SLOVENSKI STANDARD
SIST EN 61168:1995

01-maj-1995

Radiotherapy simulators - Functional performance characteristics (IEC 1168:1993)

Radiotherapy simulators - Functional performance characteristics

Sthrahlentherapie-Simulatoren - Kennmerkmale

Simulateurs de radiothérapie - Caractéristiques fonctionnelles

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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.

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

The text of document 62C(CO)64, as prepared by Sub-Committee 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.

ENDORSEMENT NOTICE

The text of the International Standard IEC 1168:1993 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

NOTE : When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
601-1	1988	Medical electrical equipment - Part 1:	EN 60601-1	1990
A1	1991	General requirements for safety	A1	1993
601-2-7	1987	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	HD 395.2.7 S1	1989
601-2-29	1993	Part 2: Particular requirements for the safety of radiotherapy simulators	-	-
788	1984	Medical radiology - Terminology	HD 501 S1	1988
1170	1993	Radiotherapy simulators - Guidelines for functional performance characteristics	-	-

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Radiotherapy simulators – Functional performance characteristics

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

RADIOTHERAPY SIMULATORS – FUNCTIONAL PERFORMANCE CHARACTERISTICS

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 1168 has been prepared by sub-committee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

DIS	Report on voting
62C(CO)64	62C(CO)72

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Annex A is for information only.

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.*

RADIOTHERAPY SIMULATORS – 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 1100 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*