

Medical electrical equipment —

Part 3: Particular requirements for performance —

Section 3.129 Methods of declaring functional performance characteristics of radiotherapy simulators

The European Standard EN 61168:1994 has the status of a
British Standard

UDC 615.849:616-073.75:621.3:620.1

Cooperating organizations

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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 June 1994

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The following BSI references relate to the work on this standard:
Committee reference HCC 81
Draft for comment 92/52057 DC

ISBN 0 580 23394 4

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is the English language version of EN 61168:1994 *Radiotherapy simulators — Functional performance characteristics*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 1168:1993 *Radiotherapy simulators — Functional performance characteristics*, published by the International Electrotechnical Commission (IEC). It is simultaneously published as BS 5724 *Medical electrical equipment* Section 3.129:1994 *Methods of declaring functional performance characteristics of radiotherapy simulators*. This Particular Standard thus forms part of the group of standards directed specifically at electrical equipment used in health care.

This Particular Standard details procedures by which the functional performance characteristics of radiotherapy simulators which use diagnostic X-ray equipment may be determined and specified. Guidance in the application of this standard is given in BS 5724-3.129:Supplement 1, which is published simultaneously. Annex A to this Particular Standard is for information only.

Attention is drawn to BS 5724-2.129 which specifies the particular requirements for the safety of radiotherapy simulators.

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.

Terms defined in clause 2 of BS 5724-1, in clause 2 of BS 5724-2.129, in 3.2 of this Particular Standard and in BS 6641: SMALL CAPITALS.

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

Textual errors. When adopting the text of the International Standard, the textual errors listed below were discovered. They have been marked in the text and have been reported to IEC in a proposal to amend the text of the International Standard.

In Table 9, after “ISOCENTRE” in the last column heading, should be inserted:

“when the table top rotation is set to 0°”.

The sentence immediately after Table 9 should be replaced by the following:

“Half the difference of the instrument readings is equal to the angle of tilt of the table top rotation axis (5) relative to the ISOCENTRIC rotation axis (6) in the direction of the line joining these two axes. Half the sum of the instrument readings is equal to the angle of tilt of the table top rotation axis (5) in the direction perpendicular to the line joining axes (5) and (6).”

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 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.

UDC 615.849:616-073.75:621.3:620.1

Descriptors: Electromedical equipment, simulator, radiotherapy, functional performance values

English version

Radiotherapy simulators — Functional performance characteristics

(IEC 1168:1993)

Simulateurs de radiothérapie
Caractéristiques fonctionnelles
(CEI 1168:1993)

Strahlentherapie-Simulatoren
Apparative Funktionsmerkmale
(IEC 1168:1993)

This European Standard was approved by CENELEC on 1992-12-09. 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.

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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 document 62C(CO)64, as prepared by Subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in February 1992.

The reference document was approved by CENELEC as EN 61168 on 9 December 1992.

NOTE Switzerland and Finland have no obligation to implement this European Standard.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1994-12-01
- latest date of withdrawal of conflicting national standards (dow) 1994-12-01

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

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Introduction

This International Standard specifies methods of disclosure of and describes methods of test for functional performance of SIMULATORS intended for RADIOTHERAPY. It permits a direct comparison between the performance data of EQUIPMENT of different manufacture.

Since this standard does not contain safety requirements it has not been numbered in the IEC 601 Publication series. It describes aspects of functional performance of RADIOTHERAPY SIMULATORS and the way in which they should be presented. It also includes suggested test methods and conditions suitable for TYPE TESTS. Alternative methods may be equally appropriate, but the specified functional performance characteristics of the RADIOTHERAPY SIMULATORS shall be related to these test methods and conditions.

Tests specified in this standard are not necessarily appropriate for ensuring that any individual RADIOTHERAPY SIMULATOR conforms with the declared functional performance during the course of its working lifetime.

Guidance on the values which may be expected are given in the technical report IEC 1170:1993, *Radiotherapy simulators — Guidelines for functional performance characteristics*.

1 Scope and object

1.1 Scope

This International Standard applies to RADIOTHERAPY SIMULATORS which use diagnostic X-RAY EQUIPMENT to geometrically simulate a RADIOTHERAPY RADIATION BEAM so that the TREATMENT VOLUME to be irradiated during RADIOTHERAPY can be localized and the position and size of the therapeutic RADIATION FIELD can be confirmed.

This standard applies to RADIOTHERAPY SIMULATORS using HIGH VOLTAGE GENERATORS operating at a voltage not exceeding 400 kV complying with IEC 601-2-7.

This standard applies to RADIOTHERAPY SIMULATORS intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY and not for any other purposes such as general diagnostic purposes.

The requirements in this standard are based on the assumption that the RADIOTHERAPY SIMULATOR consists of:

- a) a system for producing a beam of X-RADIATION not exceeding 400 kV which simulates the geometry of the RADIOTHERAPY RADIATION BEAM;

- b) a system for producing images of the transmitted X-RAY BEAM, either by RADIOGRAPHY or by RADIOSCOPY;

- c) an assembly which controls the size of the RADIATION BEAM and which delineates the intended treatment area;

- d) a mechanical structure that physically simulates the geometry and motions of a RADIOTHERAPY EQUIPMENT, and which supports an imaging system;

- e) a PATIENT SUPPORT system.

This standard applies to EQUIPMENT intended for use under the supervision of a QUALIFIED PERSON.

Except where otherwise stated this standard assumes that the RADIOTHERAPY SIMULATOR has an ISOCENTRIC GANTRY with no pitch or roll movement of the RADIATION HEAD.

This standard specifies TYPE TESTS to be performed by the MANUFACTURER at the design and construction stages of a RADIOTHERAPY SIMULATOR but does not specify SITE TESTS to be performed after installation at the USER'S site. The accompanying technical report IEC 1170, however, does suggest that many of the test procedures are appropriate for SITE TESTS.

During the course of any test procedure only those adjustments of the RADIOTHERAPY SIMULATOR are permissible that can be carried out using controls normally accessible to the OPERATOR and which are regarded as forming part of the normal operation of the RADIOTHERAPY SIMULATOR.

1.2 Object

The object of this standard is to:

- a) identify geometric parameters which are critical for the accurate simulation of a RADIOTHERAPY treatment;

- b) recommend methods of measuring these parameters.

It is recognized that inaccuracies in the test methods must be allowed for when assessing performance. However, it is not felt advisable to combine the errors into an overall performance tolerance but keep them separate in the expectation that more accurate test methods will be evolved.

It is not intended that this standard should in any way inhibit the future development of new designs of EQUIPMENT which may have operating modes and parameters different from those described herein.

1.3 Environmental conditions

1.3.1 General

Except where other allowable environmental conditions are stated in the ACCOMPANYING DOCUMENTS this standard applies to EQUIPMENT installed, used or kept in locations where the following environmental conditions prevail:

- a) the ambient temperature falls within the range 10 °C to 40 °C;
- b) the relative humidity falls within the range 30 % to 75 %;
- c) the atmospheric pressure falls within the range 70 kPa to 110 kPa (700 mbar to 1 100 mbar).

1.3.2 Transport and storage

The allowable environmental conditions for transport and storage shall be stated in the ACCOMPANYING DOCUMENTS.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards. IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

Amendment 1, 1991

IEC 601-2-7:1987, *Medical electrical equipment — Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators*.

IEC 601-2-29:1993, *Medical electrical equipment — Part 2: Particular requirements for the safety of radiotherapy simulators*.

IEC 788:1984, *Medical radiology — Terminology*.

IEC 1170:1993, *Radiotherapy simulators — Guidelines for functional performance characteristics*.

3 Terminology and definitions

3.1 Terminology

In this standard terms printed in CAPITALS are used as defined in IEC 788.

Other additional terms are listed in Appendix AA of IEC 601-2-29 and in 3.2.

3.2 Definitions

For the purpose of this International Standard, the following additional definition applies:

DELINEATED LIGHT FIELD

for RADIOTHERAPY SIMULATORS, the area of the LIGHT FIELD bounded by the DELINEATOR shadow and in a plane perpendicular to the X-RAY BEAM AXIS

4 Standardized test conditions

In determining performance characteristics in accordance with this standard, standardized test conditions according to 4.1 to 4.3 shall prevail, unless otherwise stated. The specified axes are given in Figure 1. Unless otherwise stated all measurements shall be taken at either 80 cm or 100 cm source axis distance (SAD).

4.1 Angle and linear settings

The following angles and linear settings are at zero unless otherwise stated (see Figure 1: RADIOTHERAPY SIMULATOR movements):

- GANTRY rotation, Axis (1)
- roll of RADIATION HEAD, Axis (2)
- pitch of RADIATION HEAD, Axis (3)
- rotation of the DELINEATOR, Axis (4)
- ISOCENTRIC rotation of the PATIENT SUPPORT, Axis (5)
- rotation of the table top, Axis (6)
- pitch of the table top, Axis (7)
- roll of the table top, Axis (8)
- height of the table top, Direction (9)
- lateral displacement of the table top, Direction (10)
- longitudinal displacement of the table top, Direction (11).

If in this standard the test conditions call for measurements to be made at angles of rotation of the GANTRY, Axis (1), or of the DELINEATOR, Axis (4), of 90° only, it is equally acceptable to use the angle of 270°.

4.2 Positioning of the measuring plane and RADIATION DETECTORS

Measurements are made, unless otherwise required, in the plane normal to the DELINEATED RADIATION BEAM AXIS and containing the ISOCENTRE. Measurements are generally made with RADIOGRAPHIC FILM. For geometric alignment tests other RADIATION DETECTORS with adequate spatial resolution may be used.