

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.128 Specification for X-ray source assemblies and X-ray tube assemblies for medical diagnosis

The European Standard EN 60601-2-28:1993 has the status of a
British Standard

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 September 1993

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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 60601-2-28:1993 *Medical electrical equipment — Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-28:1993 published by the International Electrotechnical Commission (IEC).

As in the General Standard (BS 5724-1:1989), 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 101. The additional annex is lettered AA and additional items aa), bb), etc. The changes from the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

“Addition” means that the text of this standard is additional to the requirements of the General Standard.

Terminology and conventions. The text of the International Standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards. In particular the following print types are used:

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 the General Standard: in SMALL CAPITALS.

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 12, 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: Electromedical equipment, X-ray source assemblies, X-ray, diagnosis, safety requirements, equipment specifications, equipment protection, test

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of X-ray
source assemblies and X-ray tube assemblies for medical
diagnosis

(IEC 601-2-28:1993)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
pour les ensembles radiogènes à
rayonnement X et les gaines équipées
pour diagnostic médical
(CEI 601-2-28:1993)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Röntgenstrahler einschließlich
Blendensystem für medizinische Diagnostik
(IEC 601-2-28:1993)

This European Standard was approved by CENELEC on 1993-03-09. 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

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Foreword

The text of document 62B(CO)103, as prepared by sub-committee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in July 1992.

The reference document was approved by CENELEC as EN 60601-2-28 on 9 March 1993.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1994-03-01
- latest date of withdrawal of conflicting national standards (dow) 1994-03-01

For products which have complied with the relevant national standard before 1994-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1993-03-01.

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given only for information. In this standard, Annex AA is informative and Annex ZA is normative.

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