SLOVENSKI STANDARD
SIST EN 60601-1-4:1998

01-september-1998

Medicinska električna oprema - 1. del: Splošne varnostne zahteve - 4. spremljevalni standard: Programirljivi električni medicinski sistemi (IEC 60601-1-4:1996)

Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996)

Medizinische elektrische Geräte - Teil 1-4: Allgemeine Festlegungen für die Sicherheit - Ergänzungsnorm: Programmierbare elektrische medizinische Systeme (IEC 60601-1-4:1996)

Appareils électromédicaux - Partie 1-4: Règles générales de sécurité - Norme collatérale: Systèmes électromédicaux programmables (CEI 60601-1-4:1996)

Ta slovenski standard je istoveten z: EN 60601-1-4:1996

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN 60601-1-4:1998 **en**

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

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1996-05

Appareils électromédicaux –

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

Medical electrical equipment

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

Bureau Central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève, Suisse

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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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 co-operation 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, express as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are 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.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 601-1-4 has been prepared by 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).

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

FDIS	Report on voting
62/83/FDIS	62/87/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.

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.

Annex AAA forms an integral part of this Collateral Standard.

Annexes BBB, CCC, DDD, EEE and FFF are for information only.

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

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, general statements, exceptions and references: smaller type;
- *test specifications and headings of subclauses: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF IEC 601-1-1 OR OF THIS COLLATERAL STANDARD OR IN IEC 788: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

INTRODUCTION

Computers are increasingly used in MEDICAL ELECTRICAL EQUIPMENT, often in critical-safety roles. The use of computing technologies in MEDICAL ELECTRICAL EQUIPMENT introduces a level of complexity which is exceeded only by the biological systems of the PATIENTS the MEDICAL ELECTRICAL EQUIPMENT is intended to diagnose and/or treat. This complexity means that systematic failures can escape practical accepted limits of testing. Accordingly, this safety standard goes beyond traditional testing and assessment of the finished MEDICAL ELECTRICAL EQUIPMENT and includes requirements for the processes by which the MEDICAL ELECTRICAL EQUIPMENT is developed. Testing of the finished product is not, by itself, adequate to address the SAFETY of complex MEDICAL ELECTRICAL EQUIPMENT.

This standard is a Collateral Standard to the General Standard. It requires that a process be followed and that a record of that process be produced to support the SAFETY of MEDICAL ELECTRICAL EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS. The concepts of RISK management and a DEVELOPMENT LIFE-CYCLE that are the basis of this standard can also be of value in the development of MEDICAL ELECTRICAL EQUIPMENT that does not include a PROGRAMMABLE ELECTRONIC SUBSYSTEM.

The effective application of the standard will require, subject to the task in hand, competency in the following:

– application of the specific MEDICAL ELECTRICAL EQUIPMENT with emphasis on SAFETY considerations;

– MEDICAL ELECTRICAL EQUIPMENT development process;

– methods by which SAFETY INTEGRITY is assured;

– techniques of RISK analysis and RISK control.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for safety –

4. Collateral Standard: Programmable electrical medical systems

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 *Scope*

This Collateral Standard applies to the SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS), hereinafter referred to as PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).

NOTE - Some systems which incorporate software and are used for medical purposes fall outside the scope of this Collateral Standard, e.g. many medical informatics systems. The distinguishing factor/criterion is whether or not the system satisfies the definition of MEDICAL ELECTRICAL EQUIPMENT in 2.2.15 of IEC 601-1 or the definition of MEDICAL ELECTRICAL SYSTEM in 2.203 of IEC 601-1-1.

1.202 *Object*

This Collateral Standard specifies requirements for the process by which a PEMS is designed. This Collateral Standard also serves as the basis of requirements of Particular Standards, including serving as a guide to SAFETY requirements for the purpose of reducing and managing RISK. This Collateral Standard is addressed to:

a) certification bodies;
b) MANUFACTURERS;
c) writers of Particular Standards.

This standard covers:

d) requirement specification;
e) architecture;
f) detailed design and implementation including software development;
g) modification;
h) VERIFICATION and VALIDATION;
j) marking and ACCOMPANYING DOCUMENTS.

Aspects not covered by this standard include:

k) hardware manufacturing;
l) software replication;
m) installation and commissioning;
n) operation and maintenance;
o) decommissioning.

1.203 *Relationship to other standards*

1.203.1 *IEC 601-1*

For MEDICAL ELECTRICAL EQUIPMENT, this Collateral Standard complements IEC 601-1 and its amendments.