SLOVENSKI STANDARD
SIST EN 60601-1-2:1995

01-maj-1995

Medical electrical equipment - Part 1: General requirements for safety - 2. collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 601-1-2:1993)

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

Medizinische elektrische Geräte -- Teil 1: Allgemeine Festlegungen für die Sicherheit -- 2. Ergänzungsnorm: Elektromagnetische Verträglichkeit - Anforderungen und Prüfungen

Appareils électromédicaux -- Partie 1: Règles générales de sécurité -- 2. Norme collatérale: Compatibilité électromagnétique - Prescriptions et essais

Ta slovenski standard je istoveten z: **EN 60601-1-2:1993**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-2:1995 **en**

EUROPEAN STANDARD EN 60601-1-2

NORME EUROPEENNE

EUROPÄISCHE NORM May 1993

UDC 615.841:621.37.001.365:620.1:614.8

Descriptors: Electromedical equipment, safety, electromagnetic compatibility

ENGLISH VERSION

Medical electrical equipment
Part 1: General requirements for safety
2. Collateral Standard: Electromagnetic compatibility - Requirements and tests
(IEC 601-1-2:1993)

Appareils électromédicaux
Première partie: Règles générales de sécurité
2. Norme Collatérale: Compatibilité électromagnétique
Prescriptions et essais

(CEI 601-1-2:1993)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die Sicherheit
2. Ergänzungs-Norm: Elektromagnetische Verträglichkeit
Anforderungen und Prüfungen
(IEC 601-1-2:1993)

This European Standard was approved by CENELEC on 1992-09-15.
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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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

FOREWORD

A draft European Standard concerning the electromagnetic compatibility of medical electrical equipment was submitted to the Unique Acceptance Procedure (UAP) as prEN 50097 in December 1991.

The 73rd Technical Board of CENELEC approved the draft on 1992-09-15, but decided that the standard would be issued as EN 60601-1-2 (endorsement of IEC 601-1-2, yet to be published).

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1993-11-30
- latest date of withdrawal of conflicting national standards	(dow)	1995-12-31

For products which have complied with the relevant national standard before 1995-12-31, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-12-31.

EN 60601-1-2 constitutes a Collateral Standard to EN 60601-1: Medical electrical equipment - Part 1: General requirements for safety, hereinafter referred to as the General Standard.

In the EN 60601 series Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;

- explanations, advice, general statements, exceptions and references: in smaller type;

- test specifications and headings of subclauses: in italic type;

- terms defined in clause 2 of the general standard or of this Collateral Standard: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information.

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annex AAA is informative and annex ZAA is normative. Annex ZAA has been added by CENELEC.

An index reproduces in alphabetic order all the terms defined in clause 2, Terminology and defintions.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-1-2:1993 was approved by CENELEC as a European Standard without any modification.

Editorial note: Annex BBB is replaced by annex ZAA.

ANNEX ZAA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

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

IEC Publication	Date	Title	EN/HD	Date
50(161)	1990	International Electrotechnical Vocabulary (IEV) - Chapter 161: Electromagnetic compatibility	-	-
601-1	1988	Medical electrical equipment	EN 60601-1	1990
A1	1991	Part 1: General requirements for safety	A1	1993
			A11, A12	1993
601-1-1	1992	Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems	-	-
801-1	1984	Electromagnetic compatibility for industrial-process measurement and control equipment - Part 1: General introduction	HD 481.1 S1	1987
801-2	1991	Part 2: Electrostatic discharge requirements	EN 60801-2	1993
801-3	-*	Part 3: Immunity to radiated radio-frequency electromagnetic fields (second edition under consideration)	-	-
801-4	1988	Part 4: Electrical fast transient/burst requirements	-	-
801-5	-	Part 5: Voltage surge immunity requirements (under consideration)	-	-
878	1988	Graphical symbols for electrical equipment in medical practice	-	-

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* IEC 801-3:1984 was harmonized as HD 481.3 S1:1987

IEC Publication	Date	Title	EN/HD	Date
CISPR 11 (mod)	1990	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	EN 55011*	1991
CISPR 14 (mod)	1985	Limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus	EN 55014*	1987

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* The title of EN 55011:1991 is: Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

EN 55014 is superseded by EN 55014:1993 which is based on CISPR 14:1993

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-1-2

Première édition
First edition
1993-04

Appareils électromédicaux

Première partie:
Règles générales de sécurité

2. Norme Collatérale: Compatibilité électromagnétique – Prescriptions et essais

Medical electrical equipment

Part 1:
General requirements for safety

2. Collateral Standard: Electromagnetic compatibility – Requirements and tests

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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Pour prix, voir catalogue en vigueur
For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT
Part 1: General requirements for safety

2. Collateral Standard:
Electromagnetic compatibility – Requirements and tests

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 601-1-2 has been prepared by IEC by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice. It constitutes a Collateral Standard to IEC 601-1: *Medical electrical equipment – Part 1: General requirements for safety,* hereinafter referred to as the General Standard.

In the 601 series of publications Collateral Standards specify general requirements for safety applicable to:

– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).