

Medical electrical equipment —

Part 2-29: Particular requirements for the safety of radiotherapy simulators

The European Standard EN 60601-2-29:1999 has the status of a
British Standard

ICS 11.040.50

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 June 1999

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Amendments issued since publication

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National foreword

This British Standard is the English language version of EN 60601-2-29:1999. It is identical with IEC 60601-2-29:1999. It supersedes BS EN 60601-2-29:1996 and its amendment A1:1997, which are withdrawn. This particular standard amends and supplements BS EN 60601-1, 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 section 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 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.

“Additional” means that the text of this standard is additional to the requirement of the general standard.

The UK participation in its preparation was entrusted to Technical Committee CH/81, Radiotherapy equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

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.

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 the general standard, or in BS 6641: 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 to iv, the EN title page, pages 2 to 24 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.

English version

Medical electrical equipment
Part 2-29: Particular requirements for the safety of
radiotherapy simulators

(IEC 60601-2-29:1999)

Appareils électromédicaux
Partie 2-29: Règles particulières
de sécurité pour les simulateurs
de radiothérapie
(CEI 60601-2-29:1999)

Medizinische elektrische Geräte
Teil 2-29: Besondere Festlegungen
für die Sicherheit von
Strahlentherapiesimulatoren
(IEC 60601-2-29:1999)

This European Standard was approved by CENELEC on 1999-04-01. 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, Czech Republic, 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 62C/250/FDIS, future edition 2 of IEC 60601-2-29, 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 IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-29 on 1999-04-01.

This European Standard supersedes EN 60601-2-29:1995 and its amendment A1:1996.

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) 2000-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2002-04-01

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

Annexes designated “informative” are given for information only.

In this standard, Annex AA and Annex ZA are normative and Annex BB and Annex ZB are informative.

Annex ZA and Annex ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-29:1999 was approved by CENELEC as a European Standard without any modification.

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Introduction

The use of RADIOTHERAPY SIMULATORS may expose PATIENTS to danger if the EQUIPMENT design does not satisfy standards of electrical, mechanical and IONIZING RADIATION safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the IONIZING RADIATION adequately and/or if there are inadequacies in the design of the SIMULATOR room.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY SIMULATORS; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT; it places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists, for example a component failure, and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.

Section 1. General

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

1.1 Scope

Addition:

This Particular Standard applies to RADIOTHERAPY SIMULATORS:

- that use diagnostic X-RAY EQUIPMENT to simulate physically a RADIOTHERAPY RADIATION BEAM, so that the TREATMENT VOLUME to be subjected to IRRADIATION during RADIOTHERAPY can be localized, and the position and size of the RADIOTHERAPY RADIATION FIELD can be confirmed;
- intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY, and not for any other purpose such as general diagnostic examinations;
- used within the environmental and electrical supply conditions SPECIFIED in the technical description;
- comprising the following parts:
 - a system for producing an X-RAY BEAM, which simulates the geometry of the RADIOTHERAPY RADIATION BEAM;
 - a system for producing images of the transmitted X-RAY BEAM, for example, either by RADIOGRAPHY or RADIOSCOPY;
 - an assembly to control the size and position of the RADIATION BEAM and to delineate the intended treatment area;
 - a mechanical structure that physically simulates the geometry and movements of the RADIOTHERAPY EQUIPMENT and supports the imaging system;
 - a PATIENT SUPPORT system.

1.2 Object

Addition:

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced mechanical and electrical safety of RADIOTHERAPY SIMULATORS; it identifies geometrical parameters that are critical for the accurate simulation of a RADIOTHERAPY treatment.

1.3 Particular Standards

Additional subclauses:

1.3.101 Relationship to the General Standard

NOTE See Appendix L for normative references.

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and corrigendum (1995) — hereinafter referred to as the General Standard — which it amends and supplements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard apply.

As in the General Standard, the requirements are followed by compliance tests. The term “this standard” is used throughout to refer to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard [but see **29.1 b)**]. The changes to the text of the General Standard, or its Collateral Standards, are SPECIFIED by the use of the following words:

“Replacement” means that the clause or subclause of the General/Collateral Standard is replaced completely by the text of this Particular Standard.

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

“Amendment” means that the clause or subclause of the General/Collateral Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

1.3.102 Relationship to other standards and documents

a) IEC 60601-2-7

This standard applies to HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS used with RADIOTHERAPY SIMULATORS [see **29.1 a)**].

b) IEC 61217

This standard gives guidance on the designation of EQUIPMENT movements, the marking of scales, their zero positions, and the direction of movement with increasing value [see **6.3.101 a)**].

1.5 Collateral Standards

Additional subclauses:

1.5.101 IEC 60601-1-1

This Collateral Standard does not apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of this Collateral Standard, together with the additions given in clause **36**, apply to RADIOTHERAPY SIMULATORS and their integral INFORMATION TECHNOLOGY EQUIPMENT (ITE).

NOTE IEC 60601-1-2 applies to EQUIPMENT and ITE used in medical applications, RADIOTHERAPY SIMULATORS and their integral ITE are not excluded from compliance with IEC 60601-1-2; at the date of publication of this standard it has not been possible to determine whether further amendments to its requirements or tests will be necessary.

1.5.103 IEC 60601-1-3

All clauses and subclauses of this Collateral Standard apply, except as amended in clause **29**.

1.5.104 IEC 60601-1-4

All clauses and subclauses of this Collateral Standard apply [see **52.1 b)**].

2 Terminology and definitions

Addition:

NOTE Annex AA lists all defined terms alphabetically with their source reference.

Definitions of additional terms used in this Particular Standard.

2.1.101

DELINEATED RADIATION BEAM

that part of the RADIATION BEAM bordered by the shadow cast by the DELINEATORS