SLOVENSKI STANDARD
SIST EN 60601-1-1:1995

01-maj-1995

Medical electrical equipment - Part 1: General requirements for safety - 1. collateral standard: Safety requirements for medical electrical systems (IEC 601-1-1:1992)

Medical electrical equipment -- Part 1: General requirements for safety -- 1. Collateral standard: Safety requirements for medical electrical systems

Medizinische elektrische Geräte -- Teil 1: Allgemeine Festlegungen für die Sicherheit -- 1. Ergänzungsnorm: Festlegungen für die Sicherheit von medizinischen elektrischen Systemen

Appareils électromédicaux -- Partie 1: Règles générales de sécurité -- 1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux

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

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

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EUROPEAN STANDARD	EN 60601-1-1
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Descriptors: Medical electrical equipment, medical electrical systems, definitions, requirements, testing, construction, safety, symbols

ENGLISH VERSION

Medical electrical equipment
Part 1: General requirements for safety
1. Collateral standard: Safety requirements for medical electrical systems
(IEC 601-1-1:1992)

Appareils électromédicaux
Première partie: Règles générales de sécurité
1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux
(CEI 601-1-1:1992)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die Sicherheit
1. Ergänzungsnorm: Sicherheitsanforderungen an Medizinische elektrische Systeme
(IEC 601-1-1:1992)

This European Standard was approved by CENELEC on 1993-09-22. 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

At the request of the CENELEC Technical Committee TC 62, Electrical equipment in medical practice, the International Standard IEC 601-1-1:1992 was submitted in November 1992 to the CENELEC Unique Acceptance Procedure (UAP).

The text of the International Standard was approved by CENELEC as EN 60601-1-1 on 22 September 1993.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1994-09-01
- latest date of withdrawal of conflicting national standards	(dow)	1994-09-01

For products which have complied with the relevant national standard before 1994-09-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1999-09-01.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given only for information.
In this standard, annexes AAA, BBB, and ZB are informative and annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-1-1:1992 was approved by CENELEC as a European Standard without any modification.

Editorial modification:

Replace annexes CCC and DDD by annexes ZA and ZB.

ANNEX ZA (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.

NOTE : 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
601-1	1988	Medical electrical equipment	EN 60601-1	1990
A1		Part 1: General requirements for safety	A1	1993
			A11	1993
			A12	1993
601-2	series	Part 2: Particular requirements for the safety of ...	HD 395.2...	series
			EN 60601-2-...	series

ANNEX ZB (informative)

Bibliography

IEC Publication	Date	Title	EN/HD	Date
50(826)	1990	International Electrotechnical Vocabulary (IEV) - Part 826: Chapter 826: Electrical installations of buildings	HD 384.2 S1	1986
65, mod	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use	EN 60065*	1993
335	series	Safety of household and similar electrical appliances	EN 60335	series
348 superseded by 1010-1, mod	1990	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	1993
A1	1992			
414, mod	1973	Safety requirements for indicating and recording electrical measuring instruments and their accessories	HD 215 S1	1974
820	1986	Electrical safety of laser equipment and installations	-	-
950, mod	1986	Safety of information technology equipment including electrical business equipment	EN 60950*	1988

Other publications quoted:

ISO 7767	1988	Oxygen analyzers for monitoring patient breathing mixtures - Safety requirements
ISO 8185	1988	Humidifiers for medical use - Safety requirements
ISO 8359	1988	Oxygen concentrators for medical use - Safety requirements

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* EN 60065 includes A2:1989 + A3: 1992 to IEC 65
  EN 60950 is superseded by EN 60950:1992 which is based on IEC 950:1991, mod

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-1-1

Première édition
First edition
1992-06

Appareils électromédicaux

Première partie:
Règles générales de sécurité

1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux

Medical electrical equipment

Part 1:
General requirements for safety

1. Collateral standard: Safety requirements for medical electrical systems

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

1. Collateral standard: Safety requirements for medical electrical systems

FOREWORD

1) 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.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

This International Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 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).

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

Six Months' Rule	Report on Voting
62A(CO)38	62A(CO)40

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 appendices are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this 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 roman 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.

With the exception of annex CCC, normative references, all annexes of this standard are informative.

The IEC and ISO publications quoted in this standard are listed in annex DDD: Bibliography.

INTRODUCTION

This Collateral Standard is the first of a series that specifies general requirements for safety, amplifying the General Standard IEC 601-1. See Foreword.

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

1. Collateral standard: Safety requirements for medical electrical systems

SECTION 1: GENERAL

1 Scope and object

*1.201 *Scope*

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS. It describes the safety requirements for MEDICAL ELECTRICAL SYSTEMS to provide protection for the PATIENT, the OPERATOR and surroundings. It is presumed that the party assembling or modifying the MEDICAL ELECTRICAL SYSTEMS will take the necessary steps to assure compliance with this standard.

2 Terminology and definitions

Where the terms "voltage" and "current" are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

For the purpose of this standard the following additional definitions apply:

2.201 **COUPLING:** All functional connections between different items of equipment.

2.202 **INDIRECT CONTACT:** Contact of persons or livestock with exposed conductive parts which have become live under fault conditions (IEV 826-03-06).

2.203 **MEDICAL ELECTRICAL SYSTEM** (hereinafter referred to as **SYSTEM**): Totality of more than one item of MEDICAL ELECTRICAL EQUIPMENT or of MEDICAL ELECTRICAL EQUIPMENT in combination with other non-medical electrical equipment that by COUPLING behaves as a unit with specified functions (see also examples given in annex BBB).

*2.204 **PATIENT ENVIRONMENT:** Any area in which intentional or unintentional contact between PATIENT and parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur.

2.205 **SEPARATION DEVICE:** A component or arrangement of components with a SIGNAL INPUT PART and SIGNAL OUTPUT PART that prevents for safety reasons a transfer of unwanted voltage or current between parts of a SYSTEM.