PD IEC/TR 60601-4-2:2016

BSI Standards Publication

Medical electrical equipment

Part 4-2: Guidance and interpretation — Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

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National foreword

This Published Document is the UK implementation of IEC/TR 60601-4-2:2016.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2016

ISBN 978 0 580 88577 8
ICS 11.040.01; 33.100.20

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2016.

Amendments/corrigenda issued since publication

Date	Text affected

IEC TR 60601-4-2

Edition 1.0 2016-05

TECHNICAL REPORT

colour inside

Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01; 33.100.20

ISBN 978-2-8322-3414-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

FOREWORD

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IEC 60601-4-2, which is a technical report, 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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/1068/DTR	62A/1073A/RVC

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

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

In this technical report, the following print types are used:

– Recommendations and definitions: roman type.

– *Test instructions: 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 THIS TECHNICAL REPORT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this technical report, 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 technical report are preceded by the term “Clause” followed by the clause number. References to subclauses within this technical report are by number only.

In this technical report, 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 technical report conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this technical report, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this technical report; however, we chose to use it in this technical report only as described in 0.3;

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

– “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 this publication will remain unchanged until the stability date indicated on the IEC website 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.

A bilingual version of this publication may be issued at a later date.

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 document using a colour printer.

INTRODUCTION

0.1 * General

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are used in the practice of medicine because they provide needed functions that are associated with the INTENDED USE. If MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM does not provide these needed functions because of a lack of IMMUNITY to ELECTROMAGNETIC DISTURBANCES that are expected to occur in the environment(s) of INTENDED USE, this can interfere with the practice of medicine.

This document provides guidance on assessing IMMUNITY, with regard to the INTENDED USE. Based on the INTENDED USE, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS should have adequate IMMUNITY to provide the performance specified by the MANUFACTURER in the presence of ELECTROMAGNETIC DISTURBANCES. See Annex A for more information regarding performance.

Guidance for IMMUNITY with regard to INTENDED USE can be useful for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for which the BASIC SAFETY AND ESSENTIAL PERFORMANCE do not include the purpose(s) for which the ME EQUIPMENT or ME SYSTEM was purchased. It is important to the OPERATOR or RESPONSIBLE ORGANIZATION and to the delivery of healthcare that these functions operate as intended in the EM ENVIRONMENTS of INTENDED USE.

Examples of performance that might not be BASIC SAFETY or ESSENTIAL PERFORMANCE but that might be INTENDED USE include the following:

– the ability to print an ultrasound image remotely;
– the ability of a scale to accurately measure PATIENT weight;
– accuracy of X-RAY TUBE VOLTAGE in X-ray equipment for radiography and radioscopy, e.g. the error is less than 5 %.

In general in IEC 60601-1-2:2014, the IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on reasonably foreseeable maximum levels of EM DISTURBANCES. In this document, IMMUNITY TEST LEVELS for performance are based on typical levels of EM DISTURBANCES. Rationales concerning test methodology can be found in Annex A of this document and in Annex A of IEC 60601-1-2:2014.

NOTE In general, typical IMMUNITY TEST LEVELS are equal to or lower than reasonably foreseeable maximum levels.

0.2 Purpose of this document

The purpose of this document is to provide a consistent method for evaluating the ability of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM to perform without degradation of performance in the presence of ELECTROMAGNETIC DISTURBANCES.

0.3 How to use this document

This document can be used in conjunction with IEC 60601-1-2 and testing for conformity to both documents can be done at the same time. This allows IMMUNITY testing of BASIC SAFETY, ESSENTIAL PERFORMANCE and performance of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM during one test, concurrently or sequentially. The main difference is the use of performance criteria instead of pass/fail criteria, and differences can also include modes and configurations. For BASIC SAFETY and ESSENTIAL PERFORMANCE, the pass/fail criteria are determined as specified by IEC 60601-1-2. For performance, the criteria are determined by the specifications, instructions and information provided by the MANUFACTURER.

This document uses “recommend” and “should” in place of “shall” in most cases. “Shall” is used where an action is required by other standards or something needs to be done in a

prescribed way in order to be effective. Also, this document has “normative” references. They are “normative” because if you choose to follow the recommendations of this document, they are indispensable for that use. An example of this would be testing for radiated RF IMMUNITY. The test methods of IEC 61000-4-3 would be indispensable for this testing.

0.4 IMMUNITY TEST LEVELS

The IMMUNITY TEST LEVELS specified in this document are typical for the locations of INTENDED USE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. However, Annex C provides a method for modifying the specified typical IMMUNITY TEST LEVELS for performance if necessary or for particular environments (e.g. SPECIAL ENVIRONMENTS) for which this document does not specify IMMUNITY TEST LEVELS.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

1 Scope and object

1.1 Scope

This part of IEC 60601 applies to the performance of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM in the presence of ELECTROMAGNETIC DISTURBANCES. Hereafter, MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM are referred to as ME EQUIPMENT or an ME SYSTEM.

1.2 Object

The object of this document is to provide guidance on the assessment of the performance of ME EQUIPMENT or an ME SYSTEM in the presence of ELECTROMAGNETIC DISTURBANCES.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 60417:2002, *Graphical symbols for use on equipment* (available from: http://www.graphical-symbols.info/equipment)

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 [1)]

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

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*
IEC 60601-1-8:2006/AMD1:2012

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*

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

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*

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

IEC 61000-4-3:2006, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*
IEC 61000-4-3:2006/AMD1:2007
IEC 61000-4-3:2006/AMD2:2010[2)]

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

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

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 measurement techniques –Voltage dips, short interruptions and voltage variations immunity tests*

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*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2015, IEC 60601-1-12:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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

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

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This document 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 *The dictionary definition of “performance” applies.

NOTE 4 An index of defined terms is found beginning on page 56.

3.1
ACCESSIBLE PART
part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

Note 1 to entry: See also 5.9.2.1 of IEC 60601-1:2005.

[SOURCE: IEC 60601-1:2005, 3,2, modified — the original NOTE has been modified to add a reference to IEC 60601-1:2005.]

3.2
APPLIED PART
part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

Note 1 to entry: See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive) of IEC 60601-1:2005.

[SOURCE: IEC 60601-1:2005, 3.8, modified — Note 1 has been modified to add a reference to IEC 60601-1:2005 and Note 2 and Note 3 have been deleted.]

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 60601-1-2:2014, 3.3]

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

[SOURCE: IEC 60601-1-2:2014, 3.4]

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 60601-1-2:2014, 3.5]

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

[SOURCE: IEC 60601-1-2:2014, 3.6]

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

[SOURCE: IEC 60601-1-2:2014, 3.7, modified – Note 1 to entry has been deleted.]

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 60601-1-2:2014, 3.8]

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

[SOURCE: IEC 60601-1-2:2014, 3.9]

3.10
INTENDED USE
INTENDED PURPOSE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note 1 to entry: INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.44]

3.11
LARGE ME EQUIPMENT
ME EQUIPMENT that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables

[SOURCE: IEC 60601-1-2:2014, 3.12]

3.12
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

[SOURCE: IEC 60601-1-2:2014, 3.13]

3.13
LOW VOLTAGE
line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V AC or 1 500 V DC

[SOURCE: IEC 60601-1-2:2014, 3.14]

3.14
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.

[SOURCE: IEC 60601-1-2:2014, 3.15]

3.15
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.

[SOURCE: IEC 60601-1-2:2014, 3.16]

3.16
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 60601-1-2:2014, 3.17]

3.17
PUBLIC MAINS NETWORK
LOW VOLTAGE electricity power lines to which all categories of consumers have access

[SOURCE: IEC 60601-1-2:2014, 3.18]

3.18
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: IEC 60601-1-2:2014, 3.19]

3.19
SIGNAL INPUT/OUTPUT PART
SIP/SOP
part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

[SOURCE: IEC 60601-1:2005, 3.115]

3.20
SPECIAL ENVIRONMENT
ELECTROMAGNETIC ENVIRONMENT with electromagnetic characteristics different from those specified in this document in Table 2 through Table 6 or that requires IMMUNITY TEST LEVELS or test methods that are different from those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT

Note 1 to entry: The definition also implies the locations where SPECIAL ENVIRONMENTS are found.

Note 2 to entry: For ME EQUIPMENT and ME SYSTEMS intended for use in SPECIAL ENVIRONMENTS, special IMMUNITY TEST LEVELS might be applicable.

[SOURCE: IEC 60601-1-2:2014, 3.20, modified — references to the source document have been changed to refer to this document, and Notes 1 and 2 to entry have been added.]

3.21
TRANSIENT (adjective and noun)
pertaining to or designating a phenomenon or a quantity that varies between two consecutive steady states during a time interval short compared with the time-scale of interest

[SOURCE: IEC 60050-161:1990, 161-02-01, modified – "which" has been changed to "that" and parentheses have been added around "adjective and noun".]

4 General recommendations

4.1 Concurrent and sequential testing

IMMUNITY testing according to this document can be performed concurrently or sequentially with the IMMUNITY testing specified in IEC 60601-1-2.

If the IMMUNITY performance criteria determined according to this document are met at the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2014, Clause 8, no further testing is needed to demonstrate conformity to the recommendations of this document.

4.2 General test conditions

4.2.1 Configurations

ME EQUIPMENT and ME SYSTEMS should be tested in representative configurations and modes consistent with INTENDED USE.

These configurations should 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 8.5, PATIENT physiological simulators as specified in 8.2 or artificial hands as specified in 4.2.2;
– 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 hardware or software might need to be used with the ME EQUIPMENT or ME SYSTEM to perform the tests specified in Clause 8. If so, this should be documented in the test plan and in the test report.

NOTE If the configurations used in IEC 60601-1-2 testing meet the recommendations of this subclause, this could facilitate concurrent or sequential testing.

4.2.2 Artificial hand

Where an artificial hand is required by this document, 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 Clause 8 of CISPR 16-1-2:2014 (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 Clause 8 of CISPR 16-1-2:2014. 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.

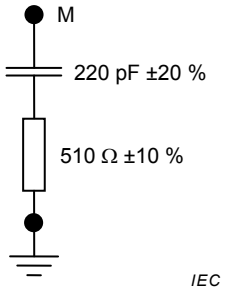

Figure 1 – RC element of the artificial hand

4.2.3 Power input voltages and frequencies

For all tests except for the IEC 61000-4-11 test, the test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage and any one RATED power frequency. Unless otherwise specified in this document, if the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency, it is not necessary to re-test at additional voltages or frequencies.

The IEC 61000-4-11 tests should be performed at the minimum RATED power input voltage and any one RATED power input frequency. ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps should be tested according to IEC 61000-4-11 at only one tap setting.

5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

5.1 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts for which the connector testing exemption specified in 8.13.2 d) is used

For ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 8.13.2 d) is used, symbol IEC 60417-5134 (2003-04) for ESD sensitivity shall be applied adjacent to each connector for which the testing exemption is used. The symbol graphic is shown below.

5.2 ACCOMPANYING DOCUMENTS

5.2.1 General

If information for BASIC SAFETY and ESSENTIAL PERFORMANCE (required by IEC 60601-1-2) and information for performance (according to this technical report) are included in the same document (e.g. instructions for use or technical description), the information for BASIC SAFETY and ESSENTIAL PERFORMANCE should be clearly distinguished from the information for performance.

5.2.2 Instructions for use

As applicable, the instructions for use should include the following information:

a) degradation of performance due to EM DISTURBANCES that is considered to be acceptable by the MANUFACTURER;

b) actions the OPERATOR or PATIENT could take to prevent or mitigate the degradation described in a);

c) the maximum recovery time following a TRANSIENT phenomenon;

d) the environments of INTENDED USE. This should be the same as the environments specified according to IEC 60601-1-2.

5.2.3 Requirements applicable to ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 8.13.2 d) is used

For ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 8.13.2 d) is used, the instructions for use shall include the following:

a) a reproduction of the ESD warning symbol (IEC 60417-5134 (2003-04)), as shown in 5.1;

b) a warning that pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used;

c) * a specification of the ESD precautionary procedures;

d) * a recommendation that all PATIENTS and OPERATORS receive an explanation of the ESD warning symbol and ESD precautionary procedures.

5.2.4 * Technical description

The technical description should include:

a) the following statement: “The [name and model or type reference of the ME EQUIPMENT or ME SYSTEM] was tested according to the recommendations of IEC TR 60601-4-2: Medical

electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

b) a list of the ELECTROMAGNETIC phenomena and IMMUNITY TEST LEVELS with which the ME EQUIPMENT or ME SYSTEM complied according to the recommendations of this document.

6 Documentation of the tests

6.1 Test plan

Prior to the start of formal testing, a detailed test plan should be provided to the test laboratory. The recommended minimum contents of a test plan for testing IMMUNITY according to this document are listed in Table 1. If testing for IMMUNITY according to this document is to be combined with testing for IMMUNITY according to IEC 60601-1-2, the test plans should be combined.

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

No.	Item	Additional detail
1	Identification and description of the ME EQUIPMENT or ME SYSTEM	Include device name and model number, describe all equipment, racks, modules, cables, etc. belonging to the ME EQUIPMENT or ME SYSTEM.
2	The INTENDED USE (including environments (locations) of INTENDED USE), functions to be tested and a description of how the performance will be monitored during each test	
3	ME EQUIPMENT or ME SYSTEM software / firmware version of the sample to be tested	
4	Number of samples to be tested	The number of samples for each EMC test
5	Applicable standards and test methods	A list of the standards (with dates) and IMMUNITY TEST LEVELS
6	Deviations from the Basic EMC standards, or this document	Include any instructions needed.
7	Applicability / tests that will not be performed	Include the decision and justification not to perform any measurement or test.
8	If the procedure specified by Annex C of this document or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made to the IMMUNITY TEST LEVELS – the adjusted typical 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	
9	IMMUNITY TEST LEVELS for each IMMUNITY test	
10	IMMUNITY performance criteria	Specific IMMUNITY performance criteria as recommended by 8.10.
11	ME EQUIPMENT or ME SYSTEM configurations, settings and operating modes	List by test.
12	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.

Table 1 *(2 of 2)*

No.	Item	Additional detail
13	ME EQUIPMENT or ME SYSTEM power input voltages and frequencies	List by test.
14	Earthing configuration	Describe how the ME EQUIPMENT OR ME SYSTEM connects to protective earth.
15	Whether the ME EQUIPMENT or ME SYSTEM will be tested as table-top or floor-standing equipment, or a combination of the two	
16	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or 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.
17	Exercising of SIP/SOPS	Describe how each SIP/SOP PORT is to be exercised.
18	For floor-standing ME EQUIPMENT or ME SYSTEMS, the height of the support	
19	Description of any PATIENT-COUPLED cable terminations to be used	
20	Simulators, accessories and auxiliary equipment	Describe simulators, ACCESSORIES and auxiliary equipment used, including PATIENT physiological and subsystem simulation
21	Documentation of any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests	
22	Planned ESD test points	If possible, include a drawing or annotated photo showing the ESD test points.
23	Dwell time for each IMMUNITY test requiring a dwell time	

6.2 Test report

The test report should meet the recommendations of Clause 9.

7 * EMISSIONS

This clause is not used in this document.

8 IMMUNITY recommendations

8.1 General

The IMMUNITY test recommendations for this document are specified by this document on a PORT-by-PORT basis. This follows the convention of the IEC 61000-6 (all parts) of generic EMC standards. Figure 2 shows the PORTS of ME EQUIPMENT and ME SYSTEMS for the purpose of IMMUNITY testing.

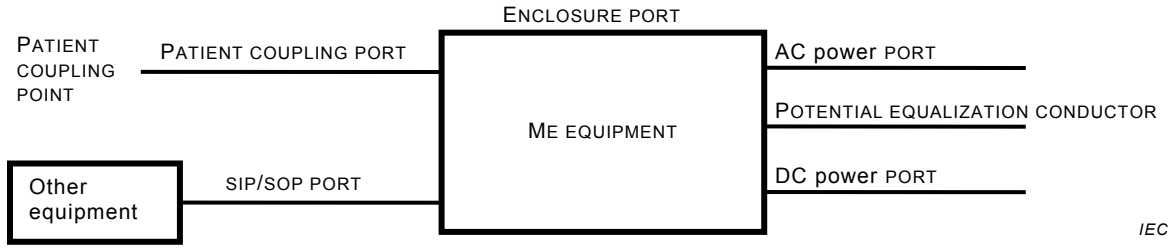

Figure 2 – * PORTS of ME EQUIPMENT and ME SYSTEMS

ELECTROMAGNETIC IMMUNITY testing:

– should be performed in a well-defined and reproducible manner,

– should 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) should 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.

The IMMUNITY test recommendations should be applied to the ports of the ME EQUIPMENT or ME SYSTEM as specified in Table 2 through Table 6. These tables recommend IMMUNITY TEST LEVELS and test conditions for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT. In this document, the recommended IMMUNITY TEST LEVELS for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT are the same. The procedure specified in Annex C 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 2 through Table 6 (higher or lower, as appropriate), based on specific EM characteristics of specific environments or specific mitigations that might be associated with 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 C may be used in place of those specified in Table 2 through Table 6.

NOTE 1 Use of Annex C can permit more precise assessment of the 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.

NOTE 2 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 document.

The dwell time for IMMUNITY tests should 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.

8.2 PATIENT physiological simulation

If simulation of the PATIENT is needed to verify normal operation of the ME EQUIPMENT or ME SYSTEM, it should 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 4.2.2.

As an alternative to the termination methods specified in 4.2.2, for the IMMUNITY tests for which they are specified 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 4.2.2.

Prior to the beginning of the test, the amplitude of simulated PATIENT physiological signals should be adjusted to be consistent with normal operation of the ME EQUIPMENT or ME SYSTEM, as specified by the MANUFACTURER.

NOTE If the signal is set close to the threshold but above it, then the outcome of the test would not be penalized by the statistics of detection and the noise floor of the detection circuitry. For example, for some ME EQUIPMENT, setting the simulated signal at twice the threshold of detection (detection threshold plus 6 dB) would put the signal close to and above but not at the threshold of detection.

8.3 Termination of PATIENT-COUPLED parts

For testing according to IEC 61000-4-4 and IEC 61000-4-6, the conditions specified in 4.2.2 apply.

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 should be tested with an artificial hand applied as specified in Clause 8 of CISPR 16-1-2:2014, sized and placed to simulate the approximate area and location of OPERATOR coupling while providing the INTENDED USE. The metal foil of the artificial hand is connected to terminal M of an RC element, as specified in Clause 8 of CISPR 16-1-2:2014 (see Figure 1), and the other terminal of the RC element should be connected to the ground reference plane. These conditions can 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 should also have artificial hands applied as specified in 4.2.2, consistent with INTENDED USE.

8.5 Subsystems

Conformity with the recommendations of this document may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. Any simulator used instead of actual equipment should 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.

8.6 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS should 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 8.11 and 8.12. If this exemption is used, such PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS should 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 should 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 2 according to the locations of INTENDED USE and the IMMUNITY TEST LEVELS of Table 7, 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 [3][3] and in CISPR 11:2015, 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 recommendations of 8.11 and 8.12 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.

8.7 Operating modes

During IMMUNITY testing, the ME EQUIPMENT or ME SYSTEM should be tested in the modes and settings (e.g. gain) that are most likely to result in unacceptable degradation of performance. This should be determined using experience, engineering analysis, or pretesting. Also see Annex D. 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 operating modes selected for testing should be documented in the test plan and in the test report.

8.8 Non-ME EQUIPMENT

If the MANUFACTURER of the ME SYSTEM has determined that non-ME EQUIPMENT could adversely affect the performance associated with the INTENDED USE, the ME SYSTEM, including the non-ME EQUIPMENT, should fulfil the IMMUNITY TEST LEVELS and performance criteria of Clause 8.

8.9 * Environments of INTENDED USE

This document refers to three environments (locations) of INTENDED USE: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and the SPECIAL ENVIRONMENT.

Additional IMMUNITY tests or higher IMMUNITY TEST LEVELS might be needed 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 and anti-theft systems). If additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher than those specified in Table 2 through Table 6 are appropriate or are specified by standards applicable to the EM ENVIRONMENT of a type of transportation, these additional tests and higher IMMUNITY TEST LEVELS should apply. Other parameters that might need special values for these environments include modulation and frequencies.

For ME EQUIPMENT and ME SYSTEMS with an INTENDED USE that includes use in aircraft, a standard that applies is ISO 7137. This is identical to EUROCAE ED-14C:1989 and RTCA DO-160C:1989. The latest editions are EUROCAE ED-14G [4] and RTCA DO-160G [5].

ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT should follow the recommendations of Table 2 through Table 7. If locations in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or any environment are identified for which the specifications in Table 2 through Table 7 are not adequate, Annex C can be used to determine appropriate IMMUNITY TEST LEVELS.

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[3] Numbers in square brackets refer to the Bibliography.

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 should apply.

8.10 * Performance criteria

Before IMMUNITY testing begins, the MANUFACTURER should determine specific, detailed IMMUNITY criteria, based on the INTENDED USE, as specified in Annex D. The MANUFACTURER should also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to verify that the specific performance criteria have been met. If the ME EQUIPMENT or ME SYSTEM is damaged by the IMMUNITY tests, the performance test result should be considered to be failure unless otherwise specified by the MANUFACTURER. These performance criteria and the specifications for monitoring performance against these criteria should be included in the test plan and the test report. If degradation is observed during IMMUNITY testing, actions that the OPERATOR or PATIENT could take to prevent or mitigate the degradation should be described in the instructions for use (see 5.2.2).

IMMUNITY performance criteria can specify degradations that are acceptable. They should be documented in the test plan.

For this document, the general performance criteria for the INTENDED USE are as follows:

a) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria during and after the following tests, without the need for OPERATOR intervention. This also applies to tests for other continuous phenomena that might be applicable to the ME EQUIPMENT or ME SYSTEM.
   - IEC 61000-4-3 for radiated EM field IMMUNITY test
   - IEC 61000-4-3 interim method for proximity fields from RF wireless communications equipment
   - IEC 61000-4-6 for conducted disturbances induced by RF fields IMMUNITY test

b) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests, without the need for OPERATOR intervention to restore operation. The MANUFACTURER should specify in the instructions for use the maximum recovery time. While operation as intended during the test is desirable, some degradation is acceptable. This also applies to tests for other TRANSIENT phenomena that might be applicable to the ME EQUIPMENT or ME SYSTEM.
   - IEC 61000-4-2 for ELECTROSTATIC DISCHARGE IMMUNITY test
   - IEC 61000-4-4 for electrical fast TRANSIENTS / bursts IMMUNITY test
   - IEC 61000-4-5 for surges IMMUNITY test
   - IEC 61000-4-11 for voltage dip IMMUNITY test (0 % U_T)

c) The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests. OPERATOR intervention is allowed to restore operation.

   NOTE While operation as intended during the test is desirable, degradation can be expected.

   - IEC 61000-4-11 for voltage dip IMMUNITY test (70 % U_T)
   - IEC 61000-4-11 for voltage interruptions IMMUNITY test.

Specific IMMUNITY performance criteria are determined as specified in Annex D.

8.11 * IMMUNITY TEST LEVELS

The IMMUNITY test recommendations should be applied to the PORTS of the ME EQUIPMENT or ME SYSTEM according to the environments of INTENDED USE, as shown in Figure 3. If applicable, an INTENDED USE environment not shown in Figure 3 should be assigned to an environment with a similar location, as determined by the MANUFACTURER. If there is no similar location in Figure 3, Annex C can be used to determine applicable IMMUNITY TEST LEVELS.

The procedure specified in Annex C can be used to determine IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS or, if justified, Annex C can be used to modify the IMMUNITY TEST LEVELS of Table 2 through Table 7 (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.

As specified in Annex C, IMMUNITY TEST LEVELS should be based on typical levels of EM DISTURBANCES.

NOTE 1 IMMUNITY TEST LEVELS are determined for each phenomenon.

NOTE 2 Use of Annex C can result in a more precise assessment of the EM phenomena and EM DISTURBANCES in the EM ENVIRONMENTS of INTENDED USE and this can be used to determine IMMUNITY TEST LEVELS that are more specific to the INTENDED USE of the ME EQUIPMENT or ME SYSTEM.

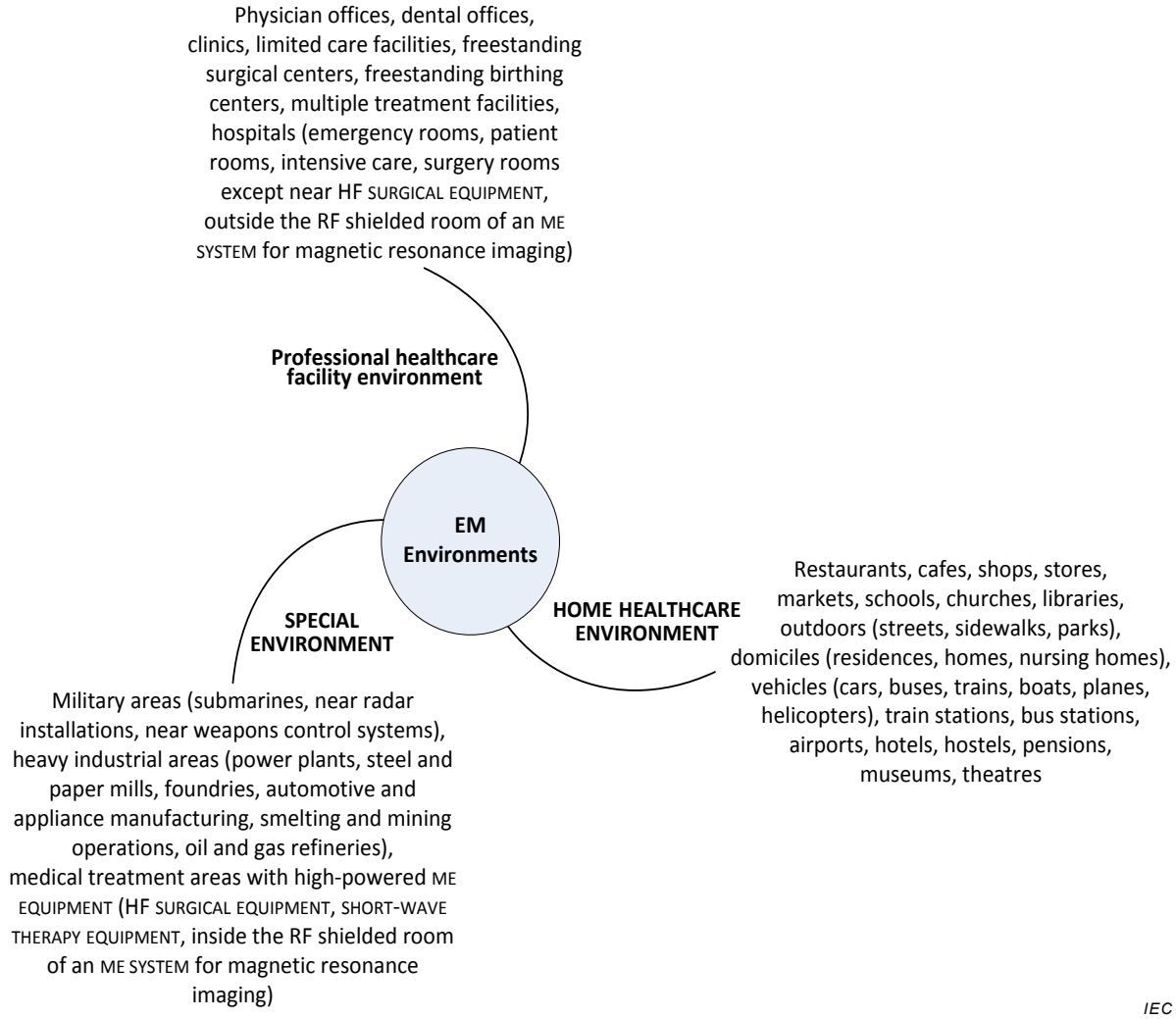
When a MANUFACTURER knows from experience, published data, or representative measurements that the environment of INTENDED USE has unique characteristics that would alter EM DISTURBANCE levels that form the basis of IMMUNITY TEST LEVELS specified in Table 2 through Table 7, the MANUFACTURER should take this into consideration. Annex C can be used to determine IMMUNITY TEST LEVELS for environments or phenomena not specified in Table 2 through Table 7 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 1 and in the test report, as specified in Table 10 (Clause 9):

a) justification for any adjusted IMMUNITY TEST LEVELS;

b) the adjusted typical 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.



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 document, the IMMUNITY recommendations for 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 (locations) of INTENDED USE

Table 2 – * ENCLOSURE PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
ELECTROSTATIC DISCHARGE [e]	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	b
Radiated RF EM field [a]	IEC 61000-4-3	3 V/m [d] 80 MHz to 2,7 GHz [b] 80 % AM at 1 kHz [c]	a
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 7	a
RATED power frequency magnetic fields [f] [g]	IEC 61000-4-8	3 A/m, 50 Hz or 60 Hz	a

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM should 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 are exempt from testing at the frequency of reception.

c) Testing may instead be performed at other modulation frequencies identified by the MANUFACTURER based on the environments of INTENDED USE.

d) Before modulation is applied.

e) See 8.13 regarding ESD testing of connectors.

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

g) 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

Table 3 – * Input AC power PORT *(1 of 2)*

Phenomenon	Basic EMC standard	Performance IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
Electrical fast TRANSIENTS / bursts [m] [p]	IEC 61000-4-4	± 1 kV 5 kHz or 100 kHz repetition frequency	b
Surges [b] [k] [p] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	b
Surges [b] [k] [l] [p] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	b
Conducted disturbances induced by RF fields [p]	IEC 61000-4-6	3 V [n] 0,15 MHz to 80 MHz 80 % AM at 1 kHz [e]	a

Table 3 *(2 of 2)*

Phenomenon	Basic EMC standard	Performance IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
Voltage dips [a) f) o)]	IEC 61000-4-11	0 % U_T; 0,5 cycle [g)] At 0° and 180° [d)]	b
		70 % U_T; 25/30 cycle [h)] Single phase: at 0°	c
Voltage interruptions [a) f) j) p)]	IEC 61000-4-11	0 % U_T; 250/300 cycle [h) i)]	c

a) The IEC 61000-4-11 tests should be performed at the minimum RATED power input voltage. These tests may be performed at any one RATED power input frequency.

b) All ME EQUIPMENT and ME SYSTEM cables that are associated with the INTENDED USE should be attached during the test

c) Not used.

d) During the 0,5 period duration test, products with a mains transformer may experience magnetic flux saturation of the transformer core. In this case, the test may be performed using both 90° and 270° switching.

e) Testing may instead be performed at other modulation frequencies identified by the MANUFACTURER based on the environments of INTENDED USE.

f) ME EQUIPMENT and ME SYSTEMS with a DC power input intended for use with AC to DC. converters should 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 AC power input of the converter.

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

h) E.g. 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.

i) At 0° for ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A. For ME EQUIPMENT and ME SYSTEMS drawing more than 16 A, the phase angle is optional.

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

k) 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).

l) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

m) A direct coupling network should be used.

n) RMS, before modulation is applied.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A per phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A per phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A per phase.

Table 4 – Input DC power PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
Electrical fast TRANSIENTS / bursts [a) f)]	IEC 61000-4-4	± 0,5 kV 5 kHz or 100 kHz repetition frequency	b
Surges [a) b)] Line-to-line	IEC 61000-4-5	± 0,5 kV	b
Surges [a) b)] Line-to-ground	IEC 61000-4-5	± 0,5 kV	b
Conducted disturbances induced by RF fields [a) c) d)]	IEC 61000-4-6	3 V [g)] 0,15 MHz to 80 MHz 80 % AM at 1 kHz [e)]	a
Electrical TRANSIENT conduction along supply lines [h)]	ISO 7637-2	As specified in ISO 7637-2:2011, 5.6.	b

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

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

c) This test does not apply to INTERNALLY POWERED ME EQUIPMENT that 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 instead be performed at other modulation frequencies identified by the MANUFACTURER based on the environments of INTENDED USE.

f) Direct coupling should be used.

g) RMS, before modulation is applied.

h) 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, the starting profile and load dump test waveforms are specified in ISO 16750-2:2012, 4.6.3 and 4.6.4, respectively.

Table 5 – * PATIENT COUPLING PORT

Phenomenon	Basic EMC standard	Performance IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
ELECTROSTATIC DISCHARGE [c) d)]	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	b
Conducted disturbances induced by RF fields [a)]	IEC 61000-4-6	3 V [b)] 0,15 MHz to 80 MHz 80 % AM at 1 kHz	a

a) The following apply:
- All PATIENT-COUPLED cables should be tested, either individually or bundled
- PATIENT-COUPLED cables should 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 should be used.
- No intentional decoupling device should be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may instead be performed at other modulation identified by the MANUFACTURER based on the environments of INTENDED USE.
- Tubes that are intentionally filled with conductive liquids should be considered to be PATIENT-COUPLED cables.

b) RMS, before modulation is applied.

c) Discharges should 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 performance.

d) See 8.13 regarding ESD testing of connectors.

Table 6 – SIGNAL INPUT/OUTPUT PARTS PORT

Phenomenon	Basic EMC standard	Performance IMMUNITY TEST LEVELS	Performance criterion (See 8.10)
ELECTROSTATIC DISCHARGE [h]	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	b
Electrical fast TRANSIENTS / bursts [b] [e]	IEC 61000-4-4	± 0,5 kV 5 kHz or 100 kHz repetition frequency	b
Surges Line-to-ground [a]	IEC 61000-4-5	± 1 kV	b
Conducted disturbances induced by RF fields [d] [g]	IEC 61000-4-6	3 V [f] 0,15MHz to 80 MHz 80 % AM at 1 kHz [c]	a

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

[b] SIP/SOP cables less than 3 m in length are excluded.

[c] Testing may instead be performed at other modulations identified by the MANUFACTURER based on the environments of INTENDED USE.

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

[e] Capacitive coupling should be used.

[f] RMS, before modulation is applied.

[g] This test does not apply to INTERNALLY POWERED ME EQUIPMENT that 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.

[h] See 8.13 regarding ESD testing of connectors.

8.12 * IMMUNITY to proximity fields from RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS should be tested as specified in Table 7 using the test methods specified in IEC 61000-4-3.

The frequencies and services listed in Table 7 are representative examples that are based on RF communications equipment in use at the time of publication of this document. The test specification does not attempt to cover every frequency and service used in every country. Testing should be performed at the additional frequencies identified that are not represented in Table 7.

NOTE It is understood that communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband.

Table 7 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency MHz	Band [a] MHz	Type of service being simulated [a]	Modulation [b]	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	6
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	9
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	3
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	9
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	9
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	9
5 240	5 100 to 5 800	W LAN 802.11 a/n	Pulse modulation [b] 217 Hz	6
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 should 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.

8.13 * ESD testing of connectors

8.13.1 Application of ESD to connectors

ESD testing of connectors should be performed as follows:

– Replace IEC 61000-4-2:2008, Table 4 with Table 8 of this document.
– Cable connections should be as shown in Table 9.
– The input AC power PORT and the input DC power PORT should be tested consistent with INTENDED USE.
– For connectors where the shell is covered by the mating connector, perform ESD testing to the mating connector.

NOTE These recommendations apply to INTENDED USE and not to "NORMAL USE" as used in IEC 61000-4-2.

Table 8 – Parts of connectors to be tested for ESD, based on the connector shell and cover material

Case	Connector shell material	Cover material	Air discharge testing to:	Contact discharge testing to:
1	Conductive	None	–	Shell
2	Conductive	Non-conductive	Cover	Shell if accessible
3	Conductive	Conductive	–	Shell and cover
4	Non-conductive	None	Shell and pins	–
5	Non-conductive	Non-conductive	Cover	–
6	Non-conductive	Conductive	–	Cover

Table 9 – * Testing of connectors and pins while connected and disconnected

Case	Cable description	Connector shell material is conductive	Connector shell material is non-conductive
1	Connector is ACCESSIBLE and cable is necessary for the INTENDED USE and normally not disconnected once installed	Test with cable connected	Test with cable connected
2	Connector is ACCESSIBLE and cable is necessary for the INTENDED USE and is normally connected and disconnected during use.	Test with cable connected	Test with cable connected and disconnected. For the case of cable disconnected, use air discharge tip. Test pins and shell of ENCLOSURE connector.
3	Connector is ACCESSIBLE and cable is not necessary for the INTENDED USE and is normally not disconnected once installed	Test with cable connected	Test with cable connected
4	Connector is ACCESSIBLE and cable is not necessary for the INTENDED USE and is normally connected and disconnected during use	Test with cable either connected or disconnected.	Test with cable disconnected.

8.13.2 Exclusions

The following exclusions apply. Discharges are not applied to these items:

a) connectors that are not ACCESSIBLE PARTS (e.g. they are covered). However, if the connector cover itself is an ACCESSIBLE PART, discharges are applied to the cover;

b) for connectors requiring a tool for disconnection, discharges are not applied to the pins;

c) connectors that are no longer ACCESSIBLE PARTS after FIXED installation or after being installed as specified in the instructions for use; for example, the bottom or wall side of ME EQUIPMENT OR ME SYSTEMS;

d) pins of a connector that for functional reasons cannot be adequately protected from ESD discharges. In this case, 5.1 and 5.2.3 apply.

NOTE For example, RF inputs from measurement, receiving or other communication equipment.

9 Test report

At a minimum, the test report should include the items listed in Table 10.

Table 10 – Test report minimum 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 INTENDED USE and important functions and a description of how the performance was 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 locations	
9	Applicable standards and test methods	A list of the standards (with dates) and IMMUNITY TEST LEVELS
10	Deviations from the Basic EMC standards or from this document	
11	Applicability / tests not performed	The decision and justification not to perform a measurement or test should be documented.
12	If the procedure specified by Annex C or an equivalent procedure is used: – a justification for any SPECIAL ENVIRONMENTS identified or adjustments made – 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	
14	IMMUNITY performance criteria	Including the monitoring specification
15	Degradation observed during IMMUNITY testing	
16	Environmental conditions as required by the relevant Basic EMC standards	
17	Test results summary statement (pass/fail)	List for each test

Table 10 *(2 of 2)*

No.	Item	Additional detail
18	Maximum recovery time following TRANSIENT phenomena testing	
19	Test data that support the performance determination for each test performed	Include units of measurement
20	ME EQUIPMENT or ME SYSTEM configuration during the test, including a block diagram	Block diagram of the ME EQUIPMENT or ME SYSTEM All peripherals and auxiliary equipment used All cables used and their positions
21	ME EQUIPMENT or ME SYSTEM settings and operating modes	List for each test
22	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.
23	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.
24	Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT or ME SYSTEM: frequencies, power and modulation of the RF test sources and test distances used.	
25	Deviations from the test plan	
26	Photographs of all test setups.	

Annex A
(informative)

General guidance and rationale

This annex provides rationale for particular clauses, subclauses and tables in the text.

Subclause 0.1 – General

Many similar definitions of “performance” can be found in online dictionaries. These include “process or manner of functioning or operating” [12], “doing something successfully” [12] and “the capabilities of a machine, vehicle, or product, especially when observed under particular conditions” [11]. Synonyms include “functioning”, “working”, “operation”, “capabilities”, “capacity”, “power” [11], “carrying into action” and “execution” [12]. In this document, “performance” refers to the ability of an ME EQUIPMENT or ME SYSTEM to perform (operate) as intended, particularly with regard to the INTENDED USE, in the environments of INTENDED USE. This document focuses on performance. However, if a failure to provide BASIC SAFETY or ESSENTIAL PERFORMANCE is found during performance testing, this should be evaluated further using IEC 60601 standards.

Subclause 5.2.3 c) – a specification of the ESD precautionary procedures

It is necessary to make PATIENTS and OPERATORS aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a HAND-HELD TOOL unless proper precautionary procedures have been followed.

Precautionary procedures include:

– methods to prevent build-up of electrostatic charge (e.g. air conditioning, humidification, conductive floor coverings, non-synthetic clothing);

– discharging one’s body to the frame of the ME EQUIPMENT or ME SYSTEM or to earth or a large metal object;

– bonding oneself by means of a wrist strap to the ME EQUIPMENT or ME SYSTEM or to earth.

Subclause 5.2.3 d) – a recommendation that all PATIENTS and OPERATORS involved receive an explanation….

PATIENTS and OPERATORS that could touch connectors identified with the ESD warning symbol should receive this explanation. If the INTENDED USE includes the professional healthcare facility environment, then this includes clinical/biomedical engineering and health-care staff.

Subclause 5.2.4 – Technical description

For this document, where tests and IMMUNITY TEST LEVELS are only recommendations, it is particularly important that the MANUFACTURER disclose to the USER or purchaser the phenomena to which the ME EQUIPMENT or ME SYSTEM was tested and the IMMUNITY TEST LEVELS. While this information might only have meaning for e.g. biomedical engineers, it should be made available.

Clause 7 – EMISSIONS

It is assumed that the ME EQUIPMENT or ME SYSTEM will be tested for EMISSIONS according to IEC 60601-1-2. This document does not recommend any further EMISSIONS testing.

Subclause 8.1 – General

Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS

"Other equipment" connected to the SIP/SOP PORT can include sensors and PORTS such as audio, video (e.g. HDMI), printers, eSATA, Ethernet, and USB.

Subclause 8.9 – Environments of INTENDED USE

The IMMUNITY TEST LEVELS are the same for the professional healthcare environment and the HOME HEALTHCARE ENVIRONMENT and are combined in Table 2 through Table 7 because the typical levels of the electromagnetic phenomena were considered to be the same in each environment.

Subclause 8.10 – Performance criteria

The general performance criteria that are used in many other EMC standards for the evaluation of IMMUNITY test results for equipment, e.g. A and B (see [6], [14], [15] and Annex E), are not appropriate for ME EQUIPMENT or ME SYSTEMS because of the "permissible loss of performance" and the reasons presented below.

Performance criterion B is not appropriate for the performance of ME EQUIPMENT or ME SYSTEMS because based on the INTENDED USE, ME EQUIPMENT and ME SYSTEMS should have adequate IMMUNITY to provide the performance specified by the MANUFACTURER in the presence of ELECTROMAGNETIC DISTURBANCES. As a consequence of this, degradations of performance that are not specified by the MANUFACTURER should not be allowed.

Performance criterion C would be equivalent to operating as intended after the test, as specified in 8.10 with self-recovery allowed and also with OPERATOR intervention to restore operation allowed. Of the IMMUNITY tests in this standard, this would only be acceptable for the IEC 61000-4-11 tests. Particularly for the voltage interruption IMMUNITY test, ME EQUIPMENT and ME SYSTEMS without battery backup cannot be expected to continue operating during the 250/300 cycles (5 s) of the mains interruption.

With the exception of the example immediately above, 8.10 specifies that ME EQUIPMENT and ME SYSTEMS are expected to continue to operate after the IMMUNITY tests listed in a) and b). ME EQUIPMENT and ME SYSTEMS are also specified to continue to operate during the IMMUNITY tests in a) because they represent continuous phenomena. ME EQUIPMENT and ME SYSTEMS are not specified to continue to operate during the IMMUNITY tests in b) because they represent TRANSIENT phenomena. In use, ME EQUIPMENT and ME SYSTEMS can be exposed to continuous EM phenomena that continue for extended periods of time. Therefore, testing for performance during the test is important. For TRANSIENT phenomena, the exposure to the ME EQUIPMENT or ME SYSTEM in use is likely to be short so that only the performance after the exposure is important. In addition, the test exposure can be so short that it would be difficult to assess the performance of the ME EQUIPMENT or ME SYSTEM during the exposure.

Subclause 8.11 – IMMUNITY TEST LEVELS

The IMMUNITY TEST LEVELS in this document are generally based on typical levels of the expected EM DISTURBANCES, rather than reasonably foreseeable maximum levels. The variation in the typical levels is however, not due to the same factors within the environment of INTENDED USE for each type of DISTURBANCE phenomenon. For example, levels of ESD exposure are a strong function of relative humidity and the materials that are present and interact to develop static charges. The relative humidity has a wide Gaussian statistical distribution as a result of seasonal and geographic variation. For IEC 60601-1-2, the reasonably foreseeable maximum ESD exposure was estimated based on the assumed minimum relative humidity of 20 %, leading to higher ESD IMMUNITY TEST LEVELS, whereas the

relative humidity used for estimating the typical ESD exposure was 35 % to 40 %, leading to lower ESD IMMUNITY TEST LEVELS.

For radiated RF DISTURBANCES, it is assumed that many of the sources are transmitters that are not located immediately within the environment of INTENDED USE. Therefore, the ME EQUIPMENT OR ME SYSTEM will be in the far field of the radiated RF signal. Within the far field, the field strength will vary largely due to the variation in attenuation characteristics within a structure, but not due to distance, as movement within a structure does not cause a significant change in the distance from the source transmitter. As a result, the statistical distribution of the expected levels of DISTURBANCE is nearly uniform, and in this case the typical and reasonably foreseeable maximum values are essentially the same. This same consideration is also applied to conducted RF DISTURBANCES induced by radiated RF fields.

For proximity fields from RF wireless communication equipment, these DISTURBANCE sources are expected to be within the environment of INTENDED USE. The ME EQUIPMENT OR ME SYSTEM is not in the far field of the transmitter, but rather in the near field, where the field strength is a function of distance from the source and also affected by absorption and reflection. Because these portable sources can be expected to move, the DISTURBANCE levels can be expected to have a wide statistical variation over time. The typical and reasonably foreseeable maximum DISTURBANCE levels are therefore considerably different. Additional considerations in determination of the proximity field IMMUNITY TEST LEVELS are discussed in the rationale for subclause 0.

Table 2 – ENCLOSURE PORT

ELECTROSTATIC DISCHARGE

An air discharge IMMUNITY TEST LEVEL of 8 kV was considered to be an appropriate typical level. As the handbook of electrostatic processes [1] shows, at 10 % relative humidity the probability of an 8 kV discharge is about 10 %. For this reason, 8 kV will be considered a typical environmental level for this phenomenon.

The contact discharge IMMUNITY TEST LEVEL was chosen to be 4 kV to harmonize with CISPR 24 [6] and IEC 61000-6-2 [15].

Table 3 – Input AC power PORT

All phase angles have been deleted in the voltage dips row except 0° for 70 % and 0° and 180° for 0,5 cycle. This is for consistency with the Basic EMC standard IEC 61000-4-11. Also, in CISPR 24 [6], all phase angles other than the zero crossings are not used. Applying this test at some phase angles to ME EQUIPMENT with transformers 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 magnetic flux saturation can be avoided by applying the test at 90° and 270° instead of 0° and 180°. Other phase angles are not necessary.

Table 5 – PATIENT COUPLING PORT

PATIENT COUPLING PORT connectors and PATIENT COUPLING POINTS (e.g. SpO_2, ECG, temperature) have a high probability of being touched by the OPERATOR of ME EQUIPMENT and ME SYSTEMS DURING INTENDED USE. For this reason, it is necessary to apply ESD to all of the specified PORTS and areas of the ME EQUIPMENT and ME SYSTEMS, to ensure that the INTENDED USE is maintained after the application of the discharges. This might include applying discharges to the pins of the PATIENT PORT connector and directly to the PATIENT COUPLING POINTS. The INTENDED USE should be verified as soon as practicable after the discharges; however, some Part 2 standards (e.g. IEC 60601-2-25 [16]) allow up to 10 s for the ME EQUIPMENT or ME SYSTEM to return to normal operation after ESD.

Subclause 8.12 – IMMUNITY to proximity fields from RF wireless communications equipment

The IMMUNITY TEST LEVELS for the proximity test of IEC 60601-1-2 where chosen based on the maximum foreseeable field strength from a transmitter as close as 0,3 m to ME EQUIPMENT or an ME SYSTEM. The probability of these levels is quite low because typical separation distances are greater than 0,3 m and because of the adaptive power control of modern digital radio services. Adaptive power control ensures that the output power of transmitting devices of many modern radio services, e.g. GSM, LTE and TETRA reduce their power in relation to the received signal from the base station. Additionally the use of high power services such as GSM will be reduced in the future because of the rising number of modern radio services such as LTE, which uses much less transmitting power than e.g. GSM. In summary, the IMMUNITY TEST LEVELS for proximity fields that are listed in Table 7 are based on typical separation distances and typical output power levels of the transmitters listed.

The assumptions on which the IMMUNITY TEST LEVELS specified in Table 7 were based are shown in Table A.1. Note that the separation distance column is not the test distance but the assumed distance between the mobile RF transmitter and the ME EQUIPMENT or ME SYSTEM that the test simulates. This assumed separation distance and the assumed typical power level were used to calculate the Table 7 IMMUNITY TEST LEVEL for that wireless service.

Table A.1 – Assumptions used in determining IMMUNITY TEST LEVELS specified in Table 7 *(1 of 2)*

Test frequency MHz	**Band** [a] MHz	**Service** [a]	**Modulation** [b]	**Typical power** W	**Separation distance** m	**IMMUNITY TEST LEVEL** V/m	**Remarks**
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	0,9	1	6	Assumed typically half power by adaptive power control and 1 m separation because the average user is more than 30 cm away from Tetra devices
450	430 to 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	1	9	Assumed typical separation distance is 1 m.
710	704 to 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0,02	0,3	3	Assumed typical LTE power of 20 mW by adaptive power control (-10 dB)
745							
780							
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	0,2	0,3	9	Assumed typical power of 200 mW by adaptive power control (-10 dB)
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	0,2	0,3	9	Assumed typical power of 200 mW by adaptive power control (-10 dB)
1 845							
1 970							

Table A.1 *(2 of 2)*

Test frequency MHz	**Band** [a] MHz	**Service** [a]	**Modulation** [b]	**Typical power** W	**Separation distance** m	**IMMUNITY TEST LEVEL** V/m	**Remarks**
2 450	2 400 to 2 570	Bluetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	1	9	RFID handbook indicates a maximum of 4 W EIRP (2,4 W ERP) indoor and 0,5 W EIRP outdoor. Separation distance is 1 m typically.
5 240	5 100 to 5 800	W LAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,1	0,3	6	Typical power is 100 mW
5 500							
5 785							

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

[b] The carrier should 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.

Subclause 8.13 – ESD testing of connectors

ESD can occur to unused connectors and to connector pins, especially when cables are being connected. Therefore, it is important to expose connectors to ESD and check the performance of the ME EQUIPMENT or ME SYSTEM after the tests and after all cables that are associated with the INTENDED USE are reconnected.

Connector covers could be in the form of a cover plate or cap. These items should be considered part of the ENCLOSURE and tested for ESD accordingly.

Many connector PORTS are designed to handle high-frequency information, either analogue or digital, and therefore cannot be provided with sufficient overvoltage protection devices. In the case of analogue signals, bandpass filters might be a solution. Overvoltage protecting diodes have too much stray capacitance to be useful at high frequencies.

Table 9 – Testing of connectors and pins while connected and disconnected

Examples of Case 4 are cables needed for charging and cables needed for service or maintenance.

Annex B
(informative)

Guide to labelling recommendations

B.1 ACCOMPANYING DOCUMENTS, instructions for use

Recommendations for information to be included in the instructions for use are found in the subclauses of this document listed in Table B.1.

Table B.1 – ACCOMPANYING DOCUMENTS, instructions for use

Description	Clause or subclause
ME EQUIPMENT or ME EQUIPMENT parts for which the connector testing exemption specified in 8.13.2. d) is used; marking of	5.1
Degradation of performance that is considered to be acceptable by the MANUFACTURER: statement of	5.2.2 a)
If degradation is observed during IMMUNITY testing, any mitigations or actions that could be taken by the OPERATOR or PATIENT as a consequence: statement of	5.2.2 b)
The maximum recovery time following a TRANSIENT phenomenon: statement of	5.2.2 c)
The environments of INTENDED USE: statement of	5.2.2 d)
Connector testing exemption; reproduction of the ESD warning symbol	5.2.3 a)
Connector testing exemption; warning that pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used	5.2.3 b)
Connector testing exemption; ESD precautionary procedures	5.2.3 c)
Connector testing exemption; recommendation for ESD explanation for PATIENTS and OPERATORS	5.2.3 d)

B.2 ACCOMPANYING DOCUMENTS, technical description

Additional recommendations for information to be included in the technical description are found in the subclauses of this document listed in Table B.2.

Table B.2 – ACCOMPANYING DOCUMENTS, technical description

Description	Clause or subclause
The ME EQUIPMENT or ME SYSTEM was tested according to the recommendations of this document: statement of	5.2.4 a)
ELECTROMAGNETIC phenomena and IMMUNITY TEST LEVELS: list of	5.2.4 b)

Annex C
(informative)

Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS

C.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 described in C.2 and C.3.

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 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: IEC TS 61000-1-2 [7] 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 typical EM DISTURBANCES related to a set of electromagnetic phenomena that are characteristic of the specified EM ENVIRONMENTS, i.e. professional healthcare facility environment and 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 special condition might not always be obvious. In general, mitigation involves an active or passive 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 has not changed or been altered.

An example of a special condition would be a SPECIAL LOCATION where the relative humidity levels are always above 80 %. 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 tables in Clause 8, but an 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 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 ESD mitigation.

In the end, it does not matter whether it’s called a 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.

C.2 EM DISTURBANCE level determination

The MANUFACTURER of an ME EQUIPMENT or ME SYSTEM should first determine the typical exposure level from EM DISTURBANCE(S). See C.6 for examples of conditions that might affect exposure levels. The new EM DISTURBANCE level will be the typical exposure level from the EM source at the location of INTENDED USE of the ME EQUIPMENT or ME SYSTEM. See C.3. This new exposure level can then be used to determine the IMMUNITY TEST LEVEL for the ME EQUIPMENT or ME SYSTEM. Each phenomenon that is mitigated will need its own assessment

Examples of sources in the location of INTENDED USE that should be considered include RF transmitters such as AM radio, FM radio, TV, RFID and mobile devices. The typical exposure level determination should take into consideration the DISTURBANCE sources that are expected to be in the location of INTENDED USE.

C.3 Assessment of EM DISTURBANCE sources

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

– evaluation of each DISTURBANCE source and determination of the EM level that will be present at the ME EQUIPMENT or ME SYSTEM locations of INTENDED USE;

– use of measured data, including field survey results;

– use of applicable standards representing the generally accepted state-of-the-art;

– use of scientific research results, including clinical data;

– use of IMMUNITY levels of ME EQUIPMENT and ME SYSTEMS in use, being considered state-of-the-art.

The above assessments are listed in preferred assessment order, i.e. “DISTURBANCE sources” should be evaluated first and “use of IMMUNITY levels of ME EQUIPMENT and ME SYSTEMS in use” should be evaluated last.

The IET *Guide to EMC for Functional Safety* [2] has useful information applicable to field survey measurements.

EM DISTURBANCE levels can be obtained from direct measurement or by obtaining MANUFACTURER’S data or other published technical information. Other references exist that describe methods for assessing the EM ENVIRONMENT. One such reference is IEC TS 61000-1-2:2016 [7], 6.1 to 6.3. In addition, IEC 61000-4-1 [8] and IEC TR 61000-2-5 [9] list EM phenomena that should be considered and which can be used as a basis for understanding compatibility levels.

C.4 Test methods

Whenever possible, the testing specifications of the Basic EMC standards (IEC 61000-4-x) should be used. For EM phenomena that are not listed in 8.11 or a Basic EMC standard for testing the EM phenomenon does not exist, a special test method might be necessary. If so, this should be documented in the test plan and the test report.

C.5 Test plan

It is important to capture the assessment performed by the MANUFACTURER of an ME EQUIPMENT or ME SYSTEM and how the IMMUNITY of the ME EQUIPMENT or ME SYSTEM will be verified. See 6.1.

C.6 Examples of mitigations and special conditions

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

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

Table C.1 – Examples of adjusted IMMUNITY TEST LEVELS due to mitigations or special conditions

Phenomenon / Basic EMC standard	Example mitigation or special condition	Example adjusted IMMUNITY TEST LEVEL	Remarks
ESD IEC 61000-4-2	Actual relative humidity < 10 % and synthetic floor coverings	± 8 kV for contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV for air discharge	See IEC 61000-4-2:2008 Table A.1 IEC 61340 (all parts)
Radiated RF EM field IEC 61000-4-3	Specified for use only in an RF shielded location SPECIAL ENVIRONMENT, including filtering of all cables passing through the shielding, with a minimum shielding effectiveness and filter attenuation of 20 dB	0,3 V/m	
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- 285 EN 61587-3 Example: bunker for electron accelerator
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 61000-4-4:2012, 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 61000-4-5:2014, Annex B
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	
Voltage dips IEC 61000-4-11	Uninterruptible power supply (UPS) sufficiently fast and powerful to provide the energy needed	No testing	Test applicable only to UPS
Voltage 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 D
(informative)

Identification of specific IMMUNITY performance criteria

D.1 General

This annex provides guidance and examples to aid in the determination of specific, detailed IMMUNITY performance criteria.

D.2 IMMUNITY performance criteria principles

D.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 INTENDED USE. The response of these functions should be monitored, with sufficient accuracy and resolution during and after IMMUNITY testing.

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

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

D.2.2 IMMUNITY performance criteria for non-ME EQUIPMENT used in an ME SYSTEM

An ME SYSTEM that includes non-ME EQUIPMENT should have a determination whether additional IMMUNITY tests and performance criteria are necessary.

D.2.3 IMMUNITY performance criteria determination

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

– the functions to be tested for IMMUNITY (to verify performance);
– the INTENDED USE;
– MANUFACTURER'S specifications;
– operating modes;
– characteristics of simulated PATIENT physiological signals;
– IMMUNITY performance criteria specified in the IEC 60601-2 (all parts) should be considered.

IMMUNITY performance criteria can specify degradations that are acceptable because they do not result in unacceptable performance.

D.3 IMMUNITY performance criteria examples

D.3.1 General examples

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

Examples of performance that could be considered failure of the test:

– malfunction;
– non-operation when operation is required;
– unwanted operation when no operation is required;
– deviation from normal operation or specifications (e.g. by a specified amount);
– component failures;
– change in programmable parameters;
– reset to factory defaults (MANUFACTURER's presets);
– change of operating mode;
– 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.

Examples of performance, during and after the applied IMMUNITY test signals, required to pass the test:

– for a mammography system, the compression full release and associated command remains fully operational;
– in ULTRASONIC DIAGNOSTIC EQUIPMENT, image quality;
– functions perform as intended;
– noise on an ECG waveform greater than a specified value.

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).

Cessation or interruption of an intended operation

Failure of therapy equipment to terminate a treatment at the intended time can be considered cessation or interruption of an intended operation. 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 an ECG monitor stops monitoring for 50 ms and then resumes operation such that performance is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

When testing multiple times might be needed

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 does something when it should and under another set of conditions to assure that it does not do something when it should not.

D.3.2 Example of immunity performance criteria for a radiological table system

During, and after the IMMUNITY tests, the radiological table system provides its specified performance (see Table D.1).

Table D.1 – Example of IMMUNITY performance criteria for a radiological table and gantry system

No.	Function	IMMUNITY performance criteria [a)]
1	System initialization at power ON	The start/initialization sequence takes less than 1 min before returning to the main menu.
2	Remote management of table and gantry movements.	The remote user interface that would be located in the control room can manage the table and gantry movements specified in the test plan.
3	Automatic repositioning of table and gantry	The auto positioner function returns the gantry or the table to the programmed position from a specified starting position in less than 30 s.
4	Manual positioning of table and gantry	The table and gantry move to a specified position from a specified starting position in less than 30 s, when commanded to do so from a remote user interface that would be located in the control room.
5	DISPLAY OF information.	Data, information and images are displayed as specified by the MANUFACTURER.
[a)] Additional specific IMMUNITY criteria might apply, based on the specifications of the system.		

D.3.3 Example of immunity performance criteria for ultrasonic diagnostic equipment

During, and after the IMMUNITY tests, the ULTRASONIC DIAGNOSTIC EQUIPMENT provides its specified performance (see Table D.2).

This example of IMMUNITY performance criteria is based on the specifications of the ME EQUIPMENT or ME SYSTEM.

Table D.2 – Example of IMMUNITY performance criteria for ULTRASONIC DIAGNOSTIC EQUIPMENT

No.	Function [a)]	IMMUNITY performance criteria [b)]
1	Ultrasound image acquisition	The EQUIPMENT displays and records an image and the features of the displayed or recorded images are recognizable as (e.g. simulated) physiologic.
2	Doppler waveform acquisition	The EQUIPMENT displays and records a Doppler waveform and the features of the displayed or recorded waveforms are fully recognizable as (e.g. simulated) physiologic.
3	Image storage	Recorded images are stored in an acceptable amount of time and have an acceptable amount of error.
4	Image transfer	Images are transferred through a network PORT and received remotely with an acceptable amount of error and in acceptable amount of time.

a) The SYSTEM SPECIFICATIONS can be used to address specific operating modes.

b) Additional specific IMMUNITY criteria might apply, based on the specifications of the system.

Annex E
(informative)

Performance criteria specified by IEC 61000-6-x generic EMC standards

The general performance criteria for the evaluation of the IMMUNITY test results for equipment are listed here for reference [14] [15]. However, they are not appropriate for ME EQUIPMENT and ME SYSTEMS for the reasons presented in Annex A.

– Performance criterion A

The equipment should continue to operate as intended during and after the test. No degradation of performance or loss of function is allowed below a performance level specified by the MANUFACTURER, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the MANUFACTURER, either of these may be derived from the product description and documentation and what the user can reasonably expect from the equipment if used as intended.

– Performance criterion B

The equipment should continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the MANUFACTURER, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is however allowed. No change of actual operating state or stored data is allowed. If the minimum performance level or the permissible performance loss is not specified by the MANUFACTURER, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.

– Performance criterion C

Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.

Annex F
(informative)

Mapping between this document and the elements of IEC 60601-1-2:2014

This annex contains a mapping of the clauses and subclauses of this document with the comparable clauses and subclauses in the fourth edition of IEC 60601-1-2. While the scope of this document is IMMUNITY and the scope of the fourth edition of IEC 60601-1-2 is BASIC SAFETY and ESSENTIAL PERFORMANCE, Table F.1 is intended to provide a tool to assist users of this document to trace between the recommendations of this document and similar requirements in the fourth edition of IEC 60601-1-2. This could be particularly helpful when testing according to the two documents is performed concurrently or sequentially.

Table F.1 – Mapping between the elements of IEC TR 60601-4-2 and IEC 60601-1-2:2014 *(1 of 5)*

IEC TR 60601-4-2		IEC 60601-1-2:2014	
Clause	**Title**	**Clause**	**Title**
	CONTENTS		CONTENTS
	FOREWORD		FOREWORD
	INTRODUCTION		INTRODUCTION
0.1	General		
0.2	Purpose of this document		
0.3	How to use this document		
0.4	IMMUNITY TEST LEVELS		
1	Scope and object	1	Scope, object and related standards
1.1	Scope	1.1	Scope
1.2	Object	1.2	Object
		1.3	Related standards
		1.3.1	IEC 60601-1
		1.3.2	Particular standards
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
4	General recommendations	4	General requirements
4.1	Concurrent and sequential testing		
		4.1	RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS
		4.2	Non-ME EQUIPMENT used in an ME SYSTEM
4.2	General test conditions	4.3	General test conditions
4.2.1	Configurations	4.3.1	Configurations
4.2.2	Artificial hand	4.3.2	Artificial hand
4.2.3	Power input voltages and frequencies	4.3.3	Power input voltages and frequencies
5	ME EQUIPMENT and ME SYSTEMS identification, marking and documents	5	ME EQUIPMENT and ME SYSTEMS identification, marking and documents

Table F.1 *(2 of 5)*

IEC TR 60601-4-2		IEC 60601-1-2:2014	
Clause	**Title**	**Clause**	**Title**
5.1	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT PARTS for which the connector testing exemption specified in 8.13.2 d) is used	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
5.2	ACCOMPANYING DOCUMENTS	5.2	ACCOMPANYING DOCUMENTS
5.2.1	General		
5.2.2	Instructions for use	5.2.1	Instructions for use
		5.2.1.1	General
		5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11
5.2.3	Requirements applicable to ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 0 d) is used		
5.2.4	Technical description	5.2.2	Technical description
		5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS
		5.2.2.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT
		5.2.2.3	Requirements applicable to ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation
		5.2.2.4	Requirements applicable to ME EQUIPMENT that includes RF transmitters
		5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS
		5.2.2.6	Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT
6	Documentation of the tests	6	Documentation of the tests
		6.1	General
6.1	Test plan	6.2	Test plan
0	Test report	6.3	Test report
7	EMISSIONS This clause is not used in this document	7	ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS
		7.1	Protection of radio services and other equipment
		7.1.1	General
		7.1.2	Operating modes
		7.1.3	Multimedia equipment
		7.1.4	Subsystems

Table F.1 *(3 of 5)*

IEC TR 60601-4-2		IEC 60601-1-2:2014	
Clause	**Title**	**Clause**	**Title**
		7.1.5	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT
		7.1.6	ME EQUIPMENT and ME SYSTEMS that include radio equipment
		7.1.7	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices
		7.1.8	ME EQUIPMENT and ME SYSTEMS containing X-ray generators
		7.1.9	PATIENT PHYSIOLOGICAL SIMULATION
		7.1.10	Artificial hand
		7.1.11	PATIENT-COUPLED cables
		7.1.12	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS
		7.2	Protection of the PUBLIC MAINS NETWORK
		7.2.1	Harmonic distortion
		7.2.2	Voltage fluctuations and flicker
		7.3	EMISSIONS requirements summary
8	IMMUNITY recommendations	8	ELECTROMAGNETIC IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS
8.1	General	8.1	General
8.2	PATIENT PHYSIOLOGICAL SIMULATION	8.2	PATIENT PHYSIOLOGICAL SIMULATION
8.3	Termination of PATIENT-COUPLED parts	8.3	Termination of PATIENT-COUPLED parts
8.4	HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD	8.4	HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD
8.5	Subsystems	8.5	Subsystems
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS	8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS
8.7	Operating modes	8.7	Operating modes
8.8	Non-ME EQUIPMENT	8.8	Non-ME EQUIPMENT
8.9	Environments of INTENDED USE		
8.10	Performance criteria		
8.11	IMMUNITY TEST LEVELS	8.9	IMMUNITY TEST LEVELS
0	IMMUNITY to proximity fields from RF wireless communications equipment	8.10	IMMUNITY to proximity fields from RF wireless communications equipment
8.13	ESD testing of connectors		
8.13.1	Application of ESD to connectors		
0	Exclusions		
9	Test report	9	Test report
Annex A	General guidance and rationale	Annex A	General guidance and rationale
		A.1	Safety and performance
		A.2	Testing of normally non-observable functions

Table F.1 *(4 of 5)*

IEC TR 60601-4-2		IEC 60601-1-2:2014	
Clause	**Title**	**Clause**	**Title**
		A.3	Rationale for particular clauses and subclauses
Annex B	Guide to labelling recommendations	Annex B	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
B.1	ACCOMPANYING DOCUMENTS, instructions for use	B.2	ACCOMPANYING DOCUMENTS, instructions for use
B.2	ACCOMPANYING DOCUMENTS, technical description	B.3	ACCOMPANYING DOCUMENTS, technical description
		Annex C	Guidance in classification according to CISPR 11
		C.1	General
		C.2	Separation into groups
		C.3	Division into classes
		Annex D	Guidance in the application of IEC 60601-1-2 to particular standards
		D.1	General
		D.2	Recommended modifications
		D.2.1	Testing requirements
		D.2.2	ACCOMPANYING DOCUMENTS
		D.3	Cautions
Annex C	Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS	Annex E	Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS
C.1	General	E.1	General
		E.3	Summary of method for E.1 b), c) and d)
C.2	EM DISTURBANCE level determination	E.4	Determination of EM DISTURBANCE level reduction
C.3	Assessment of EM DISTURBANCE sources	E.5	Assessment of EM DISTURBANCE sources
C.4	Test methods	E.2	Summary of method for E.1 a)
		E.6	Reasonably foreseeable maximum EM DISTURBANCE levels
		E.7	Determination of IMMUNITY test levels
		E.8	RF radiators in SPECIAL ENVIRONMENTS
C.5	Test plan		
C.6	Examples of mitigations and special conditions	E.9	Examples of mitigations and special conditions
		Annex F	RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES
		F.1	General
		F.2	General requirements for RISK MANAGEMENT
		F.3	RISK ANALYSIS

Table F.1 *(5 of 5)*

IEC TR 60601-4-2		IEC 60601-1-2:2014	
Clause	**Title**	**Clause**	**Title**
		F.4	RISK EVALUATION
		F.5	RISK CONTROL
		F.5.1	RISK CONTROL option analysis
		F.5.2	Implementation of RISK CONTROL measure(s)
		F.5.3	RESIDUAL RISK EVALUATION
		F.5.4	RISK/benefit analysis
		F.5.5	RISKS arising from RISK CONTROL measures
		F.5.6	Completeness of RISK CONTROL
		F.6	Evaluation of overall RESIDUAL RISK acceptability
		F.7	RISK MANAGEMENT report
		F.8	Production and post-production information
		Annex G	Guidance: Test plan
		G.1	Test plan contents
		Annex H	PATIENT-COUPLED cables EMISSIONS
		H.1	Protection of other equipment from cable conducted EMISSIONS
		H.2	Test method
		H.3	Rationale
Annex D	Identification of specific IMMUNITY performance criteria	Annex I	Identification of IMMUNITY pass/fail criteria
D.1	General	I.1	General
D.2	IMMUNITY performance criteria principles	I.2	IMMUNITY pass/fail criteria principles
D.2.1	General	I.2.1	General
D.2.2	IMMUNITY performance criteria for non-ME EQUIPMENT used in an ME SYSTEM	I.2.2	IMMUNITY pass/fail criteria for non-ME EQUIPMENt used in an ME SYSTEM
D.2.3	IMMUNITY performance criteria determination	I.2.3	IMMUNITY pass/fail criteria determination
D.3	IMMUNITY performance criteria examples	I.3	IMMUNITY pass/fail criteria examples
D.3.1	General examples	I.3.1	General examples
D.3.2	Example of IMMUNITY performance criteria for a radiological table system	I.3.2	Example of IMMUNITY pass/fail criteria for a radiological table system
D.3.3	Example of IMMUNITY performance criteria for ULTRASONIC DIAGNOSTIC EQUIPMENT		
Annex E	Performance criteria specified by IEC 61000-6-x generic EMC standards		
Annex E	Mapping between this technical report and the elements of IEC 60601-1-2:2014		
Bibliography		Bibliography	

Bibliography

[1] *Handbook of Electrostatic Processes*, Jen-Shih Chang *et al.*, Marcel Dekker, Inc., ISBN 0-8247-9254-8

[2] *Introductory Manager's Guide to EMC for Functional Safety*, The Institution of Engineering and Technology (IET), formerly the IEE, London, UK, 2008, www.theiet.org/factfiles/emc/intro-manage-EMC.cfm

[3] *International Telecommunication Union Radio Regulations*:2012 http://www.itu.int/pub/R-REG-RR-2012

[4] EUROCAE ED-14G:2011, *Environmental Conditions and Test Procedures for Airborne Equipment*

[5] RTCA DO-160G:2010, *Environmental conditions and test procedures for airborne equipment*

[6] CISPR 24, *Information technology equipment – Immunity characteristics – Limits and methods of measurement*

[7] IEC TS 61000-1-2:2016, *Electromagnetic compatibility (EMC) – Part 1-2: General – Methodology for the achievement of functional safety of electrical and electronic systems including equipment with regard to electromagnetic phenomena*

[8] IEC TR 61000-4-1:2016, *Electromagnetic compatibility (EMC) – Part 4-1: Testing and measurement techniques – Overview of IEC 61000-4 series*

[9] IEC TR 61000-2-5, *Electromagnetic compatibility (EMC) – Part 2-5: Environment – Description and classification of electromagnetic environments*

[10] ISO 16750-2:2012, *Road vehicles – Environmental conditions and testing for electrical and electronic equipment – Part 2: Electrical loads*

[11] Oxford Dictionaries online (http://www.oxforddictionaries.com/us).

[12] Vocabulary.com (http://www.vocabulary.com/dictionary).

[13] IEC 60050-161:1990, *International Electrotechnical Vocabulary – Chapter 161: Electromagnetic compatibility*

[14] IEC 61000-6-1:2005, *Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – Immunity for residential, commercial and light-industrial environments*

[15] IEC 61000-6-2:2005, *Electromagnetic compatibility (EMC) – Part 6-2: Generic standards – Immunity for industrial environments*

[16] IEC 60601-2-25, *Medical electrical equipment – Part 2-25, Particular requirements for the basic safety and essential performance of electrocardiographs*

[17] IEC 61000-6 (all parts), *Electromagnetic compatibility (EMC) – Part 6: Generic standards*

[18] IEC 61340 (all parts), *Electrostatics*

[19] 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*

[20] CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

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

Index of defined terms used in this technical report

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