

Medical electrical equipment —

Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems

The European Standard EN 60601-1-4:1996 with the incorporation of amendment A1:1999 has the status of a British Standard

ICS 11.040.01

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/64, Safety, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Dental Trade Association
- British Photographic Association
- BSI Testing Services
- College of Radiographers
- Department of Health
- GAMBICA (BEAMA Ltd.)
- Health and Safety Executive
- Institute of Physics and Engineering in Medicine and Biology
- Institution of Electrical Engineers
- Medical Sterile Products Association
- Royal College of Radiologists
- SIRA Limited

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 June 1997

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National foreword

This British Standard has been prepared by Technical Committee CH/64. It is the English language version of EN 60601-1-4:1996 *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems* including amendment A1:1999, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-1-4:1996 including amendment 1:1999, published by the International Electrotechnical Commission (IEC).

The requirements of this Collateral Standard are in addition to those of BS 5724-1:1989 hereinafter called the General Standard.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc.

A rationale for the most important requirements is given in Annex BBB. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form a normative part of the standard.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Additional information. The following print types are used in this standard.

Requirements, with which compliance can be tested, and definitions: in roman type.

Explanations, advice, general statements, exceptions and references: in small roman type.

Test procedures: in *italic* type.

Terms defined in clause 2 of BS 5724-1 or of BS EN 60601-1-1 or of this standard or in BS 6641: SMALL CAPITALS.

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 27 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Sidelining in this document indicates the most recent changes by amendment.

Medical electrical equipment —
Part 1-4: General requirements for safety — Collateral
standard: Programmable electrical medical systems

(includes amendment A1:1999)

(IEC 60601-1-4:1996 + A1:1999)

Appareils électromédicaux —
Partie 1-4: Règles générales de sécurité —
Norme collatérale: Systèmes électromédicaux
programmables
(inclut l'amendement A1:1999)
(CEI 60601-1-4:1996 + A1:1999)

Medizinische elektrische Geräte —
Teil 1-4: Allgemeine Festlegungen für
die Sicherheit — Ergänzungsnorm:
Programmierbare, elektrische, medizinische
Systeme
(enthält Änderung A1:1999)
(IEC 60601-1-4:1996 + A1:1999)

This European Standard was approved by CENELEC on 1996-07-02. Amendment A1 was approved by CENELEC on 1999-12-01. 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

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 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.

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex AAA and Annex ZA are normative and Annex BBB, Annex CCC, Annex DDD, Annex EEE and Annex 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).

Foreword to amendment A1

The text of document 62/114/FDIS, future amendment 1 to IEC 60601-1-4, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-1-4:1996 on 1999-12-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2000-09-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2002-12-01

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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 is assured;
- techniques of RISK analysis and RISK control.

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;
- i) marking and ACCOMPANYING DOCUMENTS.

Aspects not covered by this standard include:

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

When referring to IEC 601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

- “the General Standard” designates IEC 601-1 alone;
- “this Collateral Standard” designates IEC 601-1-4 alone;
- “this Standard” designates the combination of the General Standard and this Collateral Standard.

1.203.2 Particular Standards

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

Amendment No. 1 (1991).

Amendment No. 2 (1995).

IEC 601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety — 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 788:1984, *Medical radiology — Terminology*.

ISO 9000-3:1991, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.