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ÜLDNÕUDED ESMASELE OHUTUSELE JA OLULISTELE  
TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD:  
ELEKTROMAGNETILINE ÜHILDUVUS. NÕUDED JA  
KATSETUSED

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-2:2015 sisaldab Euroopa standardi EN 60601-1-2:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-2:2015 consists of the English text of the European standard EN 60601-1-2:2015.
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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  
essentielle - 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 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:

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31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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## Endorsement notice

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)

## CONTENTS

CONTENTS .....	2
FOREWORD .....	6
INTRODUCTION .....	9
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 .....	27
8.1	* General .....	27
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
9	* Test report .....	41
	Annex A (informative) General guidance and rationale .....	43
A.1	Safety and performance .....	43
A.2	Testing of normally non-observable functions .....	43
A.3	Rationale for particular clauses and subclauses .....	43
	Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....	57
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts .....	57
B.2	ACCOMPANYING DOCUMENTS, instructions for use .....	57
B.3	ACCOMPANYING DOCUMENTS, technical description .....	57
	Annex C (informative) Guidance in classification according to CISPR 11 .....	59
C.1	General .....	59
C.2	Separation into groups .....	59
C.3	Division into classes .....	60
	Annex D (informative) Guidance in the application of IEC 60601-1-2 to particular standards .....	61
D.1	General .....	61
D.2	Recommended modifications .....	61
D.2.1	Testing requirements .....	61
D.2.2	ACCOMPANYING DOCUMENTS .....	61
D.3	Cautions .....	61
	Annex E (informative) Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS .....	63
E.1	General .....	63
E.2	Summary of method for E.1 a) .....	66
E.3	Summary of method for E.1 b), c) and d) .....	66
E.4	Determination of EM DISTURBANCE level reduction .....	66
E.5	Assessment of EM DISTURBANCE sources .....	66
E.6	Reasonably foreseeable maximum EM DISTURBANCE levels .....	67
E.7	Determination of IMMUNITY TEST LEVELS .....	67
E.8	RF radiators in SPECIAL ENVIRONMENTS .....	67
E.9	Examples of mitigations and special conditions .....	68
	Annex F (informative) RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES .....	69

F.1	General.....	69
F.2	General requirements for RISK MANAGEMENT .....	70
F.3	RISK ANALYSIS.....	71
F.4	RISK EVALUATION.....	74
F.5	RISK CONTROL.....	75
	F.5.1 RISK CONTROL option analysis .....	75
	F.5.2 Implementation of RISK CONTROL measure(s).....	75
	F.5.3 RESIDUAL RISK EVALUATION.....	75
	F.5.4 Risk/benefit analysis.....	76
	F.5.5 RISKS arising from RISK CONTROL measures .....	76
	F.5.6 Completeness of RISK CONTROL .....	76
F.6	Evaluation of overall RESIDUAL RISK acceptability .....	76
F.7	RISK MANAGEMENT report .....	76
F.8	Production and post-production information .....	77
Annex G (informative)	Guidance: Test plan.....	78
	G.1 Test plan contents .....	78
Annex H (informative)	PATIENT-coupled cables EMISSIONS .....	80
	H.1 * Protection of other equipment from PATIENT cable conducted EMISSIONS .....	80
	H.2 Test method.....	80
	H.3 Rationale .....	80
Annex I (informative)	Identification of IMMUNITY pass/fail criteria .....	82
	I.1 General.....	82
	I.2 IMMUNITY pass/fail criteria principles.....	82
	I.2.1 General .....	82
	I.2.2 IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM .....	82
	I.2.3 IMMUNITY pass/fail criteria determination .....	82
	I.3 IMMUNITY pass/fail criteria examples.....	83
	I.3.1 General examples.....	83
	I.3.2 Example of IMMUNITY pass/fail criteria for a radiological table system.....	84
	Bibliography.....	86
	Index of defined terms used in this collateral standard .....	89
	Figure 1 – RC element of the artificial hand .....	18
	Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS .....	27
	Figure 3 – Examples of environments of INTENDED USE.....	33
	Figure A.1 – Examples of PORTS (from IEC 61000-6-1:2005).....	47
	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 .....	54
	Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known .....	64
	Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.....	65
	Figure F.1 – Function of this collateral standard in the RISK MANAGEMENT PROCESS.....	69
	Figure F.2 – Examples of multiple VERIFICATION methods for improving confidence in RISK levels .....	70
	Figure H.1 – Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27 .....	81

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 – Signal input/output parts PORT .....	39
Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment .....	40
Table 10 – * Minimum test report contents (1 of 2) .....	41
Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST .....	49
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts .....	57
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use .....	57
Table B.3 – ACCOMPANYING DOCUMENTS, technical description .....	58
Table E.1 – Examples of specific mitigations / environmental conditions .....	68
Table F.1 – Examples of EM phenomena that should be considered in a RISK ANALYSIS .....	72
Table G.1 – Recommended minimum test plan contents (1 of 2) .....	78
Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit .....	80
Table I.1 – Example of IMMUNITY pass criteria for a radiological table system .....	85

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## 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).

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## MEDICAL ELECTRICAL EQUIPMENT –

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

## 1 Scope, object and related standards

### 1.1 \* Scope

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

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

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

### 1.2 Object

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

### 1.3 Related standards

#### 1.3.1 IEC 60601-1

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

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

- "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);
- "this collateral standard" designates IEC 60601-1-2 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

#### 1.3.2 Particular standards

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

## 2 Normative references

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

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

IEC 60601-1:2005<sup>1)</sup>, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*  
Amendment 1:2012

IEC 60601-1-8:2006<sup>2)</sup>, *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

IEC 60601-1-11:2010, *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*

IEC 60601-1-12\_\_<sup>3)</sup> *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 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

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

IEC 61000-3-2:2005<sup>4)</sup>, *Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current  $\leq 16$  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  $\leq 16$  A per phase and not subject to conditional connection*

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

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

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

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

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

3) To be published.

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

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

IEC 61000-4-5:2005, *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 measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*

CISPR 11:2009<sup>6)</sup>, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*  
Amendment 1:2010

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

CISPR 16-1-2:2003<sup>7)</sup>, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Ancillary equipment – Conducted disturbances*  
Amendment 1:2004  
Amendment 2:2006

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

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

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

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

### 3 Terms and definitions

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

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

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

NOTE 3 An index of defined terms is found beginning on page 89.

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

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

8) To be published.