SVENSK STANDARD SS-EN 60601-1-2

Fastställd	Utgåva	Sida	Ansvarig kommitté
2015-11-18	4	1 (1+98)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 1-2: Allmänna fordringar beträffande säkerhet och väsentliga prestanda – Tilläggsstandard för elektromagnetiska störningar

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

Som svensk standard gäller europastandarden EN 60601-1-2:2015. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-2:2015.

Nationellt förord

Europastandarden EN 60601-1-2:2015

består av:

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

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60601-1-2, utgåva 3, 2007 och SS-EN 60601-1-2 C1, utgåva 1, 2010, gäller ej fr o m 2018-12-31.

ICS 11.040.01; 33.100.10; 33.100.20

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Telefon: 08 - 444 14 00.
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SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-2

September 2015

ICS 11.040.01; 33.100.10; 33.100.20

Supersedes EN 60601-1-2:2007

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)

This European Standard was approved by CENELEC on 2014-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-1-2:2015 E

SEK Svensk Elstandard

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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. However, for any use of this standard “within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

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
A1	2012		A1	2013
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	EN 60601-1-8 + corr. March	2007 2010
A1	2013		A1	2013
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	EN 60601-1-11	2010
IEC 60601-1-12	2014	Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment		
IEC 60601-2-2	2010	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high		

Publication	Year	Title	EN/HD and IEC/ISO	Year
		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 <= 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 <= 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	2005	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2006
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
CISPR 11	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011 (mod)	2009
A1	2010			
CISPR 14-1	2005	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2006
			+A1	2009
			+A2	2011
CISPR 16-1-2	2003	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity	EN 55016-1-2	2004

Publication	Year	Title	EN/HD and IEC/ISO	Year
		measuring apparatus - Ancillary equipment - Conducted disturbances		
A1	2004		+A1	2005
A2	2006		+A2	2006
CISPR 32	2012	Electromagnetic compatibility of multimedia equipment – Emission requirements	EN 55032	2012
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	EN ISO 14971	2012

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

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[1)], *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

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

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__[3)] *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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

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

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

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

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

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

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

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

CISPR 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*

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.