

### SLOVENSKI STANDARD SIST EN 60601-1-2:2008

01-januar-2008

Nadomešča: SIST EN 60601-1-2:2002 SIST EN 60601-1-2:2002/A1:2006

Medicinska električna oprema - 1-2. del: Splošne zahteve za osnovno varnost in bistvene tehnične lastnosti - Spremljevalni standard: Elektromagnetna združljivost - Zahteve in preskušanje (IEC 60601-1-2:2007) (vsebuje popravek AC:2010)

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

#### (standards.iteh.ai)

Medizinische elektrische Geräte -- Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale Ergänzungsnorm: Elektromagnetische Verträglichkeit Anforderungen und Prüfungen

Appareils électromédicaux -- Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Compatibilité électromagnétique - Exigences et essais

Ta slovenski standard je istoveten z: EN 60601-1-2:2007

#### ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

SIST EN 60601-1-2:2008

en,fr,de

SIST EN 60601-1-2:2008

## iTeh STANDARD PREVIEW (standards.iteh.ai)



## EUROPEAN STANDARD NORME EUROPÉENNE

## EN 60601-1-2

EUROPÄISCHE NORM

July 2007

ICS 11.040.01; 33.100.10; 33.100.20

Supersedes EN 60601-1-2:2001 + A1:2006 Incorporates corrigendum March 2010

English version

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

(IEC 60601-1-2:2007, modified)

Appareils électromédicaux -Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles ANDARD Norme collatérale: Compatibilité électromagnétique and ards.itel Elektromagnetische Verträglichkeit -Exigences et essais (CEI 60601-1-2:2007, modifiée) SIST EN 60601-1-2:200(IEC 60601-1-2:2007, modifiziert)

https://standards.iteh.ai/catalog/standards/sist/066327f8-dd2e-494b-842a-0a52adb27710/sist-en-60601-1-2-2008

This European Standard was approved by CENELEC on 2007-04-11. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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## CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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#### Foreword

The text of document 62A/560/FDIS, future edition 3 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 was approved by CENELEC as EN 60601-1-2 on 2007-04-11.

The following date was fixed:

-	latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-02-01
-	latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-06-01

This European Standard supersedes EN 60601-1-2:2001 and its amendment A1:2006.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

This EN 60601-1-2 was revised to structurally align it with EN 60601-1:2006 and to implement the decision of IEC SC 62A that the clause numbering structure of collateral standards written to EN 60601-1:2006 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in EN 60601-1:2006.

In the 60601 series of publications, <u>collateral6(standards)(specify general requirements for safety</u> applicable to <u>https://standards.iteh.ai/catalog/standards/sist/066327f8-dd2e-494b-842a-</u>

- 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: in roman type;
- test specifications: in 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 NOTES: IN SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Table 1 through Table 8, in the tables in Annex C and in statements required to appear in the technical description or instructions for use because they are intended for the OPERATOR or RESPONSIBLE ORGANIZATION, who may not be familiar with the defined terms of EN 60601 standards.

In referring to the structure of this standard, the term

- "clause" means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

- 3 -

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

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

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

Clauses, subclauses, items and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (\*).

Annexes ZA and ZZ have been added by CENELEC.

The contents of the corrigendum of March 2010 have been included in this copy.

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#### **Endorsement notice**

The text of the International Standard IEC 60601-1-2:2007 was approved by CENELEC as a European Standard with agreed common modifications as given below.

#### COMMON MODIFICATIONS

Annex A, Subclause 4.2:

Replace the last sentence by:

These HAZARDS shall be considered in the RISK MANAGEMENT PROCESS.

#### Bibliography

Add the following notes for the standards indicated:

CISPR 11 + A1 + A2	NOTE	Harmonized as EN 55011:2007 (modified) and A2:2007 (not modified).
CISPR 24	NOTE	Harmonized as EN 55024:1998 (modified).
IEC 61000-4-2 + A1 + A2	NOTE	Harmonized as EN 61000-4-2:1995 + A1:1998 + A2:2001 (not modified).
IEC 61000-4-3	NOTE	Harmonized as EN 61000-4-3:2006 (not modified).
IEC 61000-4-4	NOTE	Harmonized as EN 61000-4-4:2004 (not modified).
IEC 61000-4-6 + A1 + A2	Tete S	Harmonized as EN 61000-4-6:2007 (not modified).
IEC 61326-1	NOTE	<b>standards iteh.ai)</b> Harmonized as EN 61326-1:2006 (hot modified).
ISO 14971 https://	NOTE /standards.it	Harmonized as EN ISO 14971:2000 (not modified). h.ai/catalog/standards/sist/066327f8-dd2e-494b-842a-
	0	a52adb27710/sist-en-60601-1-2-2008

- 5 -

#### Annex ZA

#### (normative)

## Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication IEC 60417	<u>Year</u> Data base	<u>Title</u> Graphical symbols for use on equipment	<u>EN/HD</u> -	<u>Year</u> -
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 ⁄	2006
IEC 60601-1-8	2006 iT	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collatera Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 I	2007
IEC 61000-3-2	_ 1) https://st	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A aper phase)catalog/standards/sist/066327f8-dd2e-49	EN 61000-3-2 94b-842a-	2006 <sup>2)</sup>
IEC 61000-3-3	_ 1)	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 + corr. July	1995 <sup>2)</sup> 1997
IEC 61000-4-2	_ 1)	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995 <sup>2)</sup>
IEC 61000-4-3	_ 1)	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006 2)
IEC 61000-4-4	_ 1)	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2004 <sup>2)</sup>

<sup>&</sup>lt;sup>1)</sup> Undated reference.

<sup>&</sup>lt;sup>2)</sup> Valid edition at date of issue.

EN 60601-1-2:2007	
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Publication IEC 61000-4-5	<u>Year</u> - <sup>1)</sup>	<u>Title</u> Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	<u>EN/HD</u> EN 61000-4-5	<u>Year</u> 2006 <sup>2)</sup>
IEC 61000-4-6 + A1 + A2	2003 2004 2006	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	2007
IEC 61000-4-8	_ 1)	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993 <sup>2)</sup>
IEC 61000-4-11	_ 1)	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11 s	2004 <sup>2)</sup>
CISPR 11 (mod)	_ 1)	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagneti disturbance characteristics - Limits and methods of measurement	EN 55011 c	2007 <sup>2)</sup>
CISPR 14-1	- <sup>1)</sup>	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1 EW	2006 <sup>2)</sup>
CISPR 15	_ 1)	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	o EN 55015	2006 <sup>2)</sup>
CISPR 16-1-2	https://sta	a Specification for radio disturbance and d2e-4 immunity measuring apparatus and 008 methods - Part 1-2: Radio disturbance and immunity measuring apparatus - Ancillary equipment Conducted disturbances	9 <b>EN:550</b> 16-1-2	2004 <sup>2)</sup>
CISPR 22 (mod)	_ 1)	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55022	2006 <sup>2)</sup>

#### Annex ZZ

#### (informative)

#### **Coverage of Essential Requirements of EC Directives**

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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## IEC 60601-1-2

Edition 3.0 2007-03

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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

SIST EN 60601-1-2:2008

Appareils électromédicaux di ai/catalog/standards/sist/066327t8-dd2e-494b-842a-Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Compatibilité électromagnétique – Exigences et essais

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE CODE PRIX

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#### CONTENTS

FO	REW	ORD	5
INT	ROD	UCTION	8
1	Scop	e, object and related standards	10
	1.1	* Scope	10
	1.2	Object	10
	1.3	Related standards	10
2	Norm	native references	10
3	Term	ns and definitions	12
4	Gene	eral requirements	15
	4.1	General requirements for ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT	15
	4.2	* SINGLE FAULT CONDITION FOR ME EQUIPMENT.	
5	Ident	tification, marking and documents	
	5.1	Marking on the outside of ME EQUIPMENT OF ME EQUIPMENT parts	16
	5.2	ACCOMPANYING DOCUMENTS	17
6	ELEC	TROMAGNETIC COMPATIBILITY	39
	6.1	EMISSIONS ITCH STANDARD PREVIEW	39
	6.2	IMMUNITY (standards.iteh.ai)	42
Anr	nex A	(informative) General guidance and rationale	58
Anr	nex B	(informative)s: Guide to marking and labelling requirements)4for ME-EQUIPMENT	
anc	ME S	YSTEMS0a52adb27710/sist-en-60601-1-2-2008	88
Anr	nex C	(informative) Example completion of Table 1 through Table 8	91
Anr	nex D	(informative) Guidance in classification according to CISPR 11	103
Anr	nex E	(informative) Guidance in the application of IEC 60601-1-2 to particular	106
Anr		(informative) ELECTROMACNETIC ENVIRONMENTS	100
Ann		(informative) ELECTROMAGNETIC ENVIRONMENTS	109
EQL	JIPMEN	and that is used in an ME SYSTEM is exempt from the EMC testing ents of this collateral standard	110
Anr	nex H	(informative) Mapping between the elements of the second edition of	
IEC	6060	)1-1-2 as amended and IEC 60601-1-2:2007	112
Bib	liogra	phy	120
Ind	ex of	defined terms used in this collateral standard	121
⊢ig ME	URE 1 SYSTE	- Instructions for completing Table 1 for CISPR 11 ME EQUIPMENT and	21
Fig MF	ure 2	<ul> <li>Instructions for completing Table 1 for CISPR 14 and CISPR 15</li> </ul>	22
Fig	ure 3	– Instructions for completing Table 2	25
Fig	ure 4	<ul> <li>Instructions for completing Table 3 and Table 5 for LIFE-SUPPORTING</li> </ul>	
ME	EQUIP	MENT and ME SYSTEMS	31

60601-1-2 © IEC:2007 - 3 -	
Figure 5 – Instructions for completing Table 4 and Table ME SYSTEMS that are not LIFE-SUPPORTING	6 for ME EQUIPMENT and
Figure A.1 – Example of cable arrangement for radiated	IMMUNITY test86
Figure A.2 – Examples showing maximum dimension for with two cables	ME EQUIPMENT with one and
Figure G.1 – Procedure for determining if electrical equi and that is used in an ME SYSTEM is exempt from the EM collateral standard	pment that is not ME EQUIPMENT C testing requirements of this 
Table 1 – Guidance and MANUFACTURER'S declaration – I         for all ME EQUIPMENT and ME SYSTEMS	ELECTROMAGNETIC EMISSIONS –
Table 2 – Guidance and MANUFACTURER'S declaration []-         for all ME EQUIPMENT and ME SYSTEMS	- electromagnetic IMMUNITY – 24
Table 3 – Guidance and MANUFACTURER'S declaration –           LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS	electromagnetic IMMUNITY – for 27
Table 4 – Guidance and MANUFACTURER'S declaration –         ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORT	electromagnetic IMMUNITY – for TING28
Table 5 – Recommended separation distances between communications equipment and the ME EQUIPMENT or ME ME EQUIPMENT and ME SYSTEMS	portable and mobile RF SYSTEM – for LIFE-SUPPORTING 
Table 6 – Recommended separation distances between communications equipment and the ME EQUIPMENT or ME and ME SYSTEMS that are not LIFE-SUPPORTING	portable and mobile RF SYSTEM - for ME EQUIPMENT 
Table 7 – Guidance and MANUFACTURER'S declaration         LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS that are shielded location	specified for use only in a
Table 8 – Guidance and MANUFACTURER'S declaration ME EQUIPMENT and ME SYSTEMS that are not cire support only in a shielded location.	electromagnetic IMMUNITY – for TING and are specified for use 
Table 9 – Modulation frequency, PHYSIOLOGICAL SIMULAT           OPERATING FREQUENCY	ION FREQUENCY, and46
Table 10 – IMMUNITY TEST LEVELS for voltage dips	
Table 11 – IMMUNITY TEST LEVEL for voltage interruption .	
Table B.1 – Marking on the outside of ME EQUIPMENT, ME	SYSTEMS or their parts88
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for	use89
Table B.3 – ACCOMPANYING DOCUMENTS, technical descri	ption90
Table C.1 – Example (1) of completed Table 1	
Table C.2 – Example (2) of completed Table 1	
Table C.3 – Example (3) of completed Table 1	
Table C.4 – Example of completed Table 2	
Table C.5 – Example (1) test, IMMUNITY and COMPLIANCE	LEVELS
Table C.6 – Example of completed Table 3	
Table C.7 – Example of completed Table 5	
Table C.8 – Example of completed Table 4	
Table C.9 – Example of completed Table 6	
Table C.10 – Example (2) test, IMMUNITY and COMPLIANC	e levels99

- 4 -

#### 60601-1-2 © IEC:2007

Table C.11 – Example of completed Table 7	100
Table C.12 – Example (3) test, IMMUNITY and COMPLIANCE LEVELS	101
Table C.13 – Example of completed Table 8	102
Table F.1 – Electromagnetic environments	109
Table H.1 – Mapping between the elements of the eecond edition of IEC 60601-1-2 as amended and IEC 60601-1-2:2007	112

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#### INTERNATIONAL ELECTROTECHNICAL COMMISSION

#### MEDICAL ELECTRICAL EQUIPMENT -

#### Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – 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 committee; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 third 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.

This document cancels and replaces the second edition of IEC 60601-1-2, and constitutes a technical revision.