Elektrilised meditsiiniseadmed. Osa 1: Üldised ohutusnõuded 4. kollateraalstandard: Programmeeritavad elektrilised meditsiinisüsteemid

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-1-4:2000 sisaldab Euroopa standardi EN 60601-1-4:1996 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-4:2000 consists of the English text of the European standard EN 60601-1-4:1996.
Standard on kinnitatud Eesti Standardikeskuse 16.03.2000 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 16.03.2000 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 30.09.1996.	Date of Availability of the European standard text 30.09.1996.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.01, 35.240.80

Võtmesõnad: elektrilised meditsiiniseadmed, ohutus, programmeeritavad elektrilised meditsiinisüsteemid, riskianalüüs

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-4

September 1996

ICS 11.040.00

English version

Medical electrical equipment
Part 1: General requirements for safety
4. Collateral standard: Programmable electrical medical systems
(IEC 601-1-4:1996)

Appareils électromédicaux
Partie 1: Règles générales de sécurité
4. Norme collatérale: Systèmes électromédicaux programmables
(CEI 601-1-4:1996)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
4. Ergänzungsnorm: Programmierbare, elektrische, medizinische Systeme
(IEC 601-1-4:1996)

This European Standard was approved by CENELEC on 1996-07-02. 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

Ref. No. EN 60601-1-4:1996 E

Foreword

The text of document 62/83/FDIS, future edition 1 of IEC 601-1-4, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-4 on 1996-07-02.

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) 1997-04-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-04-01

This European Standard constitutes a Collateral Standard to EN 60601-1: Medical electrical equipment - Part 1: General requirements for safety, hereinafter refferred 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.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AAA and ZA are normative and annexes BBB, CCC, DDD, EEE and FFF are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-1-4:1996 was approved by CENELEC as a European Standard without any modification.

In the official version, for annex FFF, Bibliography, the following notes have to be added for the standards indicated:

IEC 812	NOTE: Harmonized as HD 485 S1:1987 (not modified).
IEC 1025	NOTE: Harmonized as HD 617 S1:1992 (not modified).

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 601-1	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	1995		A2 A13	1995 1996
IEC 601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 788	1984	Medical radiology - Terminology	HD 501 S1	1988
ISO 9000-3	1991	Quality management and quality assurance standards Part 3: Guidelines for the application of ISO 9001 to the developement, supply and maintenance of software	EN 29000-3	1993
ISO 9001	1994	Quality systems - Model for quality assurance in design development, production, installation and servicing	EN ISO 9001	1994

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-4

Edition 1.1

2000-04

Edition 1:1996 consolidée par l'amendement 1:1999
Edition 1:1996 consolidated with amendment 1:1999

Appareils électromédicaux –

Partie 1-4:
Règles générales de sécurité –
Norme Collatérale:
Systèmes électromédicaux programmables

Medical electrical equipment –

Part 1-4:
General requirements for safety –
Collateral Standard:
Programmable electrical medical systems

Numéro de référence
Reference number
CEI/IEC 60601-1-4:1996+A1:1999

Numéros des publications

Depuis le 1er janvier 1997, les publications de la CEI sont numérotées à partir de 60000.

Publications consolidées

Les versions consolidées de certaines publications de la CEI incorporant les amendements sont disponibles. Par exemple, les numéros d'édition 1.0, 1.1 et 1.2 indiquent respectivement la publication de base, la publication de base incorporant l'amendement 1, et la publication de base incorporant les amendements 1 et 2.

Validité de la présente publication

Le contenu technique des publications de la CEI est constamment revu par la CEI afin qu'il reflète l'état actuel de la technique.

Des renseignements relatifs à la date de reconfirmation de la publication sont disponibles dans le Catalogue de la CEI.

Les renseignements relatifs à des questions à l'étude et des travaux en cours entrepris par le comité technique qui a établi cette publication, ainsi que la liste des publications établies, se trouvent dans les documents ci-dessous:

- **«Site web» de la CEI***
- **Catalogue des publications de la CEI**
  Publié annuellement et mis à jour régulièrement
  (Catalogue en ligne)*
- **Bulletin de la CEI**
  Disponible à la fois au «site web» de la CEI* et comme périodique imprimé

Terminologie, symboles graphiques et littéraux

En ce qui concerne la terminologie générale, le lecteur se reportera à la CEI 60050: *Vocabulaire Electrotechnique International* (VEI).

Pour les symboles graphiques, les symboles littéraux et les signes d'usage général approuvés par la CEI, le lecteur consultera la CEI 60027: *Symboles littéraux à utiliser en électrotechnique,* la CEI 60417: S*ymboles graphiques utilisables sur le matériel. Index, relevé et compilation des feuilles individuelles,* et la CEI 60617: *Symboles graphiques pour schémas.*

* Voir adresse «site web» sur la page de titre.

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. 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.

Validity of this publication

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 the date of the reconfirmation of the publication is available in the IEC catalogue.

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 to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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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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