SLOVENSKI STANDARD

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

oktober 2006

Medicinska električna oprema – 1-2. del: Splošne varnostne zahteve – Spremljevalni standard: Elektromagnetna združljivost – Zahteve in preskusi (IEC 60601-1-2:2001/A1:2004)

Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2001/A1:2004)

ICS 11.040.01; 33.100.01

Referenčna številka
SIST EN 60601-1-2:2002/A1:2006(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-2/A1

May 2006

ICS 11.040.01; 33.100.10; 33.100.20

English version

Medical electrical equipment
Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
(IEC 60601-1-2:2001/A1:2004)

Appareils électromédicaux
Partie 1-2: Règles générales de sécurité -
Norme collatérale:
Compatibilité électromagnétique -
Exigences et essais
(CEI 60601-1-2:2001/A1:2004)

Medizinische elektrische Geräte
Teil 1-2: Allgemeine Festlegungen
für die Sicherheit -
Ergänzungsnorm:
Elektromagnetische Verträglichkeit -
Anforderungen und Prüfungen
(IEC 60601-1-2:2001/A1:2004)

This amendment A1 modifies the European Standard EN 60601-1-2:2001; it was approved by CENELEC on 2006-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, 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 60601-1-2:2001/A1:2006 E

Foreword

The text of document 62A/462/FDIS, future amendment 1 to IEC 60601-1-2:2001, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-1-2:2001 on 2006-03-01.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-12-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2009-03-01

Endorsement notice

The text of amendment 1:2004 to the International Standard IEC 60601-1-2:2001 was approved by CENELEC as an amendment to the European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-2

2001

AMENDEMENT 1
AMENDMENT 1
2004-09

Amendement 1

Appareils électromédicaux –

Partie 1-2: Règles générales de sécurité – Norme collatérale: Compatibilité électromagnétique – Exigences et essais

Amendment 1

Medical electrical equipment –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This bilingual version (2005-09) replaces the English version.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/462/FDIS	62A/469/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The French version of this amendment fas not been voted upon.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result 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.

INTRODUCTION

This amendment contains a first series of revisions to IEC 60601-1-2 (second edition, 2001): *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

This amendment deals primarily with requirements for EQUIPMENT and SYSTEMS that:

- comply with CISPR 11 Group 2 Class B except for the third harmonic of the fundamental frequency;
- are for use by healthcare professionals;
- are not intended for sale to the general public; and
- are intended for use in domestic establishments or connected to the PUBLIC MAINS NETWORK.

However, this amendment also includes several other corrections and additions to IEC 60601-1-2:2001.

To meet needs for change that were identified by users of this Collateral Standard, it was necessary to amend the standard before the previously approved maintenance cycle date.

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INTRODUCTION

Delete, on page 15, the paragraph beginning "This second edition allows a risk analysis…"

Page 17

2 Terminology and definitions

Replace the existing first paragraph with the following:

For the purposes of this Collateral Standard, the terms and definitions given in IEC 60601-1:1988, IEC 60601-1-1:2000, IEC 60601-1-8:2003 and ISO 14971:2000 and the following apply:

Delete definition 2.210 and change all occurrences of "ESSENTIAL PERFORMANCE" *throughout the document to normal font.*

Replace the existing definition 2.212 with the following:

***2.212**
FUNCTION (of an EQUIPMENT or SYSTEM)
clinically significant operation that the EQUIPMENT or SYSTEM is intended to perform in the diagnosis, treatment or monitoring of a PATIENT

Add the following new definitions:

***2.227**
PROFESSIONAL EQUIPMENT or SYSTEM
EQUIPMENT or SYSTEM for use by healthcare professionals and that is not intended for sale to the general public

[IEV 161-05-05, modified]

2.228
TYPE A PROFESSIONAL EQUIPMENT or SYSTEM
PROFESSIONAL EQUIPMENT or SYSTEM that complies with CISPR 11 Group 2 Class B except for the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM, in which case the third harmonic complies with the Group 2 Class A electromagnetic radiation disturbance limit

NOTE See 36.201.1 a) 6).

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3 General requirements

3.201.2 Essential performance

Replace the existing text of this subclause with the following:

Either the essential performance of the EQUIPMENT or SYSTEM shall be identified (see Annex GGG for guidance on identifying the essential performance) or the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM shall be considered essential performance for the purpose of IMMUNITY testing (see 36.202.1 j)). The essential performance shall be disclosed in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS or, if this identification is not performed, by inspection of the documents to verify that the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM has been tested in accordance with 36.202.

3.201.4 Non-medical electrical equipment

Remove the asterisk from the title and replace the existing text of this subclause with the following:

Non-medical electrical equipment that is supplied as part of a SYSTEM is exempt from the EMC testing requirements of this standard, provided all of the following conditions are met (see also Annex HHH):

a) the non-medical electrical equipment complies with applicable international EMC standards;

b) both the EMISSIONS and IMMUNITY of the non-medical electrical equipment have been determined not to adversely affect the essential performance or safety of the SYSTEM;

c) the EMISSIONS of the non-medical electrical equipment have been determined not to cause the EMISSIONS of the SYSTEM to exceed applicable limits.

Compliance is checked by inspection of the documents for this determination and other appropriate documents or certificates or, if this determination is not performed, by inspection of the documents to verify that the non-medical electrical equipment has been tested in accordance with this standard.

Add the following new subclause:

*3.201.5 General test conditions

For EMC testing, the SINGLE FAULT CONDITION requirements of the General Standard do not apply.

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6.8.201 ACCOMPANYING DOCUMENTS

Renumber this subclause as follows:

6.8 ACCOMPANYING DOCUMENTS

6.8.2.201 Instructions for use

Add the following item:

*d) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

If a TYPE A PROFESSIONAL EQUIPMENT or SYSTEM is intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), the instructions for use shall include the following warning or equivalent:

Warning
This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [EQUIPMENT or SYSTEM] or shielding the location.

where "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL or TYPE REFERENCE of the EQUIPMENT or SYSTEM.

6.8.3.201 Technical description

a) Requirements applicable to all EQUIPMENT and SYSTEMS

Replace, on page 29, the existing item a) 3) with the following:

*3) Table 201, with the modifications specified below.[1] [2] The flowchart in Figure 201 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 11 EQUIPMENT and SYSTEMS. The flowchart in Figure 202 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 14 and CISPR 15 EQUIPMENT.

- For CISPR 11 EQUIPMENT and SYSTEMS, "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.
- For CISPR 14 and CISPR 15 EQUIPMENT, "[EQUIPMENT]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT.
- For CISPR 11 Group 1 EQUIPMENT and SYSTEMS, rows 5, 12 and 13 shall be deleted.
- For CISPR 11 Group 2 EQUIPMENT and SYSTEMS, rows 4, 12 and 13 shall be deleted.
- For EQUIPMENT that complies with CISPR 14-1, rows 4 through 6 and row 13 shall be deleted

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1 See Annex BBB for examples. These modifications should be performed in the order in which they appear.

2 Row numbers refer to those in Table 201 before modifications are made.

– For EQUIPMENT that complies with CISPR 15, rows 4 through 6 and row 12 shall be deleted.

– For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class A, including TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS, "[A or B]" in column 2 of row 6 shall be replaced with "A." For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B, "[A or B]" shall be replaced with "B."

– For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-2, "[Class A, B, C, D, or Not applicable]" in column 2 of row 7 shall be replaced with the class of the EQUIPMENT or SYSTEM according to IEC 61000-3-2. For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-3, "[Complies or Not applicable]" in column 2 of row 8 shall be replaced with "Complies." For EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, "[Class A, B, C, D, or Not applicable]" and "[Complies or Not applicable]" shall each be replaced with "Not applicable."

– For CISPR 11 EQUIPMENT and SYSTEMS, column 3 of rows 6, 7 and 8 shall be merged into one cell. For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B and with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS for which use in a domestic establishment or connection to the PUBLIC MAINS NETWORK is intended and justified (see 6.8.3.201 j) and 36.201.1 a) 6)) and that comply with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 10 shall be moved into the merged cell. For CISPR 11 EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable or that comply with Class A but do not meet the requirements for TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS specified in 36.201.1 a) 6), the text in column 3 of row 11 shall be moved into the merged cell.

– For CISPR 14 or CISPR 15 EQUIPMENT, column 3 of rows 7 and 8 shall be merged into one cell. For CISPR 14 or CISPR 15 EQUIPMENT that comply with IEC 61000-3-2 and with IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For CISPR 14 or CISPR 15 EQUIPMENT for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 11 shall be moved into the merged cell.

– For EQUIPMENT and SYSTEMS specified for use only in a shielded location and for which the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used, the text specified by 6.8.3.201 c) 2) shall be added.

– Rows 9, 10 and 11 shall be deleted.

– The row numbers shall be deleted.

Add, on page 33, the following new item a) 7):

7) The performance of the equipment or system that was determined to be essential performance.

h) Requirements applicable to LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS

Replace the first paragraph of this item with the following:

For LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS for which the exemption specified in 36.202.3 b) 9) is used, the ACCOMPANYING DOCUMENTS shall include the following information:

i) Requirements applicable to EQUIPMENT and SYSTEMS found by a risk analysis to have no essential performance

In the title of item i) and in 1) and 2), delete "by a risk analysis".

Add the following new item:

*j) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), the ACCOMPANYING DOCUMENTS shall include a justification for not complying with the CISPR 11 Group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM. This justification shall be based on significant physical, technological or physiological limitations that prevent compliance. The ACCOMPANYING DOCUMENTS shall also include a justification why the EQUIPMENT or SYSTEM needs to be used in domestic establishments or connected to the PUBLIC MAINS NETWORK.

Compliance is checked by inspection.