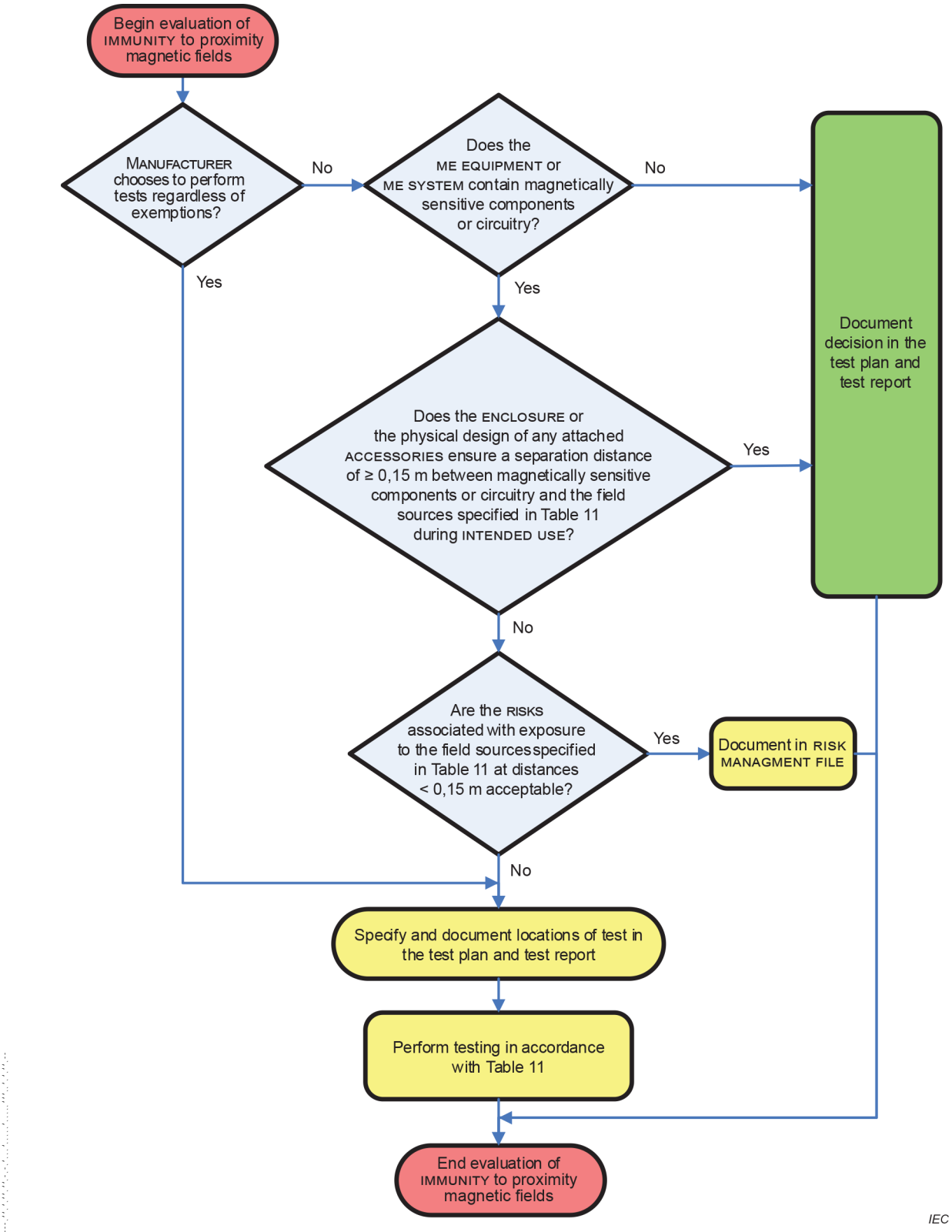


Figure A.3 – Steps for evaluation of IMMUNITY to proximity magnetic fields

The second exemption (see 8.11 b)) specified by this subclause is allowed when the ME EQUIPMENT or ME SYSTEM or an attached ACCESSORY does contain magnetically sensitive components or circuitry but these components or circuits are mounted behind the surface of the equipment ENCLOSURE (or the ENCLOSURE or other physical barrier associated with an attached ACCESSORY) such that during INTENDED USE a minimum separation distance from the sources of proximity magnetic fields specified in Table 11 is ensured. For the purposes of this collateral standard, this minimum separation distance is considered to be a “proximity threshold”, and a value of 0,15 m was assigned to it. To establish the “proximity threshold”, SC 62A considered the types of proximity magnetic field DISTURBANCE sources expected:

– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134,2 kHz and 13,56 MHz;
– electronic article surveillance (EAS) systems;
– sponge detection systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.

These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of this collateral standard. All of these sources (with the exception of wireless charging for electric vehicles) generally use coils that are small in diameter. RFID readers operating at 134,2 kHz use coils with a radius of about 0,06 m, and those operating at 13,56 MHz use coils with a radius of about 0,02 m.

The magnetic field along the axis of a “thin” coil relative to the maximum field at its centre is approximated by:

$$\frac{B(x)}{B(0)} = \frac{1}{(1+a^2)^{1,5}}$$

where

$a = \frac{x}{r}$;

x is the distance from the centre of the coil along the coil axis;

r is the radius of the coil.

Figure A.4 illustrates the field decay characteristics of coils having radii up to 0,06 m.

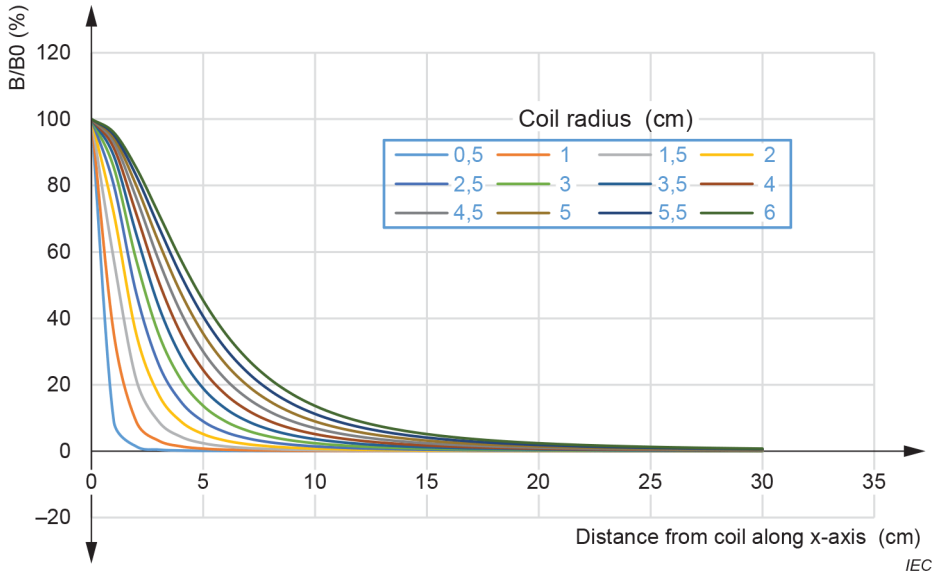


Figure A.4 – Magnetic field roll-off characteristics along the x-axis for a thin planar coil and various coil radii

This shows that at a distance of 0,15 m, the magnetic field for all coil radii up to 0,06 m has decayed to 5 % or less of the maximum field. In order to assess the impact of these reductions in field amplitude upon a receiving circuit, analysis of the field characteristics and coupling coefficients between two coils according to [50] was undertaken. The induced voltage in a single-turn coil of the same radius as the transmit coil was then estimated using Faraday's law and the coupling coefficients. The results of this analysis are shown in Figure A.5 and Figure A.6. It can be seen from these results that at a separation distance of 0,15 m, the induced voltage from an RFID reader operating at 134,2 kHz in a loop of wire with diameter of 0,12 m is approximately 45 mV peak-to-peak. Similarly, a 13,56 MHz RFID reader will induce approximately 300 µV peak-to-peak in a loop of diameter 0,04 m. The low levels determined by these calculations provide adequate justification for a "proximity threshold" of 0,15 m.

The coil sizes associated with wireless electric vehicle charging, while larger than analysed above, are not of concern because these systems employ protection mechanisms that prohibit approach closer than distances of the order of 1 m.

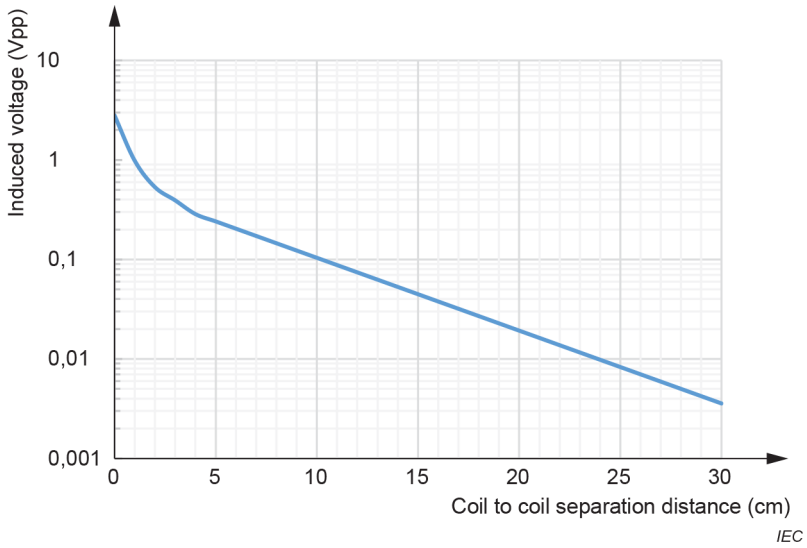


Figure A.5 – Voltage induced in a 1-turn, 6 cm radius coil by a 6 cm radiating coil operating at 134,2 kHz and H_0 of 82,65 A/m (r.m.s.)

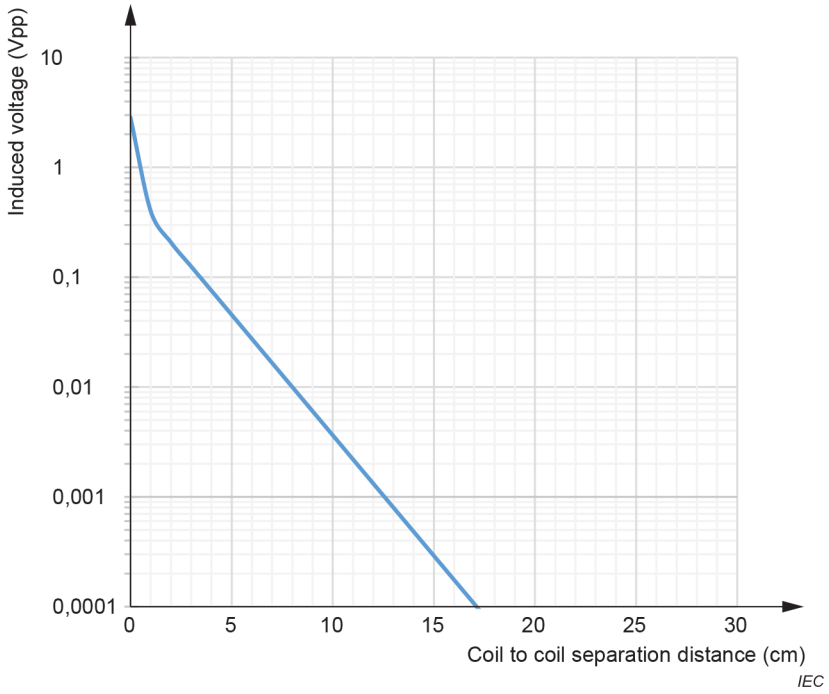


Figure A.6 – Voltage induced in a 1-turn, 2 cm radius coil by a 2 cm radiating coil operating at 13,56 MHz and H_0 of 7,5 A/m (r.m.s.)

Where neither of the exemptions specified in a) or b) are applicable, 8.11 introduces an option (see 8.11 c)) for the MANUFACTURER to perform a RISK ANALYSIS when it is known that exposure of magnetically sensitive components or circuitry with separation distances less than 0,15 m during INTENDED USE might be possible. Where the RISKS are determined to be acceptable, following documentation of the assessment in the RISK MANAGEMENT FILE, further testing for IMMUNITY to proximity magnetic fields at the frequencies specified is not necessary. If the RISKS are found to be unacceptable, or if the MANUFACTURER chooses to perform testing regardless of the exemptions or RISK ANALYSIS option, then testing proceeds according to 8.11 d).

Test levels, frequencies, and modulations

The test specifications are not intended to cover every frequency and application used in every country. The concept of testing at just a few frequencies as opposed to sweeping over a range of frequencies is predicated on the assumption that the inductive coupling into the ME EQUIPMENT within the scope of this subclause is non-resonant. Under this assumption, it only becomes necessary to test using the highest known frequency of the known emitter types. SC 62A intentionally limited the scope of frequencies for this subclause to align with the minimum test frequency of IEC 61000-4-39. For this reason, emitters operating below 9 kHz are not considered.

In the frequency range 9 kHz to 150 kHz, SC 62A considered the RISKS primarily from induction cooking appliances and the emerging sources of wireless power transfer used to charge electric vehicles. There are many operating frequencies for induction cooking appliances, but SC 62A chose the single, highest known operating frequency (30 kHz) to simplify the testing. The test level for this frequency was chosen based upon reference [45]. This test is applicable to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT, as exposure to the noted sources is not expected in the professional healthcare facility environment.

With respect to electric vehicle charging, SC 62A considered emerging standards for these systems from the Society of Automotive Engineers (SAE) and the IEC. The operating frequencies range from approximately 50 kHz to over 100 kHz and the magnetic fields are CW. The field strengths outside of the vehicles are not expected to exceed 12 A/m. This exposure level is less than that expected from pulsed magnetic sources such as electronic article surveillance (EAS) and RFID systems. Therefore, until further information becomes available, no emitter-specific test for electric vehicle charging at frequencies below 100 kHz is specified. Instead, the test at 134,2 kHz is used as a surrogate test for disturbances associated with electric vehicle charging.

SC 62A recognizes that other forms of wireless power transfer have recently been deployed or are in development (e.g. for charging of portable electronic devices (PEDs)). However, the HAZARDS associated with the potential DISTURBANCES due to this type of equipment have not yet been evaluated at the time of publication.

The HAZARDS associated with exposure to EAS and RFID equipment at 134,2 kHz and 13,56 MHz are addressed in 8.11. The IMMUNITY TEST LEVELS specified for these technologies were based upon reference [44]. For RFID equipment operating at 134,2 kHz, the test level in [44] was established by measurement of magnetic field EMISSIONS from RFID readers at a distance of 0,025 m. The analysis of induced voltage in Figure A.5 uses a field strength of 82,6 A/m as the maximum, which is the 65 A/m IMMUNITY TEST LEVEL specified in Table 11, extrapolated to a distance of 0 m. For similar equipment operating at 13,56 MHz, the test level was measured in contact with the equipment (no separation). These test levels are considered adequate to cover any other known sources in the frequency range 134 kHz to 13,56 MHz.

All test levels specified in this subclause are based on equipment standards or other source-based references. Levels associated with human exposure standards such as those published by ICNIRP or IEEE are not used because they were not developed with regard to IMMUNITY of ME EQUIPMENT or ME SYSTEMS.

The modulation type and rates shown in Table 11 for 134,2 kHz and 13,56 MHz were chosen as surrogates for the multiplicity of actual modulations associated with commercial RFID equipment. The test modulations are considered to be an adequate challenge to the ME EQUIPMENT within the scope of the tests, while at the same time avoiding the need for complex signal generation equipment.

Clause 9 – Test report / Table 10 – Minimum test report contents

ISO 17025 [25] is cited because it is a good reference for the minimum content of a test report. A similar format can be found in Table F.1 of CISPR 32.

Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT or their parts are found in 7.2 and Table C.1 of the general standard. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts are found in the subclauses listed in Table B.1.

Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Description	Clause or subclause
ME EQUIPMENT or ME SYSTEMS specified for use only in a shielded location: marking of	5.1

B.2 ACCOMPANYING DOCUMENTS, instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses of this collateral standard listed in Table B.2.

Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use

Description	Clause or subclause
Environments for which the ME EQUIPMENT or ME SYSTEM is suitable: statement of	5.2.1.1 a)
Performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES	5.2.1.1 b)
Use of ME EQUIPMENT or ME SYSTEM adjacent to or stacked with other equipment: warning of	5.2.1.1 c)
Cables, transducers and other ACCESSORIES that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 and Clause 8: list of	5.2.1.1 d)
Use of ACCESSORIES, transducers and cables other than those specified or provided by the MANUFACTURER: warning about	5.2.1.1 e)
Minimum separation from RF communication equipment: warning of	5.2.1.1 f)
CISPR 11 class A ME EQUIPMENT and ME SYSTEMS used in a residential area, warning about	5.2.1.2

B.3 ACCOMPANYING DOCUMENTS, technical description

The requirements for general information to be included in the technical description are found in Subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for general information to be included in the technical description are found in the subclauses listed in Table B.3.

Table B.3 – ACCOMPANYING DOCUMENTS, technical description

Description	Clause or subclause
Precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES: description of	5.2.2.1
Compliance for each EMISSIONS and IMMUNITY standard or test specified	5.2.2.1 a)
Deviations from this collateral standard and allowances used	5.2.2.1 b)
Maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the ELECTROMAGNETIC DISTURBANCES: instructions for	5.2.2.1 c)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: warning to use only in a shielded location	5.2.2.2 a)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: shielded location specifications	5.2.2.2 b)
ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location: test methods for measurement of RF shielding effectiveness and RF filter attenuation, recommendation for	5.2.2.2 c)
EMISSIONS characteristics of other equipment allowed inside the shielded location: specification of	5.2.2.2 d)
ME EQUIPMENT that intentionally receives RF electromagnetic energy: frequency or frequency band of reception, preferred frequency or frequency band and bandwidth	5.2.2.3
ME EQUIPMENT that includes RF transmitters: frequency or frequency band of transmission, modulation and EFFECTIVE RADIATED POWER	5.2.2.4
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: statement that an exemption has been used	5.2.2.5 a)
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: warning that testing for radiated RF IMMUNITY was done only at selected frequencies	5.2.2.5 b)
PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS: list of the frequencies and modulations used for IMMUNITY testing	5.2.2.5 c)
Statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery, if applicable	5.2.2.6

Annex C
(informative)

Guidance in classification according to CISPR 11

C.1 General

Rules for classification and separation into groups of equipment are specified in CISPR 11 and apply for this collateral standard. The purpose of this annex is to provide additional guidance in the assignment of ME EQUIPMENT or an ME SYSTEM to the appropriate CISPR 11 group and class.

Annex A of CISPR 11 gives examples of equipment classification. "Medical electrical equipment" is listed as an example of group 1 equipment, whereas "medical apparatus" is listed as an example of group 2 equipment. Only short-wave diathermy equipment and microwave therapy equipment are mentioned explicitly. No other type of ME EQUIPMENT or ME SYSTEM is listed.

C.2 Separation into groups

Most types of ME EQUIPMENT and ME SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to group 1.

Examples of group 1 ME EQUIPMENT and ME SYSTEMS are as follows:

Group 1 also includes ME EQUIPMENT and ME SYSTEMS intended to deliver energy to the PATIENT, but in a form that is other than RF electromagnetic. Examples are as follows:

– Medical imaging ME EQUIPMENT and ME SYSTEMS:
  - diagnostic X-ray systems for radiography and fluoroscopy (including cinefluoroscopy) for general purpose but also for special purposes, e.g. angiography, mammography, therapy planning, dentistry
  - computed tomography ME SYSTEMS
  - ME SYSTEMS for nuclear medicine
  - diagnostic ultrasound ME EQUIPMENT

– Therapy ME EQUIPMENT and ME SYSTEMS:
  - therapeutic x-ray ME EQUIPMENT
  - dental ME EQUIPMENT
  - electron beam accelerators
  - ultrasound ME EQUIPMENT for therapy
  - ME EQUIPMENT for extracorporeal lithotripsy
  - infusion pumps
  - radiant warmers
  - infant incubators
  - ventilators
  - anaesthesia machines

– Monitoring ME EQUIPMENT and ME SYSTEMS:
  - impedance plethysmography monitors
  - pulse oximeters

- PATIENT monitors
- electro- and magneto-cardiography ME EQUIPMENT and ME SYSTEMS
- electro- and magneto-encephalography ME EQUIPMENT and ME SYSTEMS
- electro- and magneto-myography ME EQUIPMENT and ME SYSTEMS

Only a few ME EQUIPMENT and ME SYSTEMS apply RF energy to material (in this case to PATIENTS) and are therefore members of group 2.

Examples are as follows:

– Medical imaging ME EQUIPMENT:
  - ME SYSTEMS for magnetic resonance imaging

– Therapy ME EQUIPMENT:
  - diathermy ME EQUIPMENT (short wave, ultra-short wave, microwave therapy ME EQUIPMENT)
  - hyperthermy ME EQUIPMENT

Additionally, HF SURGICAL EQUIPMENT, when active, should be classified as group 2 equipment (similar to spark erosion equipment), because it applies RF energy to the PATIENT.

C.3 Division into classes

ME EQUIPMENT and ME SYSTEMS predominantly intended for use in domestic establishments and connected to the PUBLIC MAINS NETWORK (e.g. home care ME EQUIPMENT and ME EQUIPMENT for doctors' offices in residential areas) should meet the requirements for CISPR 11 class B.

Special provisions cover professional medical electrical equipment. This means only equipment/systems for use by healthcare professionals and that are not intended for sale to the general public. These professional ME EQUIPMENT and ME SYSTEMS are allowed to meet either the requirements for CISPR 11 class A or class B under the following conditions:

– they are predominantly intended to be connected (e.g. in hospitals or doctor's offices) to dedicated supply systems (normally fed by separation transformers), or
– they have a RATED input power > 20 kVA and are intended to be powered by a dedicated power transformer and connected to it solely by a clearly identifiable power line path.

Annex D
(informative)

Guidance in the application of IEC 60601-1-2 to particular standards

D.1 General

This annex contains recommendations to standards committees and working groups writing requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for particular standards ("Part 2" standards and ISO standards) to help ensure consistency in the application of this collateral standard. Such committees are encouraged to contact subcommittee 62A with questions that arise in doing so.

This annex identifies the requirements that should be amended when this standard is applied to particular standards and provides guidance in doing so. It also identifies the requirements that should not be modified. In addition to this annex, the rationale in Annex A should be consulted for additional information and guidance in the application of this collateral standard.

Writers of particular standards are encouraged to specify the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and ME SYSTEMS within the scope of their standards.

D.2 Recommended modifications

D.2.1 Testing requirements

Writers of particular standards are encouraged to make amendments to the testing requirements as follows.

a) If the particular ME EQUIPMENT or ME SYSTEM is intended to be used in a SPECIAL ENVIRONMENT and the electromagnetic characteristics of that environment are known, appropriate IMMUNITY TEST LEVELS should be specified, using the procedure in Annex E.

b) Subclause 4.3.1, Configurations; 8.2, PATIENT physiological simulation and 8.7, Operating modes should be amended to be more specific for the particular ME EQUIPMENT or ME SYSTEM, while maintaining the intent of this collateral standard.

c) Amend the IMMUNITY pass/fail criteria paragraph in 8.1. to provide specific criteria for the particular ME EQUIPMENT or ME SYSTEM that follow the intent of that subclause.

D.2.2 ACCOMPANYING DOCUMENTS

If writers of particular standards make amendments to the testing requirements of this collateral standard, it should be determined if corresponding modifications to the ACCOMPANYING DOCUMENTS requirements are needed.

D.3 Cautions

Writers of particular standards are cautioned against making other modifications, particularly those listed below.

a) Subclause 7.1 should not be modified, except for specification of group 1 or 2, using the guidance in Annex C, and classification to class B, if the specific ME EQUIPMENT and ME SYSTEMS should only be classified as class B. Particular standards are not free to modify the EMISSIONS requirements or the test methods specified in CISPR 11 without the consent of CISPR subcommittee B.

b) Subclauses 7.1.9, PATIENT physiological simulation; 8.2, PATIENT physiological simulation; 8.3, Termination of PATIENT-COUPLED parts; 7.1.10, Artificial hand, 7.1.11, PATIENT-

COUPLED cables; and 8.4, HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD while providing its INTENDED USE should not be modified. The PATIENT cables are treated differently in different tests. The default termination requirements specify that no intentional conductive or capacitive connection be made to earth because either the termination is not considered relevant (i.e. in the surge IMMUNITY test) or the prohibited termination is considered less stringent (i.e. in the ESD and radiated RF tests). In specific tests, the artificial hand and RC element specified in 8.3 of CISPR 16-1-2 have been specified because for these tests, either it is necessary for the artificial hand and RC element to be in place to properly perform the test or the use of the artificial hand and RC element was considered to be the worst case. The general standard treats the conditions in which the PATIENT is floating and in which the PATIENT is earthed as NORMAL CONDITIONS. However, from a RF perspective, it is unlikely that a PATIENT in a medical environment would ever be as effectively earthed as in an EMC test environment in which a direct earth reference is used. As a result, the artificial hand and RC element specified in 8.3 of CISPR 16-1-2 are used to represent the earthed condition. The treatment of PATIENT cables in this collateral standard has been chosen to represent a condition of use that is worst case for each IMMUNITY test.

c) Do not exempt PATIENT cables or SIP/SOPS from the IEC 61000-4-6 test unless the effective length of the ME EQUIPMENT or ME SYSTEM plus its cables is less than 0,4 m. Otherwise, the ME EQUIPMENT or ME SYSTEM should be tested using the IEC 61000-4-3 (radiated RF IMMUNITY) test method down to the start frequency specified by IEC 61000-4-6 for the effective length. In the frequency range 0,15 MHz to 80 MHz, the IEC 61000-4-6 “conducted RF IMMUNITY” standard is actually a test for IMMUNITY to conducted DISTURBANCES that are induced by radiated RF fields. It is used as a substitute for the IEC 61000-4-3 “radiated RF IMMUNITY” standard because below 80 MHz in a moderately-sized test facility, it is difficult to achieve the EM field uniformity required by IEC 61000-4-3. IEC 61000-4-6 uses conducted methods to test equipment for IMMUNITY to the radiated RF that could occur in this frequency range. Therefore, PATIENT cables and SIP/SOPS should not be exempted from this test unless the effective length (ENCLOSURE plus cables, extended in opposite directions) will always be less than 0,4 m.

Annex E
(informative)

Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS

E.1 General

This annex specifies a procedure for determining IMMUNITY TEST LEVELS for ME EQUIPMENT and ME SYSTEMS for which the environments of INTENDED USE include one or more SPECIAL ENVIRONMENTS. The recommended determination PROCESS is shown in Figure E.1 and Figure E.2.

NOTE 1 Examples of when this might be appropriate include ME EQUIPMENT and ME SYSTEMS in the vicinity of SHORT-WAVE THERAPY EQUIPMENT (diathermy) and PERMANENTLY INSTALLED computed tomography ME SYSTEMS within an X-ray shielded room with air conditioning (controlled temperature and humidity).

NOTE 2 The following documents were used in the preparation of this annex: ISO 14971, IEC/TS 61000-1-2 [8], and IEC/TR 61000-2-5 [9] . Please refer to them for additional information.

The existing IMMUNITY TEST LEVELS of Clause 8 are based on reasonably foreseeable maximum EM DISTURBANCES related to (a set of) electromagnetic phenomena that are characteristic of the specified EM ENVIRONMENTS, i.e. the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT.

The situations that could justify new IMMUNITY TEST LEVELS or an increase or decrease in the existing IMMUNITY TEST LEVELS are as follows:

a) mitigations that might reduce exposure to EM DISTURBANCE levels resulting from the phenomena listed in Clause 8;
b) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have lower EM DISTURBANCE levels;
c) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have higher EM DISTURBANCE levels (e.g. shorter minimum separation distances for RF wireless equipment);
d) the presence of an EM DISTURBANCE from an EM phenomenon that is not listed in Clause 8.

The difference between a mitigation and a special condition might not always be obvious. In general, mitigation involves an active defence of the ME EQUIPMENT or ME SYSTEM against the EM ENVIRONMENT. An example would be the use of an uninterruptible power supply to limit the exposure to voltage dips and interruptions. Note that in this case, the EM ENVIRONMENT, per se, hasn't changed or been altered.

An example of a special condition would be a SPECIAL ENVIRONMENT where the relative humidity levels are always above 35 %. In this situation, it could be expected that the ESD DISTURBANCE levels would be lower than those specified in the tables in Clause 8. This is an example of a situation where the environment of INTENDED USE would have lower EM DISTURBANCE levels for ESD than the specifications in Clause 8, so an additional active defence of the ME EQUIPMENT or ME SYSTEM would not be necessary.

On the other hand, if an environmental chamber is used to control the relative humidity to a level above 50% and the ME EQUIPMENT or ME SYSTEM is specified and labelled to always and only be used within this chamber, then this is an example of mitigation.

In the end, it doesn't matter whether it's called mitigation or a special condition, as long as the new or adjusted IMMUNITY TEST LEVELS are appropriate for the EM DISTURBANCE levels to which the ME EQUIPMENT or ME SYSTEM will be exposed.

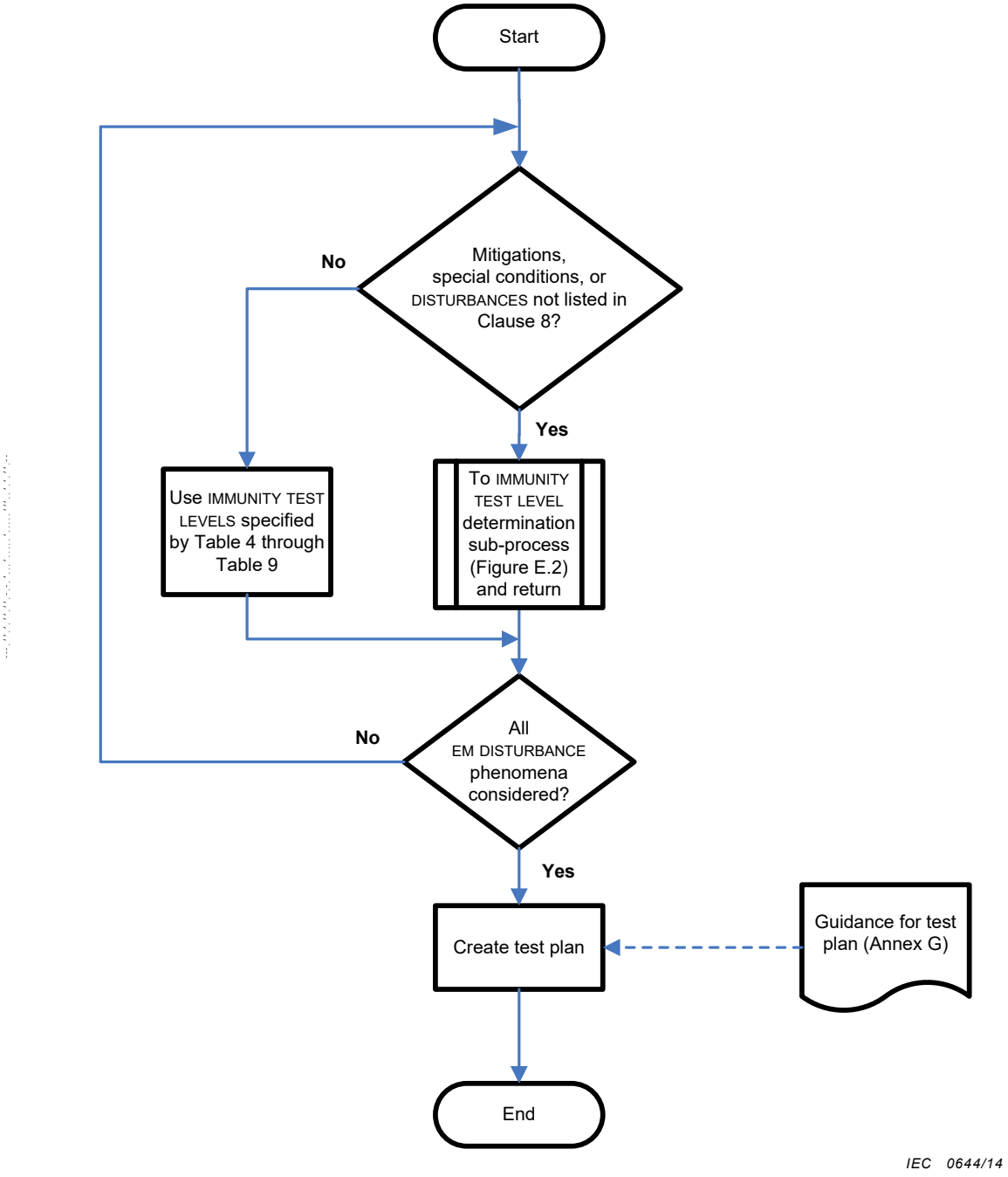


Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known

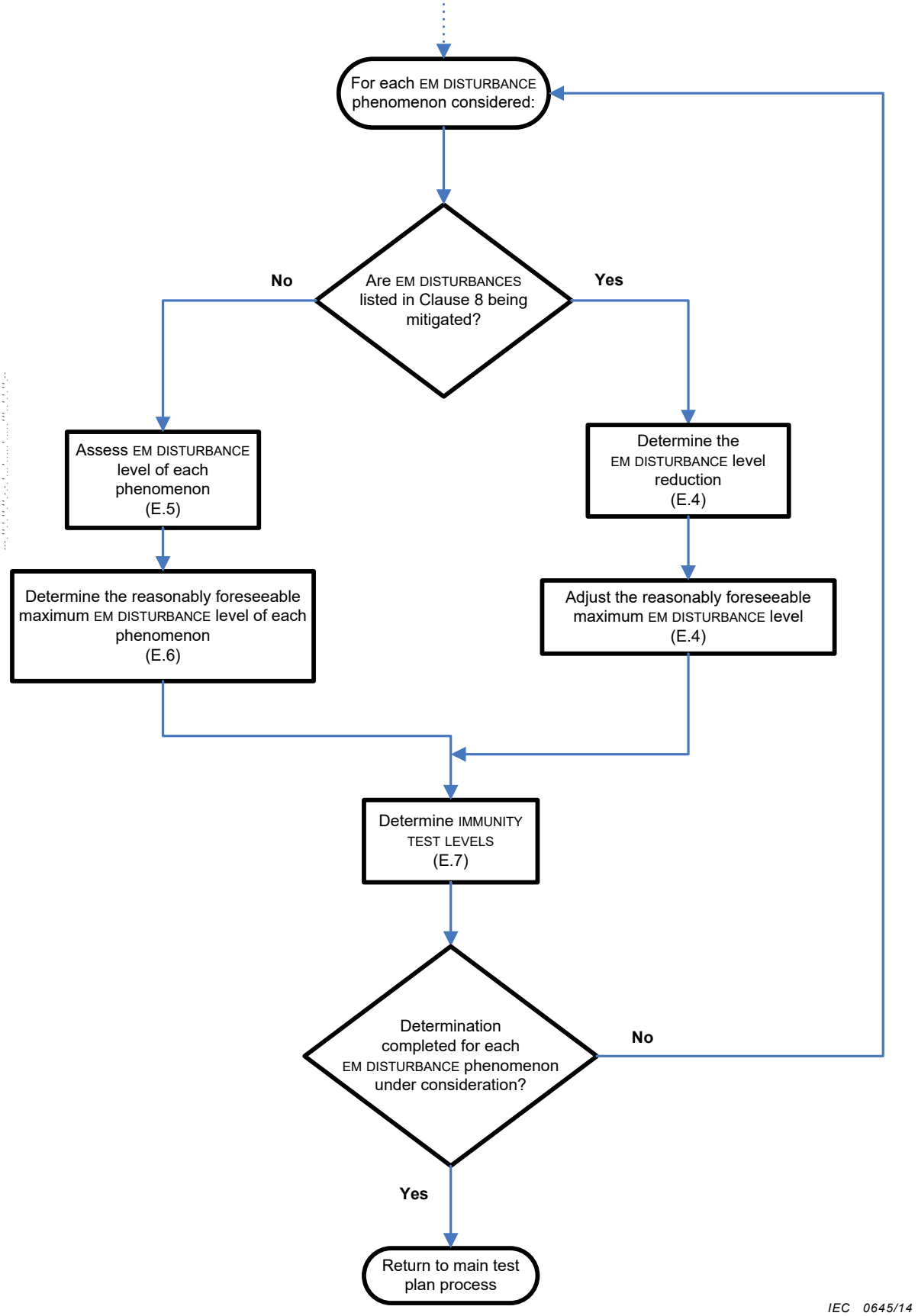


Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS

E.2 Summary of method for E.1 a)

For mitigations (E.1 a)), the following steps should be followed to determine an adjusted IMMUNITY TEST LEVEL for each phenomenon for which this is necessary:

– determination of EM DISTURBANCE level reduction (E.4);

– determination of IMMUNITY TEST LEVELS (E.7).

E.3 Summary of method for E.1 b), c) and d)

For special conditions (E.1 b) and c) and for the presence of EM phenomena described in E.1 d), the following steps should be followed to determine a new IMMUNITY TEST LEVEL for each phenomenon for which this is necessary:

– assessment of EM DISTURBANCE sources (E.5);

– determination of reasonably foreseeable maximum EM DISTURBANCE levels (E.6);

– determination of IMMUNITY TEST LEVELS (E.7).

An example of mitigations (special conditions) for two different phenomena offered by one INTENDED USE is an oncology system with an electron accelerator. The shielding effectiveness of the bunker provides mitigation for radiated RF and the limited movement of the PATIENT during treatment would be an INTENDED USE consideration for ESD.

E.4 Determination of EM DISTURBANCE level reduction

Once the MANUFACTURER of an ME EQUIPMENT or ME SYSTEM has decided to mitigate exposure to the EM DISTURBANCES caused by an EM phenomenon listed in Clause 8, a determination of mitigation reduction is needed in order to adjust the reasonably foreseeable maximum EM DISTURBANCE level of that phenomenon. Once the new level of EM DISTURBANCE has been determined, this new level can then be used to determine the IMMUNITY TEST LEVEL for that phenomenon. Each phenomenon that is mitigated, and for which the MANUFACTURER would like to adjust the IMMUNITY TEST LEVEL, will need its own assessment.

E.5 Assessment of EM DISTURBANCE sources

Once the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM has determined that in the INTENDED USE environment there might be special conditions associated with certain sources of EM DISTURBANCE (E.1 b) or c)) or there might be EM phenomena that are not listed in Clause 8 (E.1 b)), the next step is to perform an assessment of each source. The assessment will result in determination of reasonably foreseeable maximum EM DISTURBANCE levels.

Methods of making an assessment include, but are not limited to, the following:

– use of applicable standards representing the generally accepted state-of-the-art;

– comparing levels evident from medical devices already in use, being considered state-of-the-art;

– use of expert opinion;

– use of scientific research results, including clinical data;

– use of measured data, including field survey results.

The IET *Guide on EMC for Functional Safety* [36] has useful information applicable to field survey measurements.

For the case of a single source, EM DISTURBANCE levels can be obtained from direct measurement or by obtaining MANUFACTURER'S data or other published information. Other

references exist that describe methods for assessing the EM ENVIRONMENT. One such reference is IEC/TS 61000-1-2 [8], Subclauses 6.1 to 6.3. IEC/TR 61000-2-5 [9] can be used as a basis for understanding compatibility levels, from which safety levels can be evaluated.

A single source (e.g. emitter) can generate multiple EM phenomena or a single phenomenon consisting of multiple EM DISTURBANCE levels at multiple frequencies, such as RF transmitters. Such factors that are determined for the same source of EM DISTURBANCE but are based on different characteristics can be combined.

E.6 Reasonably foreseeable maximum EM DISTURBANCE levels

“Reasonably foreseeable” is generally accepted to mean the consequences that a reasonable person could expect from his or her actions. This applies to ME EQUIPMENT and ME SYSTEMS as follows: if you are aiming for a high probability of safety and bring a device into a particular EM ENVIRONMENT where it does not have sufficient IMMUNITY, it is not reasonable to expect that the device will operate safely. The consequences of this decision would be expected to be foreseeable to a reasonable person.

“Reasonably foreseeable maximum” is not the everyday (typical) exposure level expected. Neither does it mean whatever level someone can imagine. The everyday expected level would be considered to be appropriate for performance. A higher level would therefore be expected for safety because it covers a wider range of possibilities, but not higher than what is reasonably foreseeable. The current thinking is that testing to levels greater than the reasonably foreseeable maximum is not likely to result in increased safety of the ME EQUIPMENT or ME SYSTEM.

In determining these levels, one needs to consider uncertainties such as the quality of the assessment data and the effects of other EM phenomena that could be present at the same time. The PROCESS should be performed for each EM phenomenon for which this determination is necessary.

E.7 Determination of IMMUNITY TEST LEVELS

The IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE should be chosen based on a high probability of maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE. It should not be confused with RISK ASSESSMENT. The IMMUNITY TEST LEVEL should be chosen at a point that represents exposure to the reasonably foreseeable maximum EM DISTURBANCE level. This is independent from RISK mitigation following a RISK ASSESSMENT. Reducing the IMMUNITY TEST LEVEL because the probability of occurrence of HARM or the SEVERITY of that HARM is low is not appropriate.

For E.1 d), special test methods might be necessary.

See 8.9 for requirements for rounding of final IMMUNITY TEST LEVELS.

E.8 RF radiators in SPECIAL ENVIRONMENTS

One type of intentional RF radiator that is well-known is RF wireless communication services equipment. Because of the prevalence of this equipment, this collateral standard explicitly specifies requirements for IMMUNITY to EMISSIONS from this equipment in 8.10. There are also sources of RF EMISSIONS that transmit unintentionally. Examples of RF radiators the vicinity of which could be SPECIAL ENVIRONMENTS, depending on e.g. the minimum separation distance during the INTENDED USE of the ME EQUIPMENT or ME SYSTEM, include near-field communication (NFC) equipment, electronic article surveillance (EAS) (anti-theft) equipment, HF SURGICAL EQUIPMENT, and SHORT-WAVE THERAPY EQUIPMENT.

E.9 Examples of mitigations and special conditions

Example mitigations and special conditions are shown in Table E.1, listed by EM phenomenon.

Mitigations and special conditions and resulting IMMUNITY TEST LEVELS are unique to each ME EQUIPMENT and situation. These are examples only and should not be misinterpreted as recommendations or requirements.

Table E.1 – Examples of specific mitigations / environmental conditions

Phenomenon / Basic standard	Example mitigation or special condition	Example adjusted IMMUNITY TEST LEVEL	Remarks
ESD IEC 61000-4-2	Actual (not just specified) relative humidity >50 % and conductive floor	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	See IEC 61000-4-2 Table A.1 and IEC 61340 series
ESD IEC 61000-4-2	INTENDED USE for X-ray imaging: during the exposure time, no one is close to the ME EQUIPMENT except the PATIENT	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	Movements of PATIENT are very small and will not generate high electrostatic charges
Radiated RF EM fields IEC 61000-4-3	RF shielded environment, including filtering of all cables passing through the shielding (e.g. room, housing, bunker), with a minimum shielding effectiveness and filter attenuation of 20 dB	1 V/m	VG 95376-4 MIL Std 285D EN 61587-3 Example: bunker for electron accelerator
Fields from radio and TV transmitters IEC 61000-4-3	RF shielded room of an ME SYSTEM for magnetic resonance imaging	3 V/m	
Electrical fast transients / bursts IEC 61000-4-4	Signal line separation by a minimum of 30 cm required by installation guide and verified by acceptance testing.	500 V	IEC 61000-4-4 Annex B
Surges IEC 61000-4-5	Internal / external lightning protection with periodic maintenance throughout the EXPECTED SERVICE LIFE as shown in the circuit diagram / critical components list	500 V	IEC 61000-4-5, Article B.3
Conducted disturbances induced by RF fields IEC 61000-4-6	RF shielded environment including filtering of all cables passing through the shielding, with a minimum shielding effectiveness and filter attenuation of 20 dB	1 V	
RATED power frequency magnetic fields IEC 61000-4-8	PERMANENTLY INSTALLED in a controlled location ensures that no extra equipment / cables using high currents with RATED power frequency will be brought in close proximity; verified during acceptance testing and in periodic inspections throughout the EXPECTED SERVICE LIFE	No testing	
Voltage dips and interruptions IEC 61000-4-11	Uninterruptible power supply (UPS) sufficiently fast and powerful to provide the energy needed	No testing	Test applicable only to UPS

Annex F
(informative)

Guidance on the application of RISK MANAGEMENT with regard to ELECTROMAGNETIC DISTURBANCES in this collateral standard

Annex F provides specific guidance for those subclauses of this collateral standard that involve aspects of RISK MANAGEMENT. In general, this collateral standard requires the MANUFACTURER to analyse, evaluate and apply RISK CONTROLS as part of an effort to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE. The tests in this collateral standard are only one form of RISK EVALUATION.

The users of this collateral standard are reminded that particular standards IEC 60601-2-xx and ISO/IEC 80601-2-xx can include RISK MANAGEMENT requirements that could supersede (replace) those provided in this collateral standard.

NOTE 1 This collateral standard does not address how to incorporate into the design of a product RISK CONTROLS for RISKS arising from ELECTROMAGNETIC DISTURBANCES. Reference [8] provides guidance on this topic. In addition, SC 62A is developing a technical report in the IEC 60601-4-x series on RISK CONTROL with regard to ELECTROMAGNETIC DISTURBANCES.

Table F.1 lists the subclauses in this collateral standard that include RISK MANAGEMENT as part of normative requirements. Guidance is provided for these subclauses when applying RISK MANAGEMENT activities while considering the RISKS related to ELECTROMAGNETIC DISTURBANCES.

A view of the relationship between this collateral standard and ISO 14971:2019 in the form of a flowchart is provided in Figure F.1. Another useful example of the relationship between the PROCESS described in ISO 14971 and HAZARDS/HAZARDOUS SITUATIONS identified in IEC 60601-1 is provided in Figure E.1 of ISO/TR 24971:2020 [48].

NOTE 2 Subclause 3.108 of IEC 60601-1:2005+A1:2012+A2:2020 specifies the contents of the RISK MANAGEMENT FILE.

Table F.1 – Specific guidance for subclauses of this collateral standard that reference RISK MANAGEMENT *(1 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS. NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS. NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities. *Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.*	This RISK MANAGEMENT PROCESS is intended to identify whether the normative requirements specified in this collateral standard address the RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES in the environments where the ME EQUIPMENT or ME SYSTEM is intended to be used. An example of reasonably foreseeable ELECTROMAGNETIC DISTURBANCES not covered by this collateral standard is EMISSIONS from 5G mobile phones. This equipment might affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of ME EQUIPMENT or ME SYSTEMS.

Table F.1 *(2 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
4.2 Non-ME EQUIPMENT used in an ME SYSTEM In addition to 16.1 of the general standard: – non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment; – non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard.*	The RISK MANAGEMENT FILE needs to show the results of RISK ANALYSIS that leads to a determination of whether the non-ME EQUIPMENT is involved in any way with the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. If the non-ME EQUIPMENT is not tested in accordance with this collateral standard, there needs to be OBJECTIVE EVIDENCE (i.e. an EMC test report) showing that the non-ME EQUIPMENT meets its applicable requirements. For example, ITE used in conjunction with the ME SYSTEM needs to conform with CISPR 32 and CISPR 35 [49].
4.3 General test conditions **4.3.1 Configurations** ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. (other text omitted) *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The RISK MANAGEMENT FILE needs to show how the configurations to be tested were determined (i.e. experience, engineering analysis, or pretesting). Where the ME EQUIPMENT or ME SYSTEM has only one configuration, there should be a comment in the RISK MANAGEMENT FILE stating this. An example is an ultrasound system designed to work with several families of probes. The MANUFACTURER could select one probe from each family of probes as individual configurations for test. In this case, the RISK MANAGEMENT FILE would include justification for why the selected probe was representative of all other probes in a given family.
5.2 ACCOMPANYING DOCUMENTS **5.2.1 Instructions for use** **5.2.1.1 General** In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following: a) a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF SHIELDED ROOM of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.	If there are excluded environments as determined by RISK ANALYSIS, they need to be stated in both the instructions for use and the RISK MANAGEMENT FILE. For example, a statement in instructions for use could exclude the use of the ME EQUIPMENT or ME SYSTEM in the presence of active HF SURGICAL EQUIPMENT.

Table F.1 *(3 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS **8.1 General** (other text omitted) **Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal** If any equipment is damaged, it can continue to be used for the IMMUNITY test for this specific phenomenon, as long as it can be proven (e.g. by RISK MANAGEMENT, engineering analysis, experience, redundancy) that the ability of the ME EQUIPMENT or ME SYSTEM to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE can still be determined while using the damaged equipment. (other text omitted) Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE. IMMUNITY pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable RISK. (other text omitted)	RISK MANAGEMENT is applied generally in this subclause in three areas: 1) As one of several optional means to determine whether or not equipment that is being tested and subsequently damaged can continue to be used for testing. 2) Determination of pass/fail criteria when the criteria have not been provided in an applicable part two standard. 3) Provision of feedback to the RISK MANAGEMENT PROCESS concerning any effects that might be observed during testing. When RISK MANAGEMENT is used to determine any of the pass/fail criteria, the RISK MANAGEMENT FILE needs to document that this was done. If justified, Annex E is used to determine the IMMUNITY TEST LEVELS. Also see 4.1 of this table. Upon completion of testing, the effects observed need to be evaluated to determine if there is a clinical impact that could lead to unacceptable RISK. Depending on the outcome of the review, additional RISK mitigations might be required for the ME EQUIPMENT or ME SYSTEM.
Following the tests, any effects on the ME EQUIPMENT or ME SYSTEM that are observed during or after the application of the test DISTURBANCES should be considered in the on-going RISK MANAGEMENT PROCESS. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by application of the tests specified in Table 4 through Table 9 and 8.11, as applicable. If the ME EQUIPMENT or ME SYSTEM meets its specified IMMUNITY pass/fail criteria before, during and after these tests and the compliance tests of the individual subclauses of this clause are met, then compliance with Clause 8 is verified.*	

Table F.1 *(4 of 6)*

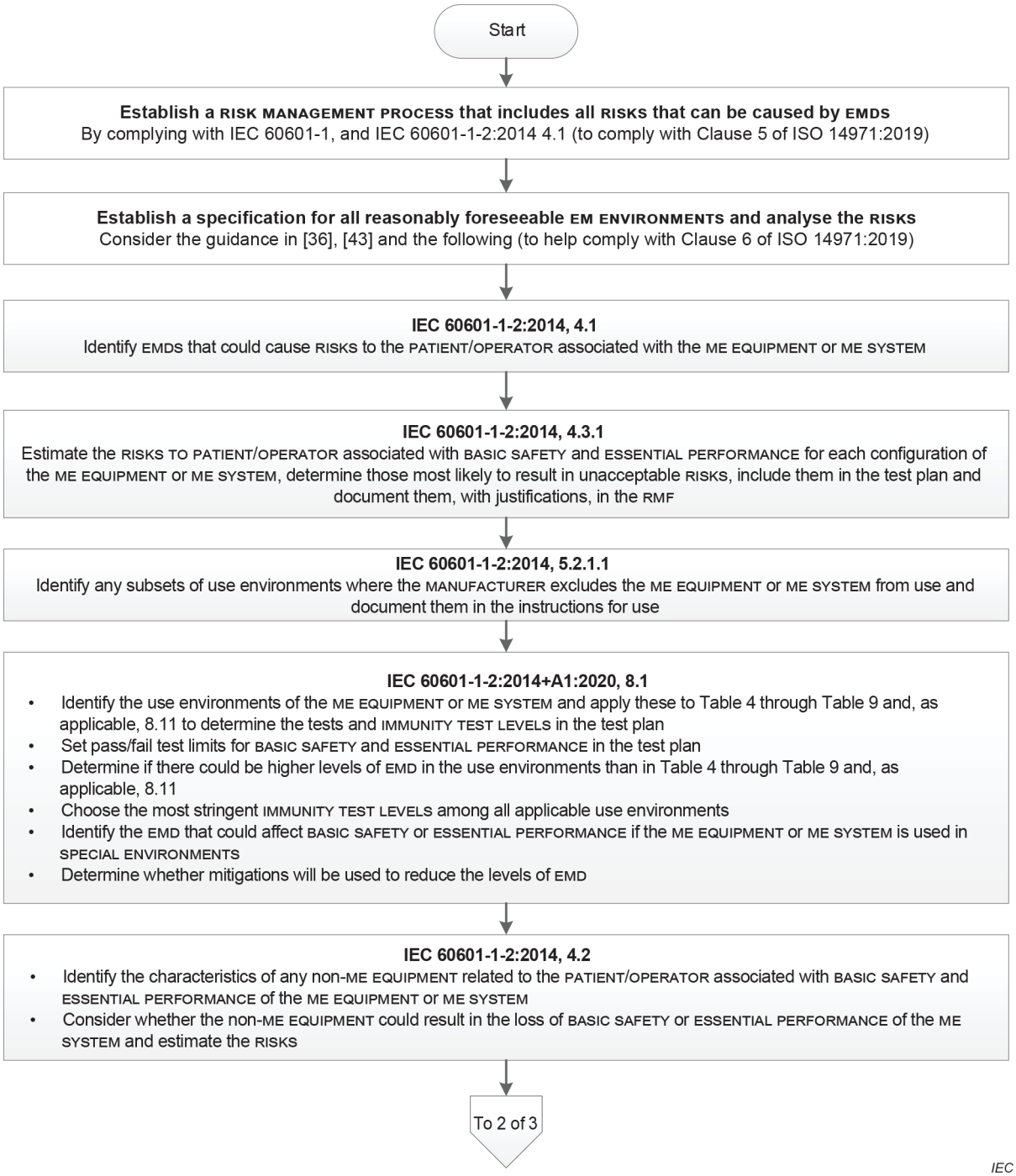
Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.5 Subsystems Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER'S knowledge of how the ME SYSTEM operates can be used to determine if normal operating conditions can be simulated. Note that normal operating conditions are, for the purposes of this subclause, defined as at least the simulation of representative electrical, mechanical, RF signals, impedances and cables and their configurations. See Annex A for further explanation regarding this subclause. The decision to perform subsystem-level testing should be documented in the RISK MANAGEMENT FILE.
8.7 Operating modes During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. If the ME EQUIPMENT or ME SYSTEM is not RATED for continuous duty, a duty cycle may be selected that is appropriate for the ME EQUIPMENT or ME SYSTEM under test. The standby mode should be considered for inclusion in IMMUNITY testing, particularly for ME EQUIPMENT and ME SYSTEMS that are in standby mode for long periods of time in the presence of PATIENTS or OPERATORS. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report. *Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report.*	For ME EQUIPMENT and ME SYSTEMS that have multiple modes of operation or operational settings, the MANUFACTURER needs to first determine the specific set of modes and settings that will be used during testing. The choice of these modes and settings is made by identifying which are most likely to result in an unacceptable RISK (loss of BASIC SAFETY or ESSENTIAL PERFORMANCE) as a result of the applied ELECTROMAGNETIC DISTURBANCE. RISK ANALYSIS is one option to make the choice, but regardless, the choices made and rationale for them should be documented in the RISK MANAGEMENT FILE.
8.8 Non-ME EQUIPMENT Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	The citation of RISK MANAGEMENT in this subclause means that the MANUFACTURER's knowledge of how the ME SYSTEM operates can be used to determine if testing of the non-ME EQUIPMENT is required according to 4.2.

Table F.1 *(5 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
8.9 IMMUNITY TEST LEVELS (other text omitted) When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 4 through Table 9 and 8.11, the MANUFACTURER shall take this into consideration in the RISK MANAGEMENT PROCESS. Annex E may be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 4 through Table 9 and 8.11 and, when justified, to adjust the specified IMMUNITY TEST LEVELS based on e.g. mitigations or conditions of INTENDED USE. If this determination or adjustment is made, the following information should be documented in the test plan, as specified in Table G.1, and shall be documented in the RISK MANAGEMENT FILE and in the test report, as specified in Table 10: a) justification for any SPECIAL ENVIRONMENTS identified or adjustments made; b) the adjusted reasonably foreseeable maximum EM DISTURBANCE levels; c) the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit; d) details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS. If mitigations are used to justify lower IMMUNITY TEST LEVELS, the RISK MANAGEMENT FILE shall include documentation explaining how it can be reasonably expected that the mitigations will continue to be effective over the EXPECTED SERVICE LIFE in all locations in which the ME EQUIPMENT or ME SYSTEM is expected to be used. In all cases, the IMMUNITY TEST LEVELS used should be documented in the test plan (see Annex G) and shall be documented in the test report (see Clause 9). *Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.*	When the environment of INTENDED USE is known to alter the reasonably foreseeable EM DISTURBANCE levels specified in this collateral standard, this knowledge needs to be incorporated into the RISK MANAGEMENT PROCESS. Specifically, this information might affect the determination of IMMUNITY TEST LEVELS, which might be increased or decreased, according to Annex E. The MANUFACTURER needs to ensure that all choices and justifications for them are documented in the RISK MANAGEMENT FILE. Most importantly, it needs to explain how any mitigations applied or assumed can be reasonably expected to remain effective over the EXPECTED SERVICE LIFE, and in all locations of INTENDED USE, for the ME EQUIPMENT or ME SYSTEM. For example, if the MANUFACTURER assumes that the ME EQUIPMENT or ME SYSTEM will be used in a controlled humidity environment where the reasonably foreseeable ESD DISTURBANCE level (and the corresponding IMMUNITY TEST LEVEL) are reduced, then the RISK MANAGEMENT FILE needs to explain why the controlled humidity environment can be expected to be maintained and the ME EQUIPMENT or ME SYSTEM will only be used in that environment over its EXPECTED SERVICE LIFE.
Table 4 – ENCLOSURE PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Table 4, table footnote c), provides the option to perform the radiated RF swept test using modulations other than those given in the table. The alternative modulation frequencies would be determined by a RISK ANALYSIS. For example, if the MANUFACTURER knows that their ME EQUIPMENT or ME SYSTEM is particularly sensitive to a specific modulation frequency or range of frequencies, they might choose to use these instead of or in addition to those specified in Table 4 as they could be the highest RISK modulations.

Table F.1 *(6 of 6)*

Subclause/requirement in this collateral standard	Rationale/guidance/examples
Table 5 – Input a.c. power PORT *(1 of 2)* Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 6 – Input d.c. power PORT Table footnotes: e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 7 – PATIENT coupling PORT Table footnotes: a), fourth indent Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
Table 8 – SIP/SOP PORT Table footnotes: c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.	Same as Table 4, table footnote c)
8.10 IMMUNITY to proximity fields from RF wireless communications equipment (other text omitted) The frequencies and services listed in Table 9 are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 9. (other text omitted) The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance.	For this subclause, RISK MANAGEMENT is used in two ways: 1) To identify communications services that might be encountered in the environment of INTENDED USE and that are not listed in Table 9. The RISK ANALYSIS needs to consider whether these services present a RISK, and if so, they should be documented in the RISK MANAGEMENT FILE and incorporated into the test plan. An example of this would be services for 5G mobile phones. 2) To identify whether the environment(s) of INTENDED USE for the ME EQUIPMENT or ME SYSTEM will routinely allow for exposure to RF wireless communications equipment at separation distances less than 0,3 m. The RISK ANALYSIS would determine a different reasonably foreseeable minimum separation distance and adjust the IMMUNITY TEST LEVELS (higher) to account for this scenario.
8.11 IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz (other text omitted) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, the tests of Table 11 need not be performed.	For this subclause, if the exemptions of 8.11 a) and b) do not apply, then a RISK ANALYSIS can be performed to determine if this test is necessary.



Key

EM = ELECTROMAGNETIC	EMD = EM DISTURBANCE
RMP = RISK MANAGEMENT PROCESS	RMF = RISK MANAGEMENT FILE

Figure F.1 – RISK MANAGEMENT flow in IEC 60601-1-2 *(1 of 3)*

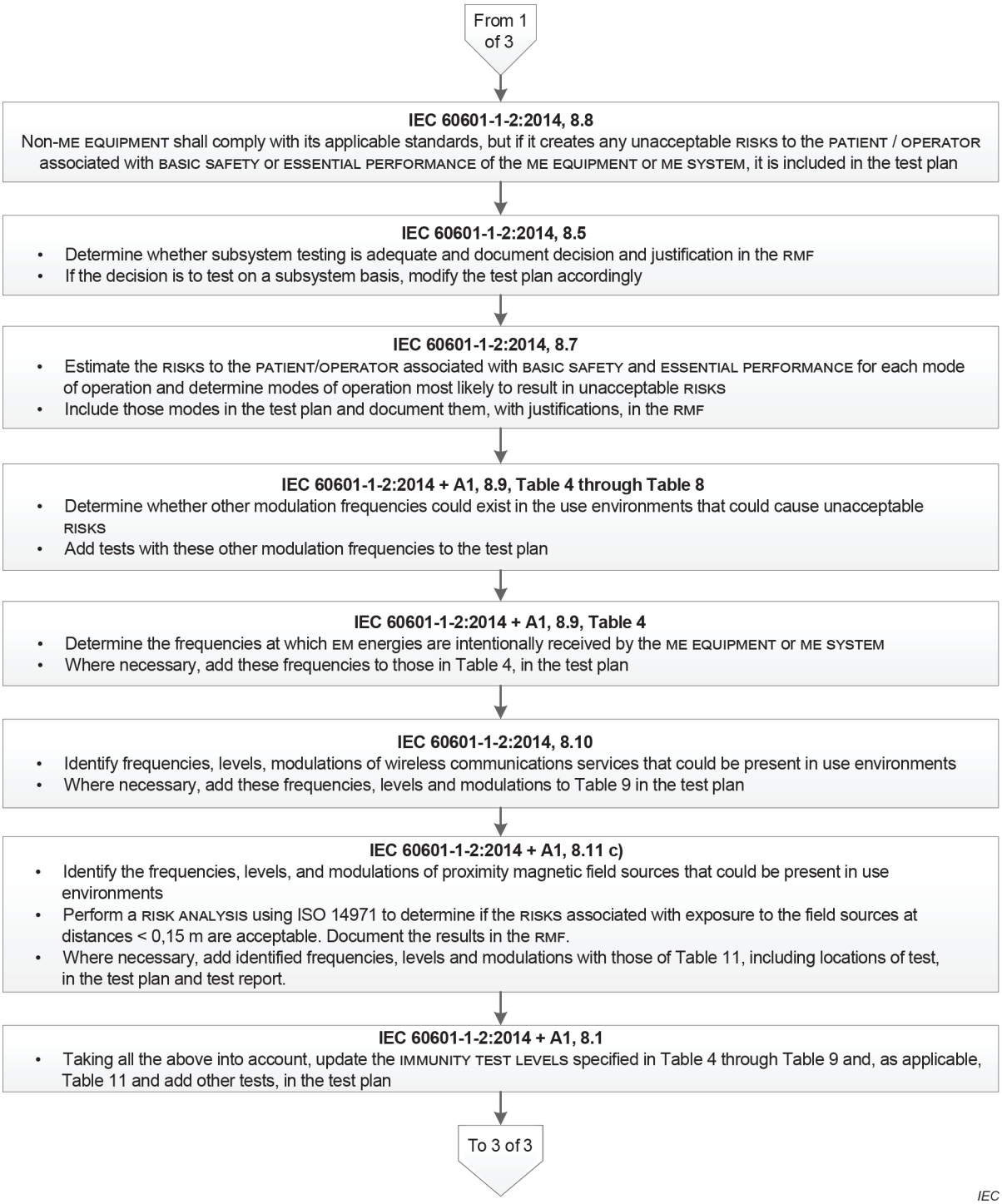


Figure F.1 *(2 of 3)*

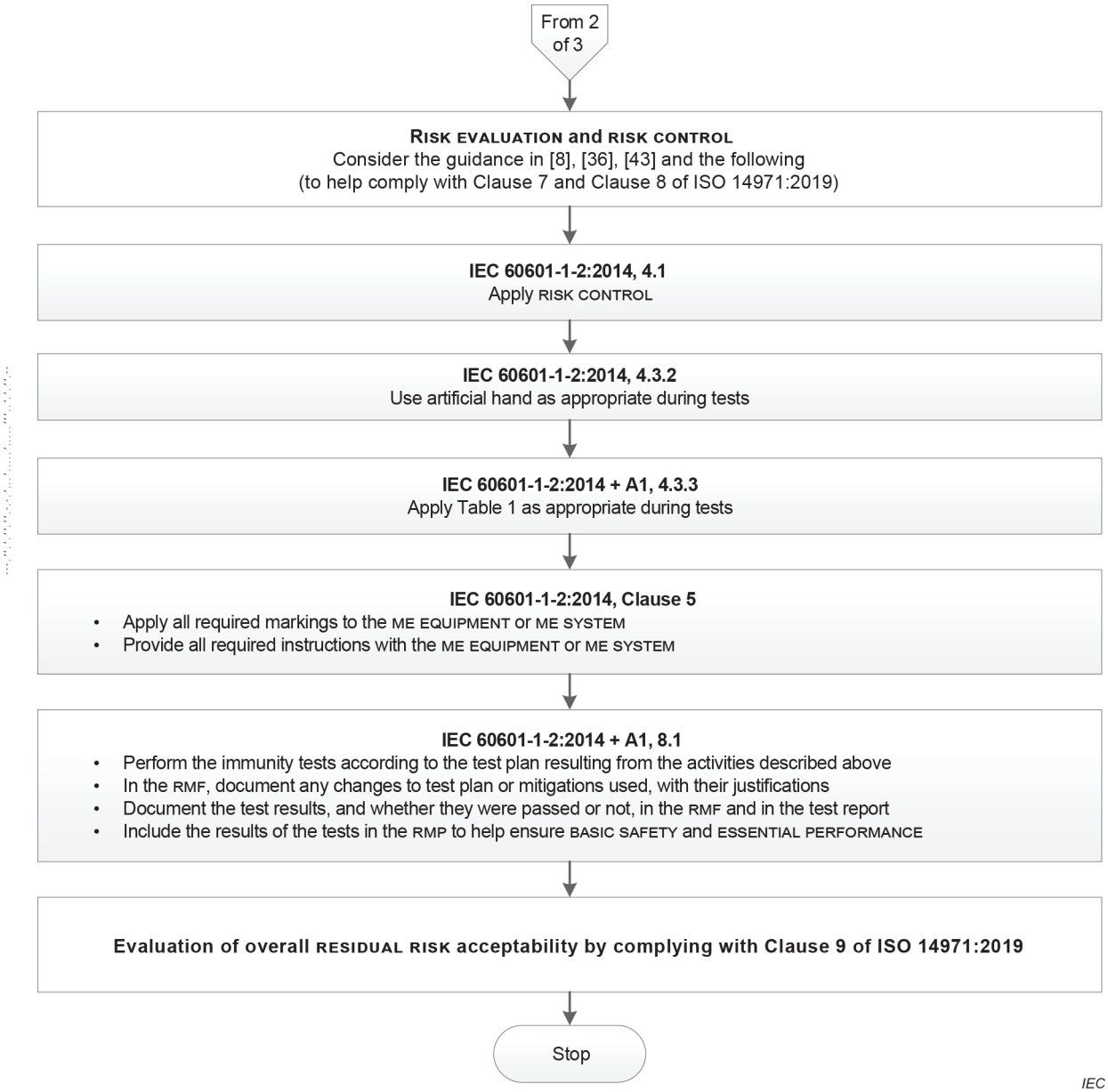


Figure F.1 *(3 of 3)*

Annex G
(informative)

Guidance: Test plan

G.1 Test plan contents

Table G.1 shows the suggested contents of a test plan.

Table G.1 – Recommended minimum test plan contents *(1 of 2)*

No.	Item	Additional detail
1	Name and address of the test facility	
2	Description of the ME EQUIPMENT or ME SYSTEM	Describe all devices, racks, modules, boards, cables, etc. belonging to the ME EQUIPMENT or ME SYSTEM.
3	Description of the BASIC SAFETY and ESSENTIAL PERFORMANCE including a description how the BASIC SAFETY and ESSENTIAL PERFORMANCE will be monitored against the pass/fail criteria during each test	
4	Identification of the ME EQUIPMENT or ME SYSTEM	Include device name and model number.
5	ME EQUIPMENT or ME SYSTEM software / firmware version of the sample to be tested	
6	Number of samples to be tested	The number of samples for each EMC test
7	INTENDED USE and intended environments	
8	Applicable standards and test methods	A list of the standards (with dates) and EMISSIONS limits or IMMUNITY TEST LEVELS
9	Deviations from the Basic EMC standards or from this collateral standard	Include any instructions needed
10	Applicability / tests that will not be performed	The decision and justification not to perform a measurement or test shall be documented.
11	If the procedure specified by Annex E or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made – the adjusted reasonably foreseeable maximum EM DISTURBANCE levels – the resulting final IMMUNITY TEST LEVELS, rounded to the nearest whole number or, if a decimal, to a single significant digit – details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS	
12	IMMUNITY TEST LEVELS for each IMMUNITY test and EMISSIONS compliance class and group	
13	IMMUNITY pass/fail criteria	Specific IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as per the RISK ANALYSIS (see Annex I)
14	ME EQUIPMENT or ME SYSTEM configurations, settings and operating modes	List by test.
15	Test setup electrical and physical diagrams	Show how the ME EQUIPMENT OR ME SYSTEM hardware will be configured and connected to the test systems, how cables will be routed and bundled, and disposition of excess cable.
16	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	List by test.

Table G.1 *(2 of 2)*

No.	Item	Additional detail
17	Earthing configuration	Describe how the ME EQUIPMENT OR ME SYSTEM connects to protective earth.
18	Whether the ME EQUIPMENT or ME SYSTEM will be tested as table-top or floor-standing equipment, or a combination of the two	
19	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or LARGE ME SYSTEM	If on-site testing is required, diagram the equipment or system in the location in which it will be installed and describe how testing will be performed.
20	Exercising of SIP/SOPS	Describe how each SIP/SOP PORT is to be exercised.
21	For floor-standing ME EQUIPMENT or ME SYSTEMS, the height of the support	
22	Description of any PATIENT-COUPLED cable terminations to be used	
23	Simulators, accessories and auxiliary equipment	Describe simulators, ACCESSORIES and auxiliary equipment used, including PATIENT physiological and subsystem simulation
24	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
25	ALARM LIMIT settings	If applicable, provide rationale for the settings chosen.
26	Planned ESD test points.	If possible, include a drawing or annotated photo showing the ESD test points.
27	Dwell time for each IMMUNITY test requiring a dwell time	
28	The locations of application of proximity magnetic fields	If the testing according to 8.11 step d) is performed.

Annex H
(informative)

PATIENT-coupled cables EMISSIONS

H.1 * Protection of other equipment from PATIENT cable conducted EMISSIONS

Conducted EMISSIONS from PATIENT-COUPLED cables should comply with the limit in Table H.1, measured using the common-mode clamp method specified in H.2. ME EQUIPMENT and ME SYSTEMS that deliver RF electromagnetic energy for diagnosis, treatment or monitoring of PATIENTS may be tested in standby mode. All other ME EQUIPMENT and ME SYSTEMS should be tested in both standby and active modes.

Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit

Frequency	Peak current
MHz	dBμA
1-30	24

H.2 Test method

For each PATIENT-COUPLED cable, the peak conducted EMISSION should be determined using a current probe having a frequency range of at least 1 MHz to 30 MHz as specified in Annex B of CISPR 16-1-2. For ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27 [3], the probe should initially be placed close to the ME EQUIPMENT or ME SYSTEM as shown in Figure H.1 and then moved to the point that maximizes the measured EMISSIONS. All other PATIENT-COUPLED cables should be non-inductively bundled and the probe should be placed at the point that maximizes the measured EMISSIONS. EMISSION measurements should be performed in accordance with the requirements in CISPR 16-1-1 [16] and should comply with the limit specified in Table H.1.

PATIENT-COUPLED cables are considered interconnecting cables in accordance with the requirements of CISPR 11. Any PATIENT-COUPLED cable termination used should be described in the documentation of the test. If simulated PATIENT physiological signals are required to simulate normal operation of the ME EQUIPMENT or ME SYSTEM, they should be provided. The PATIENT COUPLING POINT should not have an intentional conductive or capacitive connection to earth during testing.

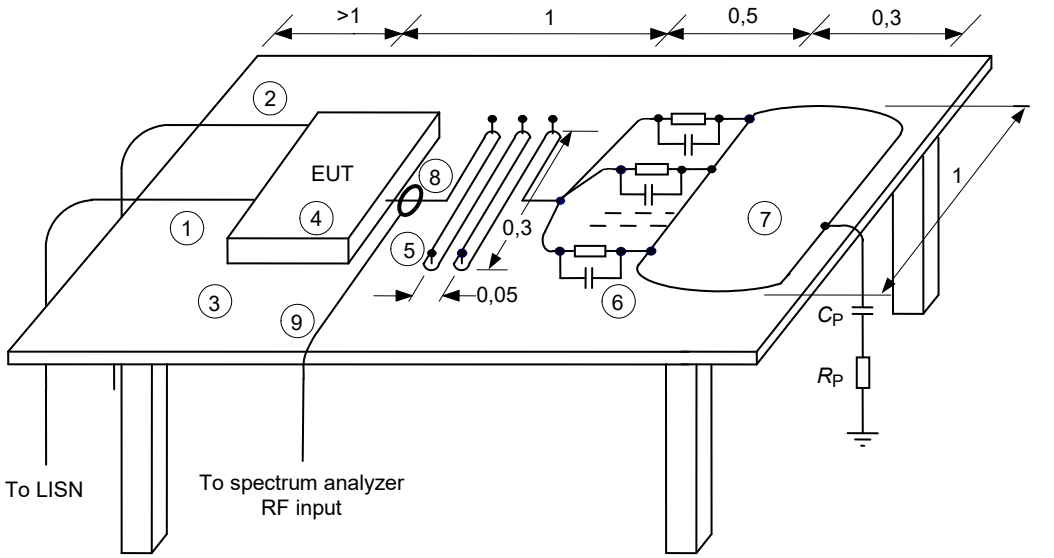
The test setup is shown in Figure H.1.

H.3 Rationale

In modern medical practice there is more and more ME EQUIPMENT coupled concurrently to the PATIENT. Often a PATIENT monitor is coupled to the same PATIENT as ULTRASOUND DIAGNOSTIC EQUIPMENT. In the electrophysiology lab there can be several separate devices coupled to the same PATIENT simultaneously. This is also true for the operating room. In fact, there is considerable evidence in medical practice that these EMISSIONS have caused image artefact in ULTRASOUND DIAGNOSTIC EQUIPMENT that was coupled to the same PATIENT as monitoring equipment. This often results from excessive coupling to the PATIENT of noise from switching power supplies.

Previously there was no specification for the amount of RF noise that PATIENT-COUPLED ME EQUIPMENT or ME SYSTEMS could couple onto the PATIENT. When there is multiple PATIENT-COUPLED ME EQUIPMENT, there can be interference from one ME EQUIPMENT to another. This

test sets a limit on the RF noise coupled to the PATIENT. It is intended to be a simple measurement that can be made quickly using the conducted EMISSIONS test setup. The RF EMISSIONS limit was set based on the susceptibility of sensitive PATIENT-COUPLED ME EQUIPMENT and ME SYSTEMS, yet accommodating the reasonably foreseeable level of RF conducted EMISSIONS from PATIENT-COUPLED APPLIED PARTS.



Components

1 Mains cable
2 Signal cable
3 Table made of insulating material
4 EQUIPMENT under test
5 PATIENT CABLE
6 Load simulating the PATIENT (51 kΩ in parallel with 47 nF)
7 Metal plate
8 Current clamp
9 Current clamp cable to spectrum analyzer RF input
C_P 220 pF
R_P 510 Ω

C_P in series with R_P simulates the body of the PATIENT.

NOTE This figure is derived from Figure 202.101 of IEC 60601-2-27:2011.

Figure H.1 – Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27

Annex I
(informative)

Identification of IMMUNITY pass/fail criteria

I.1 General

Clause 8 of this collateral standard specifies IMMUNITY TEST LEVELS. Annex E specifies methods for determining IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS. This annex provides guidance and examples to aid in the required determination of specific, detailed IMMUNITY pass/fail criteria.

I.2 IMMUNITY pass/fail criteria principles

I.2.1 General

It is necessary to identify the specific hardware, firmware, and software functions that need to be verified during IMMUNITY tests. These functions should be derived from one or more sources, including the RISK ANALYSIS. The response of these functions should be monitored, with sufficient accuracy and resolution, before, during and after IMMUNITY testing.

The IMMUNITY pass/fail criteria should be specified using quantitative values when possible. An example starting point to quantify the pass/fail criteria might be the MANUFACTURER'S accuracy specification in the ACCOMPANYING DOCUMENTS.

The selection of pass/fail criteria should include consultations with clinicians whose experience and area of expertise include the use of the particular ME EQUIPMENT or ME SYSTEM.

I.2.2 IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM

An ME SYSTEM that includes non-ME EQUIPMENT requires a determination whether additional IMMUNITY tests and pass/fail criteria are necessary.

I.2.3 IMMUNITY pass/fail criteria determination

The functions to be tested and the specific, detailed IMMUNITY pass/fail criteria should be derived from one or more sources. This includes identification of:

– the HAZARDS;
– the functions to be tested for IMMUNITY to verify freedom from unacceptable RISK;
– the criteria on which to base the pass/fail decision;
– operating modes;
– characteristics of simulated PATIENT physiological signals;
– specification of locations of INTENDED USE;
– the characteristics of the test, where these are at the discretion of the MANUFACTURER.

Part 2 standards in the IEC 60601 family can specify particular ESSENTIAL PERFORMANCE and IMMUNITY pass/fail criteria.

IMMUNITY pass/fail criteria can specify degradations that are acceptable because they do not result in unacceptable RISK.

I.3 IMMUNITY pass/fail criteria examples

I.3.1 General examples

The following are examples that can be used to develop pass/fail criteria. For ME EQUIPMENT and ME SYSTEMS with multiple functions, the pass/fail criteria should be applied to each function, parameter and channel.

Examples of test failures:

– malfunction;
– non-operation when operation is required;
– unwanted operation when no operation is required;
– deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR;
– component failures;
– change in programmable parameters;
– reset to factory defaults (MANUFACTURER's presets);
– change of operating mode;
– a FALSE POSITIVE ALARM CONDITION;
– a FALSE NEGATIVE ALARM CONDITION (failure to alarm);
– cessation or interruption of any intended operation, even if accompanied by an ALARM SIGNAL;
– initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL;
– error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
– noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring;
– artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
– failure of automatic diagnosis or treatment ME EQUIPMENT or ME SYSTEM to diagnose or treat, even if accompanied by an ALARM SIGNAL.

Example of performance during and after the applied testing stimulus required to pass the test:

– for a mammography system, the compression full release and associated command remains fully operational;
– for ULTRASOUND DIAGNOSTIC EQUIPMENT, the probe heating, dissipative power and temperature shall remain within specifications;
– safety-related functions perform as intended;
– false operation of alarms, "fail safe" modes and similar functions do not occur.

NOTE This might require performing the test twice – once to ensure the functions occur as expected and again to ensure they do not occur falsely.

Examples of acceptable degradation:

– an imaging system displays an image that could be altered, but in a way that would not affect the diagnosis or treatment;
– a heart rate monitor displays a heart rate that could be in error, but by an amount that is not clinically significant;
– a PATIENT monitor exhibits a small amount of noise or a transient on a waveform and the noise or transient would not affect diagnosis, treatment or monitoring.

Examples of ME EQUIPMENT and ME SYSTEMS with multiple functions:

– multi-parameter monitors;
– anaesthesia system with monitors;
– ventilators with monitors;
– multiple instances of the same function (e.g. multiple invasive blood pressure sensors).

Failure of therapy equipment to terminate a treatment at the intended time can be considered cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE. If the effect of the test signal on an ME EQUIPMENT or ME SYSTEM is so brief as to be transparent to the PATIENT or OPERATOR and does not affect diagnosis, monitoring or treatment of the PATIENT, this can be considered not to be cessation or interruption of an intended operation. For example, if in response to the IMMUNITY TEST LEVEL a ventilator stops pumping for 50 ms and then resumes operation such that accuracy is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

Note that it might be necessary to test the ME EQUIPMENT or ME SYSTEM multiple times, e.g. under one set of conditions to assure that it sounds an ALARM SIGNAL when it should, within the MANUFACTURER's specifications for sensitivity and response time, and under another set of conditions to assure that it does not sound an ALARM SIGNAL when it should not.

I.3.2 Example of IMMUNITY pass/fail criteria for a radiological table system

Before, during, and after the IMMUNITY tests, the radiological table system provides freedom from unacceptable RISK (see Table I.1).

This IMMUNITY pass/fail criteria determination example is an output of the RISK ANALYSIS (see).

Table I.1 – Example of IMMUNITY pass criteria for a radiological table system

No.	Function to verify for freedom from unacceptable RISK	IMMUNITY pass criteria
1	System initialization at power ON is operating correctly	No system failure able to prevent a new examination.
2	System stop and turn OFF is operating correctly	The system initialization operates correctly and the system is effective in less than xx minutes (see NOTE 1).
3	Display the PATIENT image during the X-ray acquisition	Image noise or artifact is distinguishable from physiologically-produced signals.
4	X-ray acquisition images and sequence are saved. Saved recorded images can be displayed.	PATIENT data is not lost.
5	X-ray acquisition start is under control	No uncontrolled start.
6	X-ray acquisition stop is under control	No uncontrolled stop or lock-out.
7	The positioner (table and gantry) is operating correctly.	No uncontrolled movements (see NOTE 4). The stop of the table shall be effective in yy mm maximum distance (see NOTE 1).
8	PATIENT information can be displayed.	PATIENT data is not lost.

NOTE 1 The RISK ANALYSIS and RESIDUAL RISK determination are used to determine xx, yy, and zz.

NOTE 2 During the 5 s power supply network interrupt test (IEC61000-4-11), only N images from the last acquisition sequence can be lost. The system recovers full performance in zz s maximum after the initialization sequence.

NOTE 3 More specific IMMUNITY criteria for particular subtests might be defined, depending on the RISK MANAGEMENT and RISK ANALYSIS inputs (see Annex F).

NOTE 4 While this performance could be identified to be ESSENTIAL PERFORMANCE, some standards have requirements to control unintended motion but do not identify this as ESSENTIAL PERFORMANCE (for example IEC 60601-2-44 [4]. Thus, such standards consider prevention of unintended motion to be BASIC SAFETY. The result, however, would be the same in either case. The RISK from uncontrolled movements would be unacceptable.

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