

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.29 Specification for radiotherapy simulators

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/81, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers
- National Radiological Protection Board
- Royal College of Radiologists

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 October 1993

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The following BSI references relate to the work on this standard:
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National foreword

This Section of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC 601-2-29:1993 *Medical electrical equipment — Part 2: Particular requirements for the safety of radiotherapy simulators*, published by the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724-1:1989 hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over 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 101; additional appendices are lettered AA, BB, etc., and additional items are lettered 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.

In 1995, the European Committee for Electrotechnical Standardization (CENELEC) approved the adoption of IEC 601-2-29:1993 as European Standard EN 60601-2-29:1995

Cross-references

International standard	Corresponding British Standard
	BS 5724 <i>Medical electrical equipment</i>
IEC 601-1:1988	Part 1:1989 <i>General requirements for safety</i> (Identical)
IEC 601-2-1:1981 (including Amendment No. 1:1984)	Section 2.1:1989 <i>Specification for medical electron accelerators in the range 1 MeV to 50 MeV</i> (Technically equivalent)
IEC 601-2-7:1987	Section 2.7:1987 <i>Specification for high-voltage generators of diagnostic X-ray generators</i> (Identical)
IEC 788:1984	BS 6641:1985 <i>Glossary of medical radiology terms</i> (Identical)

IEC 601-1-3 to which reference is made in clause 29 is in course of preparation. When published it will be identified within BS 5724 as Section 1.3: *Safety requirements for protection against ionizing radiation*. However, since preparing this standard, changes have been made to the draft for IEC 601-1-3 such that the numbering of subclauses will not now correspond to this standard. An amendment to this standard will therefore be issued when BS 5724-1.3 is published.

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

requirements, compliance with which can be tested, and definitions: in roman type;

explanations, advice and general statements: in small roman type;

test procedures: in italic type;

terms defined in clause **2** of the General Standard, of the Particular Standard and of BS 5724-2.1 and in BS 6641: in SMALL CAPITALS.

Appendix AA is for information only.

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 16, 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.

ICS 11.040.60

Descriptors: Medical electrical equipment, radiotherapy simulators, diagnostic X-ray equipment, therapeutic radiation beam, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2: Particular requirements for the safety of radiotherapy simulators

(IEC 601-2-29:1993)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
pour les simulateurs de radiothérapie
(CEI 601-2-29:1993)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen
für die Sicherheit von
Strahlentherapiesimulatoren
(IEC 601-2-29:1993)

This European Standard was approved by CENELEC on 1995-05-15. 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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of the International Standard IEC 601-2-29:1993, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the formal vote and was approved by CENELEC as EN 60601-2-29 on 1995-05-15 without any modification.

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) 1996-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-07-01

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

Endorsement notice

The text of the International Standard IEC 601-2-29:1993 was approved by CENELEC as a European Standard without any modification.