

Medical electrical equipment —

Part 1: General requirements for safety —

Section 1.2 Collateral standard: Electromagnetic compatibility — Requirements and tests

The European Standard EN 60601-1-2:1993 has the status of a
British Standard

ICS 11.040.01; 33.100

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 August 1993

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Amendments issued since publication

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is the English language version of EN 60601-1-2:1993 *Medical electrical equipment — Part 1: General requirements for safety* 2. *Collateral Standard: Electromagnetic compatibility — Requirements and tests*, incorporating Corrigendum December 1997 published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-1-2:1993 published by the International Electrotechnical Commission (IEC).

The Corrigendum of December 1997 incorporates a change to the date of withdrawal of national standards in the EN foreword and the deletion of the fourth paragraph.

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 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 14, 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.

Descriptors: Electromedical equipment, safety, electromagnetic compatibility

English version

Medical electrical equipment
Part 1: General requirements for safety
2. Collateral Standard: Electromagnetic compatibility —
Requirements and tests

(IEC 601-1-2:1993)

Appareils électromédicaux
Première partie: Règles générales de
sécurité
2. Norme Collatérale: Compatibilité
électromagnétique —
Prescriptions et essais
(CEI 601-1-2:1993)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die
Sicherheit
2. Ergänzungs-Norm: Elektromagnetische
Verträglichkeit —
Anforderungen und Prüfungen
(IEC 601-1-2:1993)

This European Standard was approved by CENELEC on 1992-09-15. 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

A draft European Standard concerning the electromagnetic compatibility of medical electrical equipment was submitted to the Unique Acceptance Procedure (UAP) as prEN 50097 in December 1991. The 73rd Technical Board of CENELEC approved the draft on 1992-09-15, but decided that the standard would be issued as EN 60601-1-2 (endorsement of IEC 601-1-2, yet to be published). The following dates were fixed:

- latest date of publication
of an identical national
standard (dop) 1993-11-30
- latest date of withdrawal
of conflicting national
standards (dow) 1997-12-31

EN 60601-1-2 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.

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 type;
- test specifications and headings of subclauses: in italic type;
- terms defined in clause 2 of the General Standard 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 (*) in 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 only for information. In this standard, Annex AAA is informative and Annex ZAA is normative. Annex ZAA has been added by CENELEC.

An index reproduces in alphabetic order all the terms defined in clause 2, Terminology and definitions.

Editorial note. Annex BBB is replaced by Annex ZAA.