

Medical electrical equipment —

Part 1: General requirements for safety —

Section 1.1 Collateral standard: Safety requirements for medical electrical systems

The European Standard EN 60601-1-1:1993 has the status of a
British Standard

ICS 11.040.01

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/64, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-Care Industries
- Association of X-Ray Equipment Manufacturers (BEAMA Ltd.)
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Dental Trade Association
- British Photographic Association
- British Surgical Trades' Association
- College of Radiographers
- Department of Health
- Electro Medical Trade Association Limited
- Gambica (BEAMA Ltd.)
- Health and Safety Executive
- Institute of Hospital Engineering
- Institute of Physical Sciences in Medicine (IPSM)
- Institution of Electrical Engineers
- Medical Sterile Products Association
- Ministry of Defence
- Royal College of Radiologists
- Scottish Health Services
- Sira Limited

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National foreword

This British Standard has been prepared by Technical Committee CH/64 (formerly HCC/64) and is the English language version of EN 60601-1-1:1993 *Medical electrical equipment — Part 1. General requirements for safety — Section 1.1 Collateral standard: Safety requirements for medical electrical systems* and its amendment A1, published by the European Committee for Electrotechnical Standardization (CENELEC). It is based on IEC 601-1-1:1992 including its amendment 1, published by the International Electrotechnical Commission (IEC). This Collateral Standard amends BS 5724-1:1989 hereinafter called the General Standard. The requirements of this Collateral Standard are in addition to those of 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 AAA. 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.

In 1993 the European Committee for Electrotechnical Standardization (CENELEC) accepted IEC 601-1-1:1992 as European Standard EN 60601-1-1:1993. As a consequence of implementing the European Standard this British Standard is renumbered as BS EN 60601-1-1 and any reference to BS 5724-1.1 should be read as a reference to BS EN 60601-1-1.

Cross-references

International standard	Corresponding British Standard
	BS 5724 <i>Medical electrical equipment</i>
ISO 7767:1988	Section 2.27:1989 <i>Specification for oxygen analysers for monitoring patient breathing mixtures</i> (Identical)
ISO 8185:1988	Section 2.24:1989 <i>Specification for humidifiers</i> (Identical)
ISO 8359:1988	Section 2.23:1989 <i>Specification for oxygen concentrators</i> (Identical)
IEC 335	BS 3456 <i>Specification for safety of household and similar electrical applications</i> (Most Sections technically equivalent)
IEC 348:1978	BS 4743:1979 <i>Specification for safety requirements for electronic measuring apparatus</i> (Identical)
IEC 414:1973	BS 5458:1977 <i>Specification for safety requirements for indicating and recording electrical measuring instruments and their accessories</i> (Identical)
	BS 5724 <i>Medical electrical equipment</i>
IEC 601-1:1988	Part 1:1989 <i>General requirements for safety</i> (Identical)
IEC 601-2	Part 2 <i>Particular requirements for safety</i> (Most Sections identical)

The Technical Committee has reviewed the provisions of IEC 50:1990, IEC 820:1996 and IEC 1010-1:1990 to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

Related standards to IEC 65:1985 and IEC 950:1986 are BS 415:1990 and BS 7002:1989, respectively.

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 to iv, the EN title page, pages 2 to 20, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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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

(includes amendment A1:1996)
(IEC 601-1-1:1992 + A1:1995)

Appareils électromédicaux
Première partie: Règles générales de sécurité
1. Norme collatérale. Règles de sécurité pour
systèmes électromédicaux
(inclut l'amendement A1:1996)
(CEI 601-1-1:1992 + A1:1995)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die
Sicherheit
1. Ergänzungsnorm: Sicherheitsanforderungen
an Medizinische elektrische Systeme
(enthält Änderung A1:1996)
(IEC 601-1-1:1992 + A1:1995)

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, Annex AAA, Annex BBB, and Annex ZB are informative and Annex ZA is normative.

Editorial modification:

Replace Annex CCC and Annex DDD by Annex ZA and Annex ZB.

Foreword to amendment A1

The text of document 62A/184/DIS, future amendment 1 to IEC 601-1-1:1992, 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 amendment A1 to EN 60601-1-1:1993 on 1995-11-28.

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) 1996-09-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-09-01

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given for information only. In this standard, Annex EEE and Annex ZA are normative and Annex FFF is informative. Annex ZA has been added by CENELEC.

Section 1. General

1 Scope and object

1.201 *Scope

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.203. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

NOTE 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

combination of either more than one item of MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL EQUIPMENT and other non-medical electrical equipment having a specified function and inter-connection by:

- COUPLING, and/or
- a MULTIPLE PORTABLE SOCKET-OUTLET.

NOTE The SYSTEM includes those accessories which are needed for operating the SYSTEM and are to be specified by the manufacturer.

(See also examples given in Annex BBB and Annex FFF.)

2.204

*PATIENT ENVIRONMENT

any volume in which intentional or unintentional contact between PATIENT and parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur (see for illustration Figure 201)

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

2.206

*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

3 General requirements

3.201 General requirements for the SYSTEM

A SYSTEM after installation or subsequent modification shall not cause a SAFETY HAZARD for the PATIENT, the OPERATOR or surroundings.

A SYSTEM as a whole shall provide:

- within the PATIENT ENVIRONMENT the same level of safety as MEDICAL ELECTRICAL EQUIPMENT complying with IEC 601-1, and
- outside the PATIENT ENVIRONMENT the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

Compliance is considered to exist if the requirements of subclauses 3.201.1, 3.201.2 and 3.201.3 are met.

3.201.1 MEDICAL ELECTRICAL EQUIPMENT shall comply with the general safety requirements according to IEC 601-1 and its relevant particular standards (see current IEC catalogue).

Compliance is checked by inspection of appropriate documents or certificates.

3.201.2 *Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant for the equipment in question.

See also Annex DDD: Bibliography.

Equipment of class 0 shall not be used in a SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

3.201.3 *COUPLING of equipment in a SYSTEM shall not result in a safety level for the PATIENT that is inferior to the level given in IEC 601-1.

3.201.4 A SYSTEM using equipment, components or forms of construction different from those detailed in relevant standards as mentioned in subclauses 3.201.1 and 3.201.2 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.