Elektrilised meditsiiniseadmed. Osa 1: Üldised ohutusnõuded 1. kollateraalstandard: Ohutusnõuded elektrilistele meditsiinisüsteemidele

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 60601-1-1:2002 sisaldab Euroopa standardi EN 60601-1-1:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 60601-1-1:2002 consists of the English text of the European standard EN 60601-1-1:2001. This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard is the first of a new series of collateral standards that specify general requirements for safety applicable to a group of electromedical equipment not fully addressed in the General Standard. This publication deals with safety requirements for medical electrical systems	**Scope:** This standard is the first of a new series of collateral standards that specify general requirements for safety applicable to a group of electromedical equipment not fully addressed in the General Standard. This publication deals with safety requirements for medical electrical systems

ICS 11.040.01

Võtmesõnad:

EUROPEAN STANDARD **EN 60601-1-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM April 2001

ICS 11.040.01

Supersedes EN 60601-1-1:1993 + A1:1996

English version

Medical electrical equipment
Part 1-1: General requirements for safety
Collateral standard: Safety requirements for medical electrical systems
(IEC 60601-1-1:2000)

Appareils électromédicaux
Partie 1-1: Règles générales de sécurité -
Norme collatérale: Règles de sécurité
pour systèmes électromédicaux
(CEI 60601-1-1:2000)

Medizinische elektrische Geräte
Teil 1-1: Allgemeine Festlegungen
für die Sicherheit -
Ergänzungsnorm: Festlegungen für die
Sicherheit von medizinischen elektrischen
Systemen
(IEC 60601-1-1:2000)

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 60601-1-1:2001 E

Foreword

The text of document 62A/312/FDIS, future edition 2 of IEC 60601-1-1, 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 60601-1-1 on 2000-12-01.

This European Standard supersedes EN 60601-1-1:1993 + A1:1996.

The following dates were 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) 2001-10-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-12-01

This European Standard is a Collateral Standard to EN 60601-1:1990, hereinafter referred to as the General Standard, and is the first of a series of Collateral Standards amplifying the General Standard.

In the 60601 series of publications, Collateral Standards specify general requirements for safety applicable to
– a group of MEDICAL ELECTRICAL EQUIPMENT (for example, radiological equipment);
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (for example, 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.

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 roman type;
– *test specifications: 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 (*) at 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 for information only.
In this standard, annexes EEE and ZA are normative and annexes AAA, BBB, FFF and ZB are informative.
Annexes ZA and ZB replace annexes CCC and DDD of IEC 60601-1-1:2000.

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Endorsement notice

The text of the International Standard IEC 60601-1-1:2000 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding 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 (including amendments).

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 60083	1997	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60884-1	1994	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	-	-
A1	1994		-	-
A2	1995		-	-
IEC 60989	1991	Separating transformers, autotransformers, variable transformers and reactors	-	-

Annex ZB
(informative)

Bibliography

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	1998	Audio, video and similar electronic apparatus - Safety requirements	EN 60065	1998
IEC 60335-1 (mod)	1991	Safety of household and similar electrical appliances Part 1: General requirements	EN 60335-1 + corr. January	1994 1995
A1 (mod)	1994		A1	1996
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	1999		A1	1999
IEC 60825-1	1993	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February	1994 1995
A1	1997		-	-
IEC 60950 (mod) + corr. January	1999 2000	Safety of information technology equipment	EN 60950	2000
IEC 61010-1 (mod)	1990	Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements		
+ A1 (mod)	1992		EN 61010-1[1)]	1993
A2	1995		A2[1)]	1995
ISO 7767	1997	Oxygen monitors for monitoring patient breathing mixtures - Safety requirements	-	-
ISO 8185	1997	Humidifiers for medical use - General requirements for humidification systems	EN ISO 8185	1997
ISO 8359	1996	Oxygen concentrators for medical use Safety requirements	-	-
ISO 9918	1993	Capnometers for use with humans - Requirements	-	-
ISO 10079-1	1991	Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements	EN ISO 10079-1	1996

[1)] EN 61010-1:1993 + A2:1995 are superseded by EN 61010-1:2001, which is based on IEC 61010-1:2001.

INTERNATIONAL STANDARD

IEC 60601-1-1

Second edition
2000-12

Medical electrical equipment –

Part 1-1:
General requirements for safety –
Collateral standard: Safety requirements for medical electrical systems

*This **English-language** version is derived from the original **bilingual** publication by leaving out all French-language pages. Missing page numbers correspond to the French-language pages.*

Reference number
IEC 60601-1-1:2000(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site (www.iec.ch)**

- **Catalogue of IEC publications**

  The on-line catalogue on the IEC web site (www.iec.ch/searchpub) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

  This summary of recently issued publications (www.iec.ch/online_news/ justpub) is also available by email. Please contact the Customer Service Centre (see below) for further information.

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International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE U

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a world-wide organisation for standardisation comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardisation 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 organisations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organisation for Standardisation (ISO) in accordance with conditions determined by agreement between the two organisations.
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 specifications, 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.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1-1 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 second edition of 60601-1-1 cancels and replaces the first edition published in 1992 and its amendment 1(1995) and constitutes a technical revision.

This second edition is a Collateral Standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety,* hereinafter referred to as the General Standard, and is the first of a series of Collateral Standards amplifying the General Standard.

The text of this Collateral Standard is based on the following documents:

FDIS	Report on voting
62A/312/FDIS	62A/318/RVD

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

In the 60601 series of publications, Collateral Standards specify general requirements for safety applicable to

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Annexes AAA, BBB, DDD and FFF are for information only.

Annexes CCC and EEE form an integral part of this Collateral Standard.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

– reconfirmed;
– withdrawn;
– replaced by a revised edition, or
– amended.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems

SECTION ONE — GENERAL

1 Scope and object

*1.201 Scope

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.201. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

2 Terminology and definitions

In this Collateral Standard, terms printed in small capitals are used in accordance with their definitions in IEC 60601-1.

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
MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM)
combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and inter-connected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET

NOTE Equipment, when mentioned in connection with a SYSTEM, should be taken to include EQUIPMENT. (See also examples given in annexes BBB and FFF.)

***2.202**
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between PATIENT and parts of the SYSTEM or between PATIENT and other persons touching parts of the SYSTEM (see figure 201)

***2.203**
SEPARATION DEVICE
a component or arrangement of components with input parts and output parts that, for safety reasons, prevent a transfer of unwanted voltage or current between parts of a SYSTEM

***2.204**
MULTIPLE PORTABLE SOCKET-OUTLET
a combination of two or more socket-outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to another while connected to the supply

NOTE A MULTIPLE PORTABLE SOCKET-OUTLET may be a separate item or an integral part of medical or non-medical equipment