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Australian/New Zealand Standard

Radiotherapy simulators

Part 1: Functional performance characteristics

[IEC title: Radiotherapy simulators—Functional performance characteristics]

STANDARDS AUSTRALIA ✓

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AS/NZS 4213.1:1994

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee on Medical Diagnostic Imaging Equipment, HT/23, under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 1168:1993 *Radiotherapy simulators—Functional performance characteristics*.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover, inside cover and title page.

For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (c) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		Australian/New Zealand Standard	
IEC		AS	
601	Medical electrical equipment	3200	Approval and test specification— Medical electrical equipment
601-1	Part 1: General requirements for safety, Amendment No. 1, 1991	3200.1	Part 1: General requirements for safety (NZS 6150:1990) Amdt 1 December 1992
601-2-7	Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	—	
601-2-29	Part 2-29: Particular requirements for safety of radiotherapy simulators	—	
788	Medical radiology—Terminology	—	
1170	Radiotherapy simulators—Guidelines for functional performance charac- teristics	4213 4213.2	Radiotherapy simulators Part 2: Guidelines for functional per- formance characteristics

The term ‘informative’ has been used in this Standard to define the application of the Annex to which it applies. An ‘informative’ Annex is only for information and guidance.

CONTENTS

Clause	Page
1 Scope and object	1
2 Normative references	2
3 Terminology and definitions	3
4 Standardized test conditions	3
5 Indication of DELINEATED RADIATION FIELDS	4
6 Indication of DELINEATED RADIATION BEAM AXIS	8
7 ISOCENTRE	11
8 Indication of the distance along the DELINEATED RADIATION BEAM AXIS	14
9 Zero position of rotational scales	16
10 Congruence of opposed DELINEATED RADIATION FIELDS	18
11 Movements of the PATIENT SUPPORT	18
Figure 1 – RADIOTHERAPY SIMULATOR movements	23
Annex	
A Format for presentation of functional performance values	24
Tables	
1 Conditions for testing the numerical field-indicator and the LIGHT FIELD-INDICATOR	5
2 Conditions for testing reproducibility of DELINEATED RADIATION FIELDS	7
3 Conditions for testing the geometry of the DELINEATOR	7
4 Conditions for testing the indication of the DELINEATED RADIATION BEAM AXIS on the ENTRANCE SURFACE	9
5 Conditions for testing the indication of the DELINEATED RADIATION BEAM AXIS on the exit surface	10
6 Conditions for testing the displacement of the DELINEATED RADIATION BEAM AXIS from the TEST DEVICE or reference pointer indicating the ISOCENTRE	13
7 Conditions for testing the vertical movement of the table top	19
8 Conditions for testing the ISOCENTRIC rotation of the PATIENT SUPPORT	20
9 Conditions for testing the parallelism of rotational axes of the PATIENT SUPPORT	21
10 Conditions for testing the PATIENT SUPPORT lateral rigidity	22

AUSTRALIAN/NEW ZEALAND STANDARD

Radiotherapy simulators

Part 1:

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.

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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*

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.

4.3 FOCAL SPOT and LOADING FACTORS

Unless otherwise required the tests shall be made with the small FOCAL SPOT and the MANUFACTURER'S recommended LOADING FACTORS of the X-RAY TUBE.

5 Indication of DELINEATED RADIATION FIELDS

5.1 Numerical field-indicator

The numerical field-indicator shall DISPLAY the dimensions of the DELINEATED RADIATION FIELD at one or several specified source axis distance(s).

5.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum differences between the numerical field indication and the distances along the major axes of the opposing DELINEATED RADIATION FIELD edges at source axis distances specified in table 1.

The maximum differences shall be given in millimetres or shall be expressed as a percentage of the size of the DELINEATED RADIATION FIELD. The maximum difference shall be given in mm for DELINEATED RADIATION FIELDS up to 20 cm × 20 cm and in % for DELINEATED RADIATION FIELDS greater than 20 cm × 20 cm.

The maximum difference(s) shall apply to all DELINEATED RADIATION FIELDS for which the smaller dimension is equal to or greater than 3 cm and for all angular positions of the GANTRY and of the DELINEATOR.

5.1.2 Test

NOTE – The numerical indicators of the DELINEATED RADIATION FIELD refer to the plane normal to the RADIATION BEAM AXIS at a specified source axis distance.

RADIOGRAPHIC FILMS for these tests are placed so that they are centred in the DELINEATED RADIATION FIELD at the axis of rotation of the GANTRY in a plane normal to the DELINEATED RADIATION BEAM AXIS.

For the set of conditions given in table 1 the DELINEATED RADIATION FIELD dimensions shall be determined under the following conditions:

The DELINEATED RADIATION FIELD shall be set using the numerical field-indicators.

The edges of the DELINEATED LIGHT FIELD shall be marked on the RADIOGRAPHIC FILM cover.

Table 1 – Conditions for testing the numerical field-indicator and the LIGHT FIELD-INDICATOR

Angular position of		DELINEATED RADIATION FIELD	SAD*	Distance source to film	Remark
GANTRY	DELINEATOR				
Axis (1)	Axis (4)	cm x cm	cm	cm	
90°	0°	3 x 3 10 x 10 ** 20 x 20 30 x 30 **	100 and 80	SAD	
270°	90°	10 x 10 ** 30 x 30 **	100 and 80		
0°	135°	10 x 10 ** maximum	minimum	SAD	Only for numerical test (5.1.2)
180°	180°	10 x 10 ** maximum	maximum	SAD	
0°	45°	10 x 10 ** maximum	100 and 80	SAD	Only for LIGHT FIELD INDICATOR test (5.2.2)
180°	180°	10 x 10			
0°	0°	maximum			
* SAD = source axis distance ** These symmetrical fields shall be tested also in the asymmetrical mode as follows: One edge of the DELINEATED RADIATION FIELD is set to half the field size of the symmetrical field and the other edge to zero.					

The LIGHT FIELD-INDICATOR may also be included in this test (see 5.2.2).

Before moving the films from the exposure position, pierce the edges close to the corner points of the DELINEATED LIGHT FIELD and its central axis as shown by the central cross with a sharp pin. Other devices (e.g., a radiopaque jig) may be used to define the DELINEATED LIGHT FIELD on the exposed film.

The centre of the DELINEATOR shadow shall be taken as the reference. The maximum difference between the DELINEATED RADIATION FIELD and the DELINEATED LIGHT FIELD should be measured and the DELINEATED RADIATION FIELD dimensions compared with their numerical indication.

5.2 LIGHT FIELD-INDICATOR

The LIGHT FIELD-INDICATOR shall indicate the DELINEATED RADIATION FIELD on the ENTRANCE SURFACE by means of light.

5.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state:

- a) the maximum distance measured along each major axis between any edge of the DELINEATED LIGHT FIELD and the corresponding edge of the DELINEATED RADIATION FIELD at a source axis distance of 100 cm (or nearest, if not available) and at a RADIATION SOURCE to measuring plane distance 1,5 times the value of the source axis distance;
- b) the maximum distance between the centre of the DELINEATED LIGHT FIELD and the DELINEATED RADIATION BEAM AXIS at a source axis distance of 100 cm (or nearest, if not available) and at the RADIATION SOURCE to measuring plane distance 1,5 times the value of the source axis distance.

All tests shall be carried out using both small and large FOCAL SPOTS if available.

The maximum distance for a) shall be given in millimetres for DELINEATED RADIATION FIELD up to 20 cm × 20 cm and shall be expressed as a percentage of its size for DELINEATED RADIATION FIELDS greater than 20 cm × 20 cm.

The maximum distance for b) shall be given in millimetres.

The maximum difference shall apply for:

- all DELINEATED RADIATION FIELDS for which the smaller dimension is equal to or greater than 3 cm;
- all angles of rotation of the GANTRY and of the DELINEATOR;
- both large and small FOCAL SPOTS, if available.

5.2.2 Test

See 5.1.2, which includes the test of the LIGHT FIELD-INDICATOR.

5.3 Reproducibility

NOTE – This may be alternatively checked by the use of either the numerical indicator or the DELINEATED LIGHT FIELD.

5.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum variation in millimetres of the size of the DELINEATED RADIATION FIELD for repeated settings of the same numerical field-indications at 100 cm source axis distance.

5.3.2 Test

For the set of test conditions given in table 2, the test according to 5.1.2 shall be carried out six times approaching the same setting of the numerical field-indicators alternately from larger and smaller indicated values.