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

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**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-2

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 - Norme collatérale: Compatibilité électromagnétique - Exigences et essais (CEI 60601-1-2:2007, modifiée)

Medizinische elektrische Geräte - Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Elektromagnetische Verträglichkeit - Anforderungen und Prüfungen (IEC 60601-1-2:2007, modifiziert)

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.

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

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

Ref. No. EN 60601-1-2:2007 E

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, 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: 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).

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.

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	NOTE	Harmonized as EN 61000-4-6:2007 (not modified).
IEC 61326-1	NOTE	Harmonized as EN 61326-1:2006 (not modified).
ISO 14971	NOTE	Harmonized as EN ISO 14971:2000 (not modified).

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	Year	Title	EN/HD	Year
IEC 60417	Data base	Graphical symbols for use on equipment	-	-
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	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	2007
IEC 61000-3-2	- [1)]	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	EN 61000-3-2	2006 [2)]
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 ≤ 16 A per phase and not subject to conditional connection	EN 61000-3-3 + corr. July	1995 [2)] 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 [2)]
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 [2)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

Publication	Year	Title	EN/HD	Year
IEC 61000-4-5	- [1)]	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2006 [2)]
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 [2)]
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	2004 [2)]
CISPR 11 (mod)	- [1)]	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	EN 55011	2007 [2)]
CISPR 14-1	- [1)]	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2006 [2)]
CISPR 15	- [1)]	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	EN 55015	2006 [2)]
CISPR 16-1-2	- [1)]	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity measuring apparatus - Ancillary equipment - Conducted disturbances	EN 55016-1-2	2004 [2)]
CISPR 22 (mod)	- [1)]	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55022	2006 [2)]

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.

IEC 60601-1-2

Edition 3.0 2007-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

INTERNATIONAL
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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 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 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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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.