



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 60601-1-2:2015+A1:2021. It is identical to IEC 60601-1-2:2014, incorporating amendment 1:2020. It supersedes [BS EN 60601-1-2:2015](#), which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee 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 committee manager.

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More information on legislation can be found at www.gov.uk.

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Published by BSI Standards Limited 2021

ISBN 978 0 580 97719 0

ICS 11.040.01; 33.100.10; 33.100.20

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2015.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2021	Implementation of IEC amendment 1:2020 with CENELEC endorsement A1:2021

English Version

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

Appareils électromédicaux - Partie 1-2: Exigences
générales pour la sécurité de base et les performances
essentielles - Norme collatérale: Perturbations
électromagnétiques - Exigences et essais
(IEC 60601-1-2:2014)

Medizinische elektrische Geräte - Teil 1-2: Allgemeine
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale - Ergänzungsnorm:
Elektromagnetische Störgrößen - Anforderungen und
Prüfungen
(IEC 60601-1-2:2014)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62A/916/FDIS, future edition 4 of IEC 60601-1-2, prepared by SC 62A, "Common aspects of electrical equipment used in medical practice", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-2:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-03-18
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

This document supersedes EN 60601-1-2:2007.

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The text of the International Standard IEC 60601-1-2:2014 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-2:2007	NOTE	Harmonized as EN 60601-1-2:2007 (not modified)
IEC 60601-2-27:2011	NOTE	Harmonized as EN 60601-2-27:2006 (not modified)
IEC 60601-2-44:2009	NOTE	Harmonized as EN 60601-2-44:2009 (not modified)
IEC 61000-3-11:2000	NOTE	Harmonized as EN 61000-3-11:2000 (not modified)
IEC 61000-3-12:2011	NOTE	Harmonized as EN 61000-3-12:2011 (not modified)
IEC 61000-3-12:2011	NOTE	Harmonized as EN 61000-3-12:2011 (not modified)
IEC 60601-6-1:2005	NOTE	Harmonized as EN 60601-6-1:2007 (not modified)
IEC 60601-6-2:2005	NOTE	Harmonized as EN 60601-6-2:2005 (not modified)
IEC 61496-1:2008	NOTE	Harmonized as EN 61496-1:2008 (not modified)
CISPR 16-1-1:2010	NOTE	Harmonized as EN 55016-1-1:2010 (not modified)
CISPR 16-2-3:2010	NOTE	Harmonized as EN 55016-2-3:2010 (not modified)
CISPR 24:2010	NOTE	Harmonized as EN 55024:2010 (not modified)
CISPR 25:2008	NOTE	Harmonized as EN 55025:2008 (not modified)
ISO 17025:2005	NOTE	Harmonized as EN ISO/IEC 17025:2005 (not modified)

Foreword to amendment A1

The text of document 62A/1390/FDIS, future IEC 60601-1-2/A1, prepared by SC 62A “Common aspects of electrical equipment used in medical practice” of IEC/TC 62 “Electrical equipment in medical practice” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-2:2015/A1:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2021-09-19 level by publication of an identical national standard or by endorsement
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IEC 61000-1-2:2016	NOTE	Harmonized as EN 61000-1-2:2016 (not modified)
IEC 60601-2 (series)	NOTE	Harmonized as EN 60601-2 (series)
ISO/TR 24971:2020	NOTE	Harmonized as CEN ISO/TR 24971:2020 (not modified)
CISPR 35:2016	NOTE	Harmonized as EN 55035:2017

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60417	Data base	Graphical symbols for use on equipment available from http://www.graphical-symbols.info/equipment	IEC 60417	2004
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		-	-
IEC 60601-1-8	2006	Medical electrical equipment – Part 1–8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	-	-
+ A1	2012		+ A1	2013
-	-		+ AC	2014
+ A2	2020		-	-
IEC 60601-1-11	2015	Medical electrical equipment – Part 1–11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	-	-
+ A1	2020		-	-
IEC 60601-1-12	2014	Medical Electrical Equipment – Part 1–12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment	-	-
+ A1	2020		+ A1	2020

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD and IEC/ISO</u>	<u>Year</u>
IEC 60601-2-2	2010	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories		
IEC 60601-2-3	2012	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment		
IEC 61000-3-2	2005	Electromagnetic compatibility (EMC) - Part 3- 2: Limits - Limits for harmonic current emissions (equipment input current $\leq$ 16 A per phase)	EN 61000-3-2	2006
A1	2008		+A1	2009
A2	2009		+A2	2009
IEC 61000-3-3	2013	Electromagnetic compatibility (EMC) - Part 3- 3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low- voltage supply systems, for equipment with rated current $\leq$ 16 A per phase and not subject to conditional connection	EN 61000-3-3	2013
IEC 61000-4-2	2008	Electromagnetic compatibility (EMC) - Part 4- 2: Testing and measuring techniques - Electrostatic discharge immunity test	EN 61000-4-2	2009
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4- 3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006
A1	2007		+A1	2008
			+IS1	2009
A2	2010		+A2	2010
IEC 61000-4-4	2012	Electromagnetic compatibility (EMC) - Part 4- 4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2012
IEC 61000-4-5	2014	Electromagnetic compatibility (EMC) - Part 4–5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2014
+A1	2017		+A1	2017
IEC 61000-4-6	2013	Electromagnetic compatibility (EMC) - Part 4- 6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields		
IEC 61000-4-8	2009	Electromagnetic compatibility (EMC) - Part 4- 8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	2010
IEC 61000-4-11	2004	Electromagnetic compatibility (EMC) - Part 4- 11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	2004
+A1	2017		+A1	2017
IEC 61000-4-39	2017	Electromagnetic compatibility (EMC) – Part 4–39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test	EN 61000-4-39	2017

EN 60601-1-2:2015+A1:2021 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD and IEC/ISO</u>	<u>Year</u>
CISPR 11 (mod)	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
+ A1	2016		+ A1	2017
-	-		+ A11	2020
+ A2	2019		-	-
CISPR 14-1	2016	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2017
-	-		+ A11	2020
CISPR 16-1-2	2014	Electromagnetic compatibility of multimedia equipment - Emission requirements	EN 55032	2015
-	-		+ A11	2020
CISPR 32	2015	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	EN 55016-1-2	2014
+A1	2017		+A1	2017
ISO 7637-2	2011	Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only		

Application of Annexes of the EN 60601 series

The Annex ZZ of EN 60601-1:2006+A1:2013 applies.

Annex ZZ (informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretionary choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 7 According to the scope of this standard the coverage in Table ZZ.1 only applies to protection of ME equipment and ME systems against electromagnetic disturbances. This European Standard lists in Table ZZ.1 only the essential requirements covered.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1: Relationship between Essential Requirements of Directive 93/42/EEC, and Clauses and Subclauses of this standard

No.	Essential Requirements	Coverage EN 60601-1-2
I.	GENERAL REQUIREMENTS	
1.	General Guidance notes 1-7 shall be observed	
1	<p>The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.</p> <p>This shall include:</p>	<p>If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to EMC-aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to clauses 4 to 9 of this collateral standard) without covering the risk benefit balancing.</p>
	<ul style="list-style-type: none"> - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and 	<p>Covered in respect to</p> <p>7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network, and</p> <p>8.9 Immunity test levels</p>
2.	General Guidance notes 1-7 shall be observed	
2	<p>The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.</p> <p>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:</p>	<p>1st paragraph:</p> <p>Covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account.</p> <p>2nd paragraph (including the following 3 bullets): Not covered.</p>
	<ul style="list-style-type: none"> - eliminate or reduce risks as far as possible (inherently safe design and construction), 	
	<ul style="list-style-type: none"> - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, 	
	<ul style="list-style-type: none"> - inform users of the residual risks due to any shortcomings of the protection measures adopted. 	
II.	REQUIREMENTS FOR DESIGN AND CONSTRUCTION	
	General Guidance notes 1-7 shall be observed	
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is	

No.	Essential Requirements	Coverage EN 60601-1-2
	possible:	
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	Covered in respect to electromagnetic disturbances, see 8.9 Immunity test levels.
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network.
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	
11	Protection against radiation	General Guidance note 1-7 shall be observed
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment.
12	Requirements for medical devices connected to or equipped with an energy source	General Guidance notes 1-7 shall be observed
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment.
13	Information supplied by the manufacturer	General Guidance notes 1-7 shall be observed
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered in respect to aspects related to accessories, components and subassemblies contained in 5.2.1.1 d) and e)

CONTENTS

FOREWORD	6
INTRODUCTION	9
INTRODUCTION to Amendment 1	10
1 Scope, object and related standards	11
1.1 * Scope	11
1.2 Object	11
1.3 Related standards	11
1.3.1 IEC 60601-1	11
1.3.2 Particular standards	11
2 Normative references	11
3 Terms and definitions	13
4 General requirements	17
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS	17
4.2 * Non-ME EQUIPMENT used in an ME SYSTEM	17
4.3 General test conditions	17
4.3.1 * Configurations	17
4.3.2 Artificial hand	18
4.3.3 * Power input voltages and frequencies	18
5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents	20
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	20
5.2 ACCOMPANYING DOCUMENTS	20
5.2.1 Instructions for use	20
5.2.2 Technical description	21
6 Documentation of the tests	23
6.1 General	23
6.2 Test plan	23
6.3 Test report	23
7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS	23
7.1 Protection of radio services and other equipment	23
7.1.1 * General	23
7.1.2 Operating modes	23
7.1.3 Multimedia equipment	24
7.1.4 * Subsystems	24
7.1.5 ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT	24
7.1.6 ME EQUIPMENT and ME SYSTEMS that include radio equipment	24
7.1.7 * ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices	25
7.1.8 ME EQUIPMENT and ME SYSTEMS containing X-ray generators	25
7.1.9 PATIENT physiological simulation	25
7.1.10 Artificial hand	25
7.1.11 PATIENT-coupled cables	25
7.1.12 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS	25

7.2	Protection of the PUBLIC MAINS NETWORK	26
7.2.1	* Harmonic distortion	26
7.2.2	* Voltage fluctuations and flicker	26
7.3	EMISSIONS requirements summary	26
8	Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS	26
8.1	* General	26
8.2	PATIENT physiological simulation	30
8.3	Termination of PATIENT-COUPLED parts	30
8.4	HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD	30
8.5	* Subsystems	31
8.6	* PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS	31
8.7	* Operating modes	31
8.8	* Non-ME EQUIPMENT	32
8.9	* IMMUNITY TEST LEVELS	32
8.10	* IMMUNITY to proximity fields from RF wireless communications equipment	39
8.11	* IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz	41
9	* Test report	41
Annex A	(informative) General guidance and rationale	44
A.1	Safety and performance	44
A.2	Testing of normally non-observable functions	44
A.3	Rationale for particular clauses and subclauses	44
Annex B	(informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	68
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	68
B.2	ACCOMPANYING DOCUMENTS, instructions for use	68
B.3	ACCOMPANYING DOCUMENTS, technical description	68
Annex C	(informative) Guidance in classification according to CISPR 11	70
C.1	General	70
C.2	Separation into groups	70
C.3	Division into classes	71
Annex D	(informative) Guidance in the application of IEC 60601-1-2 to particular standards	72
D.1	General	72
D.2	Recommended modifications	72
D.2.1	Testing requirements	72
D.2.2	ACCOMPANYING DOCUMENTS	72
D.3	Cautions	72
Annex E	(informative) Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS	74
E.1	General	74
E.2	Summary of method for E.1 a)	77
E.3	Summary of method for E.1 b), c) and d)	77
E.4	Determination of EM DISTURBANCE level reduction	77
E.5	Assessment of EM DISTURBANCE sources	77
E.6	Reasonably foreseeable maximum EM DISTURBANCE levels	78
E.7	Determination of IMMUNITY TEST LEVELS	78
E.8	RF radiators in SPECIAL ENVIRONMENTS	78

E.9	Examples of mitigations and special conditions	79
Annex F (informative)	Guidance on the application of RISK MANAGEMENT with regard to ELECTROMAGNETIC DISTURBANCES in this collateral standard	80
Annex G (informative)	Guidance: Test plan	89
G.1	Test plan contents	89
Annex H (informative)	PATIENT-coupled cables EMISSIONS	91
H.1	* Protection of other equipment from PATIENT cable conducted EMISSIONS	91
H.2	Test method	91
H.3	Rationale	91
Annex I (informative)	Identification of IMMUNITY pass/fail criteria	93
I.1	General	93
I.2	IMMUNITY pass/fail criteria principles	93
I.2.1	General	93
I.2.2	IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM	93
I.2.3	IMMUNITY pass/fail criteria determination	93
I.3	IMMUNITY pass/fail criteria examples	94
I.3.1	General examples	94
I.3.2	Example of IMMUNITY pass/fail criteria for a radiological table system	95
Bibliography		97
Index of defined terms used in this collateral standard		101
Figure 1	– RC element of the artificial hand	18
Figure 2	– PORTS of ME EQUIPMENT and ME SYSTEMS	27
Figure 3	– Examples of locations within EM ENVIRONMENTS	33
Figure A.1	– Examples of PORTS (from IEC 61000-6-1:2005)	50
Figure A.2	– IEC 61000-4-2 Figure A.1 – Maximum values of electrostatic voltages to which OPERATORS can be charged while in contact with the materials mentioned in A.2	57
Figure A.3	– Steps for evaluation of IMMUNITY to proximity magnetic fields	62
Figure A.4	– Magnetic field roll-off characteristics along the x-axis for a thin planar coil and various coil radii	64
Figure A.5	– Voltage induced in a 1-turn, 6 cm radius coil by a 6 cm radiating coil operating at 134,2 kHz and H_0 of 82,65 A/m (r.m.s.)	65
Figure A.6	– Voltage induced in a 1-turn, 2 cm radius coil by a 2 cm radiating coil operating at 13,56 MHz and H_0 of 7,5 A/m (r.m.s.)	65
Figure E.1	– Test plan development flow when SPECIAL ENVIRONMENTS are known	75
Figure E.2	– Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS	76
Figure F.1	– RISK MANAGEMENT flow in IEC 60601-1-2 (1 of 3)	86
Figure H.1	– Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27	92
Table 1	– Power input voltages and frequencies during the tests (1 of 2)	19
Table 2	– EMISSION limits per environment	26
Table 3	– Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal	28
Table 4	– * ENCLOSURE PORT	34

Table 5 – * Input a.c. power PORT (1 of 2)	35
Table 6 – Input d.c. power PORT	37
Table 7 – * PATIENT coupling PORT	38
Table 8 – SIP/SOP PORT	39
Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment	40
Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields	41
Table 10 – * Minimum test report contents (1 of 2)	42
Table A.2 – Example calculations for applying the allowance to test at a single RATED power input voltage	46
Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST	53
Table A.3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment	60
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	68
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use	68
Table B.3 – ACCOMPANYING DOCUMENTS, technical description	69
Table E.1 – Examples of specific mitigations / environmental conditions	79
Table F.1 – Specific guidance for subclauses of this collateral standard that reference RISK MANAGEMENT (1 of 6)	80
Table G.1 – Recommended minimum test plan contents (1 of 2)	89
Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit	91
Table I.1 – Example of IMMUNITY pass criteria for a radiological table system	96

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

This fourth edition cancels and replaces the third edition of IEC 60601-1-2, published in 2007, and constitutes a technical revision.

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

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

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

and the following additions:

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

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62A/916/FDIS	62A/924/RVD

Full information on the voting for the approval of this standard 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 the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

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

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

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

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

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

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

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

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this collateral standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this collateral standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

INTRODUCTION to Amendment 1

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

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

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

1 Scope, object and related standards

1.1 * Scope

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

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

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

1.2 Object

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

1.3 Related standards

1.3.1 IEC 60601-1

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

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

- Ⓐ – "the general standard" designates IEC 60601-1 alone, including any amendments;
- "this collateral standard" designates IEC 60601-1-2 alone, including any amendments; Ⓐ
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

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

2 Normative references

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

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

A1 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

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

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

IEC 60601-1-12:2014 *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020 **A1**

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

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

IEC 61000-3-2:2005²⁾, *Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
Amendment 1:2008
Amendment 2:2009

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

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

IEC 61000-4-3:2006³⁾, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*
Amendment 1:2007
Amendment 2:2010

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

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

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

- ▣^{A1} IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017 ^{A1}

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*

- ▣^{A1} IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

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

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

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

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

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements* ^{A1}

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

- ▣^{A1} ISO 14971:2019, *Medical devices – Application of risk management to medical devices* ^{A1}

3 Terms and definitions

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

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

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

NOTE 3 An index of defined terms is found beginning on page 101.

3.1

*** EFFECTIVE RADIATED POWER** (of any device in a given direction)

ERP

the power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

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

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

3.2

ELECTROMAGNETIC COMPATIBILITY

EMC

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

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

3.3

ELECTROMAGNETIC DISTURBANCE

EM DISTURBANCE

any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

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

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

3.4

(ELECTROMAGNETIC) EMISSION

the phenomenon by which electromagnetic energy emanates from a source

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

3.5

ELECTROMAGNETIC ENVIRONMENT

EM ENVIRONMENT

the totality of electromagnetic phenomena existing at a given location

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

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

3.6

ELECTROSTATIC DISCHARGE

ESD

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

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

3.7

ENCLOSURE PORT

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

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

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

3.8

* IMMUNITY (TO A DISTURBANCE)

the ability of ME EQUIPMENT or an ME SYSTEM to perform without degradation in the presence of an ELECTROMAGNETIC DISTURBANCE

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

3.9

IMMUNITY TEST LEVEL

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

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

3.10

INFORMATION TECHNOLOGY EQUIPMENT

ITE

equipment designed for the purpose of

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

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

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

3.11

INTERMITTENT MODE

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

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

3.12

LARGE ME EQUIPMENT

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

3.13

LARGE ME SYSTEM

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

3.14

LOW VOLTAGE

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

3.15

PATIENT-COUPLED

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

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

3.16

PATIENT COUPLING POINT

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

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

3.17

PORT

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

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

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

3.18

* PUBLIC MAINS NETWORK

LOW VOLTAGE electricity power lines to which all categories of consumers have access

3.19

RADIO FREQUENCY

RF

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

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

3.20

SPECIAL ENVIRONMENT

ELECTROMAGNETIC ENVIRONMENT with electromagnetic characteristics different from those specified in this collateral standard in [A1](#) Table 2 through Table 9 and Table 11 [A1](#) or that requires EMISSIONS limits, IMMUNITY TEST LEVELS or test methods that are different from those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT

4 General requirements

4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS

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

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

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

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

4.2 * Non-ME EQUIPMENT used in an ME SYSTEM

In addition to 16.1 of the general standard:

- non-ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment;
- non-ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT shall be tested according to the requirements of this collateral standard.

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

4.3 General test conditions

4.3.1 * Configurations

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

These configurations shall include:

- attachment of cables to all PORTS as necessary to achieve the INTENDED USE (including SIP/SOPs and, if applicable, the POTENTIAL EQUALIZATION CONDUCTOR);
- attachment of all tubing and filling of all fluid containers;
- termination of the cables with the intended equipment, subsystem simulators as specified in 7.1.4 and 8.5, PATIENT physiological simulators as specified in 7.1.9 and 8.2 or artificial hands as specified in 7.1.10 and 8.4;
- earthing on the ENCLOSURE PORT, if applicable, including connections to the terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR;
- use of cables and connectors that meet the specifications of the ME EQUIPMENT or ME SYSTEM MANUFACTURER.

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

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

4.3.2 Artificial hand

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

- For PATIENT COUPLING POINTS that do not have a conductive contact, the PATIENT COUPLING POINT is terminated with the artificial hand and (series) RC element shown in Figure 9a of 8.3 of CISPR 16-1-2 (see Figure 1). The metal foil of the artificial hand is sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of the RC element and the other terminal of the RC element is connected to the ground reference plane.
- For PATIENT COUPLING POINTS that have conductive contact to the PATIENT (PATIENT CONNECTION), terminal M of the RC element is connected directly to the PATIENT COUPLING POINT, and the other terminal of the RC element is connected to the ground reference plane. If normal operation of the ME EQUIPMENT or ME SYSTEM cannot be verified with terminal M connected to the PATIENT COUPLING POINT, an insulating material with a maximum thickness of 5 mm may be applied between the metal foil of the artificial hand and the PATIENT COUPLING POINT. In this case, the metal foil of the artificial hand is to be sized and placed to simulate the approximate area and location of PATIENT coupling when the ME EQUIPMENT or ME SYSTEM is providing its INTENDED USE, and terminal M of the RC element is to be connected to the metal foil but not to the PATIENT COUPLING POINT. The other terminal of the RC element is connected to the ground reference plane in all cases.
- For ME EQUIPMENT and ME SYSTEMS that have multiple PATIENT COUPLING POINTS intended to be connected to a single PATIENT, each PATIENT COUPLING POINT and each PATIENT-COUPLED part is to have an artificial hand applied as specified above. The artificial hands are connected to a single common connection and this common connection is connected to terminal M of the RC element, as specified in 8.3 of CISPR 16-1-2. For ME EQUIPMENT and ME SYSTEMS intended to be connected to multiple PATIENTS, artificial hands are to be applied as specified above and a separate common connection and RC element is to be used for each PATIENT for which the capacitive coupling effect and RF impedance is to be simulated. The other terminal of each RC element is connected to the ground reference plane in all cases.

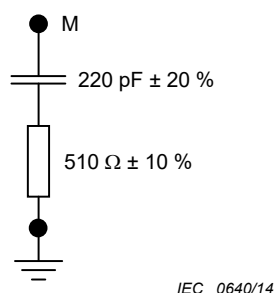


Figure 1 – RC element of the artificial hand

4.3.3 * Power input voltages and frequencies

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

Compliance is checked by inspection of the test report.

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

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



Table 1 (2 of 2)

Test	Power input voltage	Power frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage ^{a)}	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the power frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. ^{b)}
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage ^{c)} ^{d)}	Any one frequency ^{b)}
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage ^{a)}	Any one frequency ^{b)}
Proximity magnetic fields IEC 61000-4-39	Any one voltage ^{a)}	Any one frequency ^{b)}
^{a)} The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages. ^{b)} The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies. ^{c)} If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage. ^{d)} ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.		



5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents

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

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

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

5.2 ACCOMPANYING DOCUMENTS

5.2.1 Instructions for use

5.2.1.1 * General

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

- * a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- * the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

- c) * a warning statement to the effect that “WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.”

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

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

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

- e) * a warning statement to the effect that “WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
- f) * a warning statement to the effect that: “WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

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

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

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

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

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

5.2.2 Technical description

5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

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

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

- a) the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL;
- b) any deviations from this collateral standard and allowances used;

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

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

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

- a) a warning to the effect that: "WARNING: Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services";
- b) specifications for the shielded location, including:
 - minimum RF shielding effectiveness;
 - for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and
 - the frequency range(s) over which the specifications apply;
- c) recommended test methods for measurement of RF shielding effectiveness and RF filter attenuation;
- d) one or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location:
 - a specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM;
 - a list of specific equipment allowed;
 - a list of types of equipment prohibited.

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

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

- each frequency or frequency band of reception;
- the preferred frequency or frequency band, if applicable; and
- the bandwidth of the receiving section of the ME EQUIPMENT in those bands.

5.2.2.4 Requirements applicable to ME EQUIPMENT that includes RF transmitters

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

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

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

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