

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Medical electron accelerators – Functional performance characteristics

Appareils électromédicaux – Accélérateurs médicaux d'électrons – Caractéristiques fonctionnelles de performance



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – FUNCTIONAL PERFORMANCE CHARACTERISTICS

FOREWORD

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International standard IEC 60976 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989. It constitutes a technical revision.

This second edition includes the addition of performance standards and test methods relating to the following new technologies:

- dynamic beam delivery techniques, such as
 - MOVING BEAM RADIOTHERAPY,
 - INTENSITY-MODULATED RADIATION THERAPY (IMRT),
 - IMAGE-GUIDED RADIOTHERAPY (IGRT) and
 - PROGRAMMABLE WEDGE FIELDS;
- STEREOTACTIC RADIOTHERAPY (SRT) / STEREOTACTIC RADIOSURGERY (SRS);



- use of ELECTRONIC IMAGING DEVICES.

This standard, together with IEC TR 60977, should be read in conjunction with IEC 60601-2-1.

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

FDIS	Report on voting
62C/429/FDIS	62C/433/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and notes: in small roman type;
- *test specifications and headings of sub-clauses: in italic type;*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

Standards containing safety requirements for medical ELECTRON ACCELERATORS have been published by the IEC, details of which will be found in Clause 2.

The present standard specifies methods of testing and methods of disclosure of functional performance of medical ELECTRON ACCELERATORS intended for RADIOTHERAPY. It permits a direct comparison between the performance data of equipment of different MANUFACTURERS.

Since this standard does not contain safety requirements, it has not been numbered in the IEC 60601 publication series. It describes aspects of functional performance of medical ELECTRON ACCELERATORS and the way in which they should be presented. It also includes test methods and conditions suitable for TYPE TESTS. These test methods are suggested test methods and alternative methods may be equally appropriate, but the specified functional performance characteristics of medical ELECTRON ACCELERATORS shall be related to these test methods and conditions. Tests specified in this standard are not necessarily appropriate for ensuring that any individual medical ELECTRON ACCELERATOR conforms to the declared functional performance during the course of its working lifetime. Guidance on the values which may be expected is given in the technical report, IEC 60977.

This International Standard was first published in 1989. With the rapidly increasing use of medical ELECTRON ACCELERATORS equipped with multi-element BEAM LIMITING DEVICES (BLDs), amendments to both this standard and the associated report, IEC 60977, were published in 2000. Amendment 1 was intended mainly to address the basic performance issues associated with the applications of multi-element BLDs to static RADIATION FIELDS. This second edition includes the addition of performance standards and test methods relating to several relatively new technologies introduced within the last few years, including dynamic beam delivery techniques, such as MOVING BEAM RADIOTHERAPY, INTENSITY-MODULATED RADIATION THERAPY (IMRT), IMAGE-GUIDED RADIOTHERAPY (IGRT), and PROGRAMMABLE WEDGE FIELDS (PWF). Also included are STEREOTACTIC RADIOTHERAPY (SRT)/STEREOTACTIC RADIOSURGERY (SRS) and the use of certain ELECTRONIC IMAGING DEVICES.

In recognition of the diversity of equipment produced by MANUFACTURERS in each of these technologies, this second edition has specified performance standards, methods of test, and methods of disclosure of functional performance, that are as basic and generic as possible. MANUFACTURERS may add more detailed information and special tests of performance characteristics to each performance category, in their ACCOMPANYING DOCUMENTS.

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – FUNCTIONAL PERFORMANCE CHARACTERISTICS

1 Scope

This International Standard applies to medical ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

This standard applies to medical ELECTRON ACCELERATORS which deliver a RADIATION BEAM of either X-RADIATION or ELECTRON RADIATION with NOMINAL ENERGIES in the range 1 MeV to 50 MeV at maximum ABSORBED DOSE RATES between $0,001 \text{ Gy s}^{-1}$ and 1 Gy s^{-1} at 1 m from the RADIATION SOURCE and at NORMAL TREATMENT DISTANCES between 50 cm and 200 cm from the RADIATION SOURCE.

The present standard describes measurements and test procedures to be performed by the MANUFACTURER at the design and construction stage of a medical ELECTRON ACCELERATOR but does not specify ACCEPTANCE TESTS to be performed after installation at the purchaser's site. The accompanying report, IEC 60977, however, does suggest that many of the test procedures are appropriate for ACCEPTANCE TESTS.

The measurement conditions described in the present standard differ from those previously in use. This applies particularly to the PHANTOM position for measurements and the measurement of distances from the ISOCENTRE. These new conditions should be substituted for and not be added to previous methods.

This standard specifies test procedures for the determination and disclosure of functional performance characteristics, knowledge of which is deemed necessary for proper application and use of a medical ELECTRON ACCELERATOR and which are to be declared in the ACCOMPANYING DOCUMENTS together with the greatest deviation or variation to be expected under specific conditions in NORMAL USE. A format for presentation of functional performance values is given in Annex A.

It is recognized that inaccuracies in the test methods must be allowed for when assessing performance. However, it was not felt to be advisable to combine the errors into an overall performance tolerance but to 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, provided that such equipment achieves equivalent levels of performance for the TREATMENT OF PATIENTS.

Except where otherwise stated this standard assumes that the medical ELECTRON ACCELERATORS have an ISOCENTRIC GANTRY. Where the equipment is non-isocentric, the description of performance and test methods may need to be suitably adapted.

NOTE A statement of compliance with this standard does not necessarily imply that these tests will be or have been applied as TYPE TESTS or as individual tests.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60580:2000, *Medical electrical equipment – Dose area product meters*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-1:1998, *Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV*
Amendment 1 (2002)

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60977, *Medical electrical equipment – Medical electron accelerators in the range 1 MeV to 50 MeV – Guidelines for functional performance characteristics*

IEC 61217, *Radiotherapy equipment – Coordinates, movements and scales*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60580:2000, IEC 60601-1:2005, IEC 60601-2-1:1998, IEC 60788:2004, IEC 61223-1:1993 and the following apply.

3.1

BASE DEPTH

depth in a PHANTOM of the plane containing the distal point of 90 % of the maximum ABSORBED DOSE on the RADIATION BEAM AXIS

3.2

BEAM LIMITING DEVICE

BLD

<RADIOTHERAPY> structure, fixed or movable, intended to block or collimate IONIZING RADIATION, resulting in shielding the TREATMENT region from unintended X-RADIATION or ELECTRON RADIATION

3.3

DEPTH OF DOSE MAXIMUM

depth in a PHANTOM of the maximum ABSORBED DOSE on the RADIATION BEAM AXIS

3.4

DYNAMIC RANGE

<RADIOTHERAPY> maximum usable signal divided by the minimum usable signal (the root mean square noise)

NOTE The DYNAMIC RANGE is expressed in decibels.

3.5**ELECTRONIC IMAGING DEVICE****EID**

device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

NOTE See also 3.6.

3.6**ELECTRONIC PORTAL IMAGING DEVICE****EPID**

device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed normal to the RADIATION BEAM AXIS, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen, using the medical ELECTRON ACCELERATOR'S RADIATION BEAM as the RADIATION SOURCE

NOTE The primary function of an EPID is in verification of PATIENT set-up, and so replaces the need for port-films for this same purpose.

3.7**GEOMETRICAL FIELD SIZE**

geometrical projection as seen from the centre of the front surface of the RADIATION SOURCE on a plane perpendicular to the axis of the beam of the distal end of the BEAM LIMITING DEVICE

NOTE The field is thus of the same shape as the aperture of the BEAM LIMITING DEVICE. The GEOMETRICAL FIELD SIZE may be defined at any distance from the VIRTUAL SOURCE.

3.8**IMAGE-GUIDED RADIOTHERAPY****IGRT**

RADIOTHERAPY process by which the location of a RADIOTHERAPY BEAM relative to the intended TARGET VOLUME within a PATIENT'S anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of beam to TARGET VOLUME

3.9**INTENSITY-MODULATED RADIATION THERAPY****IMRT**

TREATMENT procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the PATIENT, and beam size; either in a continuous or a discrete manner, and as pre-determined by a TREATMENT plan

NOTE The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned TARGET VOLUME, while minimizing dose to surrounding healthy tissue.

3.10**ISOCENTRIC**

used in presence of an ISOCENTRE

3.11**ISOCENTRIC EQUIPMENT**

equipment for RADIOTHERAPY designed and constructed in such a manner that it has an ISOCENTRE

3.12**ISOCENTRIC TREATMENT**

<RADIOTHERAPY> TREATMENT of a PATIENT in which the position of the TARGET VOLUME is referred to the ISOCENTRE

3.13

NOMINAL ENERGY ENERGY

ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

3.14

NORMAL TREATMENT DISTANCE NTD

<ELECTRON RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane

<X-RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

3.15

PENETRATIVE QUALITY

depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is 80 % of the dose at the DEPTH OF DOSE MAXIMUM, measured on the RADIATION BEAM AXIS in a SPECIFIED RADIATION FIELD and with the surface of the PHANTOM at a SPECIFIED distance

3.16

PRACTICAL RANGE

<ELECTRON RADIATION> depth in a PHANTOM with its surface at the NORMAL TREATMENT DISTANCE, for which on the depth dose chart the extrapolation of the steepest fall-off section of the ABSORBED DOSE distribution along the RADIATION BEAM AXIS intercepts the extrapolated tail of the ABSORBED DOSE distribution

3.17

PRIMARY-SECONDARY DOSE MONITORING SYSTEM

combination of two DOSE MONITORING SYSTEMS in which one is arranged to be the PRIMARY DOSE MONITORING SYSTEM and the other is to be the SECONDARY DOSE MONITORING SYSTEM

3.18

PROGRAMMABLE WEDGE FIELD PWF

generation of a wedge-shaped dose profile, with or without the use of a fixed metal WEDGE FILTER placed in the X-RAY BEAM, where the programmed wedge DOSE profile may be generated by controlling the relationship between the beam intensity and a moveable BEAM LIMITING DEVICE

3.19

QUALITY INDEX

<X-RADIATION> ratio of the ABSORBED DOSE measured at a depth of 20 cm to that measured at a depth of 10 cm

NOTE The detector is at the NORMAL TREATMENT DISTANCE. The measurement is made in a PHANTOM on the RADIATION BEAM AXIS for a RADIATION FIELD of 10 cm × 10 cm.

3.20

RADIATION TYPE

nature of the waves or corpuscles comprising the RADIATION, for example whether the RADIATION is X-RADIATION or ELECTRON RADIATION

3.21

REDUNDANT DOSE MONITORING SYSTEM

combination of two DOSE MONITORING SYSTEMS in which both systems are arranged to be the PRIMARY DOSE MONITORING SYSTEM

3.22**RELATIVE SURFACE DOSE**

ratio of the ABSORBED DOSE on the RADIATION BEAM AXIS at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS both measured in a PHANTOM with its surface at a specified distance

[IEC 60601-2-1:1998, definition 2.1.116, modified]

3.23**SIGNAL-TO-NOISE RATIO**

<RADIOTHERAPY> mean value of the signal divided by the standard deviation, of the signal from the image pixels, for a uniform input fluence

NOTE The SIGNAL-TO-NOISE RATIO is expressed as % or decibels.

3.24**STANDARD MEASUREMENT DEPTH**

<IONIZING RADIATION> specified depth in a PHANTOM

3.25**STEREOTACTIC FRAME OF REFERENCE**

three-dimensional coordinate system for numerical specification of the position of those parts of a PATIENT'S anatomy intended for SRS/SRT TREATMENT

3.26**STEREOTACTIC RADIOSURGERY****SRS**

specific version of STEREOTACTIC RADIOTHERAPY, in which a single high dose of RADIATION is delivered to the TARGET VOLUME, using a STEREOTACTIC FRAME OF REFERENCE in conjunction with anatomical registration points

3.27**STEREOTACTIC RADIOTHERAPY****SRT**

TREATMENT procedure in which RADIATION BEAMS of generally small size are oriented from various angles, and precisely positioned relative to a TARGET VOLUME within the PATIENT

NOTE Precise location of the TARGET VOLUME is enabled by use of a three-dimensional frame of reference, which may include anatomical registration points or markers, and immobilisation methods, or imaging techniques.

3.28**STEREOTACTIC REGISTRATION POINT**

reference point on the PATIENT'S anatomy, used to establish the STEREOTACTIC FRAME OF REFERENCE for an SRS/SRT TREATMENT

3.29**TERMINATE RADIATION**

to stop IRRADIATION without the possibility of restarting without reselection of operating conditions

NOTE That means returning to the PREPARATORY STATE

- when the pre-selected value of DOSE MONITOR UNITS is reached, or
- when the pre-selected value of elapsed time is reached, or
- by deliberate manual act, or
- by the operation of an INTERLOCK, or
- by pre-selected value of GANTRY angular position in MOVING BEAM RADIOTHERAPY.

3.30

WEDGE ANGLE

<X-RADIATION> angle defined by the slope of the line joining two points equidistant from the RADIATION BEAM AXIS and half the width of the geometrical field apart on an isodose curve passing through the RADIATION BEAM AXIS at STANDARD MEASUREMENT DEPTH

NOTE See 9.1.5.1.

3.31

WEDGE FACTOR

ratio of the ABSORBED DOSE on the RADIATION BEAM AXIS at the STANDARD MEASUREMENT DEPTH between a WEDGE X-RAY FIELD and a non-wedge X-ray field of the same ENERGY and field size

NOTE For WEDGE X-RAY FIELDS produced by a fixed metal WEDGE FILTER, the WEDGE FACTOR would be the ratio with and without the WEDGE FILTER present in the RADIATION BEAM.

3.32

WEDGE X-RAY FIELD

X-RADIATION field with a dose distribution that changes approximately linearly with distance from the beam edge along a line perpendicular to and passing through the RADIATION BEAM AXIS

4 Environmental conditions

4.1 General

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

- a) the ambient temperature falls within the range 15 °C to 35 °C;
- b) the relative humidity falls within the range 30 % to 75 %;
- c) the atmospheric pressure falls within the range 7×10^4 Pa to 11×10^4 Pa (700 mbar to 1 100 mbar).

4.2 Transport and storage

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

4.3 Power supply

For power supply modalities, see 4.10.2 of IEC 60601-1:2005.

Sufficiently low internal impedance is needed to prevent voltage fluctuations between on-load and off-load steady states exceeding ± 5 %.

5 General information to the USER

5.1 Functional performance characteristics

The ACCOMPANYING DOCUMENTS shall state all functional performance characteristics contained in Clauses 6 to 16 and the information required in 5.2 to 5.9, 4.1 and 4.2.

5.2 Available nominal energies and ABSORBED DOSE RATES

The ACCOMPANYING DOCUMENTS shall state the available NOMINAL ENERGIES and the available associated ABSORBED DOSE RATES at NORMAL TREATMENT DISTANCE under conditions of

maximum BUILD UP in a PHANTOM for the maximum and 10 cm × 10 cm RADIATION FIELDS (or if not available, the MANUFACTURER'S specified reference field size) for both X-RADIATION and ELECTRON RADIATION.

Where an SRT/SRS mode is available, the above information shall be provided for the applicable NOMINAL ENERGIES and X-RADIATION fields.

5.3 Available RADIATION FIELDS

The ACCOMPANYING DOCUMENTS shall list the available RADIATION FIELDS in dimensions given in centimetres at NORMAL TREATMENT DISTANCE for both X-RADIATION and ELECTRON RADIATION.

For a multi-element BLD, the ACCOMPANYING DOCUMENTS shall provide the information specified in 10.3.

5.4 NORMAL TREATMENT DISTANCE

The ACCOMPANYING DOCUMENTS shall state the NORMAL TREATMENT DISTANCE in centimetres.

5.5 Available WEDGE X-RAY FIELDS

Where WEDGE X-RAY FIELD capability is provided, the ACCOMPANYING DOCUMENTS shall provide the following information:

- a) designation;
- b) NOMINAL ENERGIES;
- c) WEDGE ANGLES available;
- d) isodose value used for the determination of WEDGE X-RAY FIELD angles for the specified X-RAY FIELD;
- e) WEDGE X-RAY FIELD orientations available;
- f) minimum and maximum RADIATION FIELD sizes available, both symmetric and asymmetric, for the available combinations of WEDGE ANGLES and RADIATION ENERGIES and information about asymmetric WEDGE ANGLE;
- g) WEDGE FACTOR as discrete or continuous function of RADIATION FIELD size, for each applicable X-ray ENERGY;
- h) description of the process to deliver the PROGRAMMABLE WEDGE FIELD when applicable;
- i) examples of isodose charts measured with the surface of the PHANTOM as indicated in 6.3 obtained using different types of WEDGE X-RAY FIELDS available on an ELECTRON ACCELERATOR of the same specification.

Together with each isodose chart a warning shall be given that the values shown are only typical values and must not be used for the planning of the TREATMENT of the PATIENT unless they have been verified by measurements on the individual ELECTRON ACCELERATOR.

5.6 Available flattening FILTERS

The ACCOMPANYING DOCUMENTS shall give examples of isodose charts measured with the PHANTOM as specified in 6.3. The measurement shall be done with FIELD FLATTENING FILTERS (where provided) of the same design on an ELECTRON ACCELERATOR of the same specifications.

Together with each isodose chart a warning shall be given that the values shown are only typical values and must not be used for the planning of the TREATMENT of the PATIENT unless they have been verified by measurements on the individual ELECTRON ACCELERATOR.

5.7 Availability

The ACCOMPANYING DOCUMENTS shall state the time necessary to reach the READY STATE from the STAND-BY STATE.

5.8 Influencing quantities

The ACCOMPANYING DOCUMENTS shall state any information necessary concerning environmental conditions and extreme conditions of use (for example a maximum period of continuous operation) possibly affecting the functional performance characteristics contained in this standard.

5.9 Maintenance

The ACCOMPANYING DOCUMENTS shall contain information about the procedure necessary to enable the functional performance of the ELECTRON ACCELERATOR to be maintained within the values stated in this standard.

5.10 Presentation

The information to the USER required by this standard shall be provided in the format shown in Annex A.

5.11 Dimensions, clearances within the RADIATION HEAD, and in the region RADIATION HEAD to ISOCENTRE, of BEAM LIMITING DEVICES

For multi-element BLDs, the ACCOMPANYING DOCUMENTS shall include an equipment layout drawing with all dimensions indicated in centimetres, in which is detailed the following information:

- a) the NORMAL TREATMENT DISTANCE;
- b) the distances from the X-RADIATION source (front surface of the X-RADIATION TARGET), or ELECTRON RADIATION window, if applicable, to the proximal or distal surfaces of all BLDs, including any of the multi-element type;
- c) the thicknesses of all BLDs; and
- d) the dimensions, and location, relative to the NORMAL TREATMENT DISTANCE or to the X-RADIATION source, of
 - 1) the fixed RADIATION HEAD surface, proximal to the NORMAL TREATMENT DISTANCE, to which demountable ACCESSORIES may be attached, and
 - 2) any combinations of demountable or fixed RADIATION HEAD ACCESSORY structures, and RADIATION FIELD shaping devices such as ELECTRON BEAM APPLICATORS, WEDGE FILTERS, RADIATION FIELD shaping blocks or jaws, including those used in conjunction with multi-element BLDs.

See Figure 10, which provides an example of the layout of a RADIATION HEAD, with multi-element BLD (in this case a tertiary type) and several X-RADIATION ACCESSORIES. Where a multi-element BLD is used with ELECTRON RADIATION, a similar layout diagram, with multi-element BLD and/or ELECTRON BEAM APPLICATOR, and any other ELECTRON RADIATION ACCESSORIES included, shall also be provided.

5.12 IMRT

For equipment with IMRT the ACCOMPANYING DOCUMENTS shall specify the smallest and the largest numbers of DOSE MONITOR UNITS for which the specifications in Clauses 7, 8 and 9 are met.

6 Standardized test conditions

6.1 General

In determining functional performance characteristics in accordance with this standard, standardized test conditions given in 6.2 to 6.6 shall prevail unless otherwise required.

6.2 Angle settings

The angles of

- a) the roll of the RADIATION HEAD, Axis ②,
- b) the pitch of the RADIATION HEAD, Axis ③,
- c) rotation of the BEAM LIMITING SYSTEM, Axis ④,

are at zero unless otherwise required. See Figures 2 to 4.

If in this standard the test conditions call for measurements to be made at angular positions of the GANTRY, Axis ①, or of the BEAM LIMITING SYSTEM (BLS), Axis ④, of 90° only, it is equally acceptable to use the angular position of 270°.

6.3 Properties and positioning of the PHANTOM

Unless otherwise required, the PHANTOM is a water PHANTOM. If a PHANTOM made of any other material is used, appropriate corrections shall be made.

For any test involving the use of a PHANTOM the surface of the PHANTOM is normal to the RADIATION BEAM AXIS.

The PHANTOM extends at least 5 cm outside the RADIATION BEAM, unless it can be shown that a smaller PHANTOM does not significantly affect the results of the measurement.

The depth of the PHANTOM is at least 5 cm greater than the depth of the measuring point.

6.4 Positioning of measuring points

Unless required otherwise, the measurements are made

- a) on the RADIATION BEAM AXIS, or
- b) in a plane normal to the RADIATION BEAM AXIS at STANDARD MEASUREMENT DEPTHS in a PHANTOM,

whichever is appropriate.

For measurements in the X-RAY BEAM in ISOCENTRIC ELECTRON ACCELERATORS the measurement plane contains the ISOCENTRE, unless otherwise required. The surface of the PHANTOM is 10 cm from the ISOCENTRE in the direction to the RADIATION SOURCE.

For measurements both in the ELECTRON BEAMS and in the X-RAY BEAMS in non-isocentric ELECTRON ACCELERATORS the surface of the PHANTOM is at the NORMAL TREATMENT DISTANCE, unless otherwise required.

6.5 RADIATION DETECTORS

Measurements are made with a RADIATION DETECTOR

- a) from whose SCALE READINGS relative ABSORBED DOSE can be determined when corrections for spatial changes of the RADIATION SPECTRUM are made, and

- b) that has adequate spatial resolution in regions of high dose gradients, for example at the edges of the RADIATION FIELD.

6.6 STANDARD MEASUREMENT DEPTHS

6.6.1 X-RAY BEAMS

The STANDARD MEASUREMENT DEPTH for measurements in the X-RAY BEAM is 10 cm. A depth of 5 cm may be used for energies less than 6 MeV.

6.6.2 ELECTRON BEAMS

The STANDARD MEASUREMENT DEPTH for measurements in the ELECTRON BEAM is half the specified PENETRATIVE QUALITY for a 10 cm × 10 cm RADIATION FIELD.

6.7 RADIATION FIELDS

Except as otherwise indicated, all measurements shall be performed with symmetrical rectangular or square RADIATION FIELDS. Where in the test procedure RADIATION FIELDS of specified sizes are not available, RADIATION FIELDS having the nearest equivalent square shall be used. The sizes of RADIATION FIELDS are quoted in cm at the NORMAL TREATMENT DISTANCE.

Maximum RADIATION FIELD refers to the maximum square RADIATION FIELD, unless otherwise indicated.

The ACCOMPANYING DOCUMENTS shall state that when either

- asymmetrical and irregular RADIATION FIELDS, or
- the special RADIATION FIELDS that may be employed with SRS or SRT,

are considered, then the functional performance characteristics under investigation may differ from those obtained with symmetrical rectangular or square RADIATION FIELDS, as in the case, for example, of Clauses 7, 8 and 9.

For RADIATION FIELDS shaped by a multi-element BLD, the ACCOMPANYING DOCUMENTS shall also state the criteria governing the use of any back-up adjustable BLDs.

6.8 Adjustments during test

During the course of any test procedure only those adjustments of the ELECTRON ACCELERATOR 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 ELECTRON ACCELERATOR.

6.9 Use of RADIOGRAPHIC FILM or alternative imaging method

Where film measurements are suggested, an alternative imaging method, such as an ELECTRONIC IMAGING DEVICE may be used, provided its performance is shown to be adequate for the test performed. Equivalence shall be described in the ACCOMPANYING DOCUMENTS.

7 DOSE MONITORING SYSTEM

7.1 General

The ACCOMPANYING DOCUMENTS shall state the information to the USER required in Clause 7 as follows:

- a) in the case of a PRIMARY-SECONDARY DOSE MONITORING SYSTEM: for the PRIMARY DOSE MONITORING SYSTEM;
- b) in the case of a REDUNDANT DOSE MONITORING SYSTEM: for both systems.

The ACCOMPANYING DOCUMENTS shall state, for all intended modes of operation, the range of ABSORBED DOSES and ABSORBED DOSE RATES over which the DOSE MONITORING SYSTEM is working in compliance with the data provided according to this standard.

7.2 Reproducibility

7.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum COEFFICIENT OF VARIATION of the ratio of the measured values of the ABSORBED DOSE and the DOSE MONITOR UNITS for X-RADIATION and ELECTRON RADIATION if the same value of DOSE MONITOR UNITS is set under otherwise identical conditions for IRRADIATION.

The maximum COEFFICIENT OF VARIATION shall be expressed as a percentage.

The maximum COEFFICIENT OF VARIATION shall apply for:

- a) all NOMINAL ENERGIES;
- b) all ABSORBED DOSE RATES.

7.2.2 Test

The reproducibility s is determined as a coefficient of variation using the formula:

$$s = \frac{100}{\bar{R}} \left[\sum_{i=1}^n \frac{(\bar{R} - R_i)^2}{n-1} \right]^{1/2} \%$$

where

R_i is the ratio of measured values of DOSE MONITOR UNITS and ABSORBED DOSE of the i^{th} measurement,

$\bar{R}$ is the average value of the ratios R_i determined from $\bar{R} = \frac{1}{n} \sum_{i=1}^n R_i$,

n is the number of determinations.

For each set of test conditions given in Table 1, ten consecutive IRRADIATIONS are made under otherwise identical conditions, each resulting in an ABSORBED DOSE of approximately 1 Gy at the NORMAL TREATMENT DISTANCE. The measurements shall be made with the detector in a PHANTOM or with appropriate BUILD UP. These measurement conditions shall apply for all measurements of R .

Table 1 – Conditions for testing reproducibility

Angular position of		RADIATION FIELD cm x cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	10 × 10	Maximum	X-RADIATION	Each
			Minimum		
0° or 90°	0°	10 × 10	Maximum	ELECTRON RADIATION	Each
			Minimum		

^a See Figures 2, 3 and 4.

^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.

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7.3 Proportionality

7.3.1 Requirement

The relationship between the measured values of DOSE MONITOR UNITS and ABSORBED DOSES shall be linear and of the form

$$D = S \times U$$

where

D is the ABSORBED DOSE,

S is the proportionality factor,

U is the value of the DOSE MONITOR UNIT.

7.3.2 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum deviation of the measured ABSORBED DOSE from the product of the measured value of DOSE MONITOR UNITS and the proportionality factor.

The maximum deviation shall be expressed as a percentage of the value calculated from the equation in 7.3.1.

The maximum deviation shall be given for each NOMINAL ENERGY for both X-RADIATION and ELECTRON RADIATION.

The maximum deviation shall apply over the specified ranges of ABSORBED DOSES and ABSORBED DOSE RATES at the NORMAL TREATMENT DISTANCE, for all TREATMENT modes (including large and small values of ABSORBED DOSE) provided.

7.3.3 Test

Five series of IRRADIATIONS are made for each set of test conditions given in Table 2, each delivering a different ABSORBED DOSE at approximately equal intervals within the specified range of ABSORBED DOSE at the NORMAL TREATMENT DISTANCE.

Table 2 – Conditions for testing proportionality of the DOSE MONITORING SYSTEM

Angular position of		RADIATION FIELD cm x cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	10 × 10	Each ^c	X-RADIATION	Each
				ELECTRON RADIATION	
a See Figures 2, 3 and 4.					
b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.					
c If continuously variable with four ABSORBED DOSE RATES over the range from 20 % to maximum.					

7.4 Dependence on angular positions

7.4.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum differences between the maximum value and the minimum value of the ratio $\bar{R}$ for both X-RADIATION and ELECTRON RADIATION when the equipment is placed in different positions through the full range of rotations.

The maximum differences shall be expressed as percentages of the mean value of $\bar{R}$ for both X-RADIATION and ELECTRON RADIATION.

7.4.2 Test

$\bar{R}$ is determined from five measurements for each set of test conditions given in Table 3, using a detector with appropriate BUILD UP attached to the RADIATION HEAD, with each IRRADIATION resulting in an ABSORBED DOSE of approximately 1 Gy at the NORMAL TREATMENT DISTANCE. During the measurements for each set of test conditions the equipment is stationary.

Table 3 – Conditions for testing dependence of the DOSE MONITORING SYSTEM on equipment position

Angular position of GANTRY	BEAM LIMITING SYSTEM	RADIATION FIELD cm x cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
Axis ① ^a	Axis ④ ^a				
0°	0°	10 × 10	One fixed	X-RADIATION	Maximum
					Minimum
0°	0°	10 × 10	One fixed	ELECTRON RADIATION	Maximum
					Minimum
90°	0°	10 × 10	One fixed	X-RADIATION	Maximum
					Minimum
90°	0°	10 × 10	One fixed	ELECTRON RADIATION	Maximum
					Minimum
180°	0°	10 × 10	One fixed	X-RADIATION	Maximum
					Minimum
180°	0°	10 × 10	One fixed	ELECTRON RADIATION	Maximum
					Minimum
270°	0°	10 × 10	One fixed	X-RADIATION	Maximum
					Minimum
270°	0°	10 × 10	One fixed	ELECTRON RADIATION	Maximum
					Minimum
0°	90°	10 × 10	One fixed	X-RADIATION	Maximum
					Minimum
0°	90°	10 × 10	One fixed	ELECTRON RADIATION	Maximum
					Minimum

^a See Figures 2, 3 and 4.

^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.

7.5 Dependence on GANTRY rotation

7.5.1 Information to the USER

For equipment which has a facility for delivering a RADIATION BEAM while the GANTRY is rotating, the ACCOMPANYING DOCUMENTS shall state the maximum difference for X-RADIATION and ELECTRON RADIATION:

- between the value of the ratio $\bar{R}$ measured as the GANTRY rotates continuously through different parts of its angular range (as for MOVING BEAM RADIOTHERAPY) and
- the mean of the greatest and least values of the ratio $\bar{R}$ determined according to 7.2 with the GANTRY stationary at different angular positions of the GANTRY and of the BEAM LIMITING SYSTEM (as in stationary beam RADIOTHERAPY).

The maximum differences shall be expressed as a percentage of the mean value of $\bar{R}$ for both X-RADIATION and ELECTRON RADIATION.

7.5.2 Test

$\bar{R}$ is determined from four measurements for each set of test conditions given in Table 4, using a detector with appropriate BUILD UP attached to the RADIATION HEAD. Each IRRADIATION should result in an ABSORBED DOSE of approximately 1 Gy at the NORMAL TREATMENT DISTANCE as the GANTRY rotates through each different angular range of approximately 45°.

If possible, two of the IRRADIATIONS are made in the forward direction of rotation and two in the reverse direction.

Table 4 – Conditions for testing dependence of the DOSE MONITORING SYSTEM on GANTRY rotation

Angular position of GANTRY	BEAM LIMITING SYSTEM	RADIATION FIELD cm x cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
Axis ① ^a	Axis ④ ^a				
Through each 45° sector	0°	10 × 10	One	X-RADIATION ELECTRON RADIATION	One
^a See Figures 2, 3 and 4.					
^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.					

7.6 Dependence on the shape of the RADIATION FIELD

7.6.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the dependence of the calibration of the DOSE MONITORING SYSTEM on the length to width ratio of rectangular fields for X-RADIATION and ELECTRON RADIATION.

The maximum difference in the value of $\bar{R}$ shall be expressed as a percentage of the mean value for both X-RADIATION and ELECTRON RADIATION.

7.6.2 Test

$\bar{R}$ is determined from five measurements for each set of test conditions given in Table 5, each IRRADIATION resulting in an ABSORBED DOSE of approximately 1 Gy at NORMAL TREATMENT DISTANCE.

Measurements are made consecutively in RADIATION FIELDS of the same dimensions in directions normal to each other.

Table 5 – Conditions for testing dependence on the shape of the RADIATION FIELD

Angular position of		RADIATION FIELD cm × cm dimensions X and Y ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	5 × 20 ^c	One	X-RADIATION	Each
		20 ^c × 5			
0°	0°	5 × 20 ^c	One	ELECTRON RADIATION	Each
		20 ^c × 5			

^a See Figures 2, 3 and 4.

^b With scale ④ at zero, X⑭ is the dimension parallel to axis ① or ② and Y⑮ is the perpendicular dimension.

^c Or at maximum dimension if this is less than 20 cm.

7.7 Stability of calibration

7.7.1 Stability after high ABSORBED DOSE delivered

7.7.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum difference between the ratios $\bar{R}$ of the measured DOSE MONITOR UNITS and ABSORBED DOSE determined from measurements made

- a) immediately following the ELECTRON ACCELERATOR having reached the READY STATE after an extended period in the STAND-BY STATE, and
- b) immediately after
 - i) the delivery of an ABSORBED DOSE of 100 Gy under standard test conditions, or
 - ii) a period of 30 min at the highest ABSORBED DOSE RATE specified for this period, whichever results in the shorter period.

The maximum difference shall be expressed as a percentage of the value of $\bar{R}$ before the delivery of the dose for both X-RADIATION and ELECTRON RADIATION.

7.7.1.2 Test

$\bar{R}$ is determined from five measurements for each set of test conditions given in Table 6, using a detector with appropriate BUILD UP, each IRRADIATION resulting in an ABSORBED DOSE of approximately 1 Gy at the NORMAL TREATMENT DISTANCE:

- a) immediately following a period of at least 3 h in which the ELECTRON ACCELERATOR is maintained in the STAND-BY STATE, and

b) immediately following an IRRADIATION with the required maximum ABSORBED DOSE.

During the test, corrections for changes of temperature, pressure and humidity are applied according to the ACCOMPANYING DOCUMENTS.

**Table 6 – Conditions for testing stability of calibration
of the DOSE MONITORING SYSTEM**

Angular position of		RADIATION FIELD cm x cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	10 × 10	One	X-RADIATION	Maximum
					Minimum
0°	0°	10 × 10	One	ELECTRON RADIATION	Maximum
					Minimum
^a See Figures 2, 3 and 4.					
^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.					

7.7.2 Stability throughout the day

7.7.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state for X-RADIATION and ELECTRON RADIATION the maximum difference between the ratios $\bar{R}$ of the measured values of DOSE MONITOR UNITS and ABSORBED DOSE determined from measurements made:

- immediately following the ELECTRON ACCELERATOR having reached the READY STATE after an extended period in the STAND-BY STATE, and
- following a period of 8 h of successive cycles each consisting of an IRRADIATION at a typical ABSORBED DOSE RATE and resulting in an ABSORBED DOSE of approximately 4 Gy followed by about 10 min without IRRADIATION.

The maximum difference shall be expressed as a percentage of the value of $\bar{R}$ determined at the beginning of the test.

7.7.2.2 Test

$\bar{R}$ is determined from five measurements for each set of test conditions given in Table 6, in a PHANTOM, each IRRADIATION resulting in an ABSORBED DOSE of approximately 4 Gy at NORMAL TREATMENT DISTANCE.

The measurement shall be made before and after an 8 h period, as described in 7.7.2.1.

During the test, corrections for changes of temperature, pressure and humidity are applied according to the ACCOMPANYING DOCUMENTS.

7.7.3 Stability throughout the week

7.7.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state for X-RADIATION and ELECTRON RADIATION the maximum difference between the highest and lowest ratios $\bar{R}$ of the measured values of DOSE MONITOR UNITS and ABSORBED DOSE, determined from measurements made on five consecutive

days immediately following the ELECTRON ACCELERATOR having reached the READY STATE after an extended period in the STAND-BY STATE.

The maximum difference shall be expressed as a percentage of the mean value $\bar{R}$ of all measured values of $\bar{R}$.

7.7.3.2 Test

$\bar{R}$ is to be determined each day immediately following a period of at least 3 h during which the ELECTRON ACCELERATOR is maintained in the STAND-BY STATE. Five measurements for each set of test conditions given in Table 6 are made in a PHANTOM attached to the RADIATION HEAD, each IRRADIATION resulting in an ABSORBED DOSE of approximately 1 Gy at NORMAL TREATMENT DISTANCE.

During the test, corrections for changes of temperature, pressure and humidity are applied according to the ACCOMPANYING DOCUMENTS.

7.8 Stability in MOVING BEAM RADIOTHERAPY

7.8.1 Information to the USER

When MOVING BEAM RADIOTHERAPY is produced by GANTRY rotation, in which the DOSE MONITOR UNITS per angle is constant, and the angle of rotation of the GANTRY TERMINATES IRRADIATION, the ACCOMPANYING DOCUMENTS shall state the maximum difference between the reading in DOSE MONITOR UNITS and the value calculated by multiplying the set value of DOSE MONITOR UNITS per angle by the set value of angle of rotation of the GANTRY.

The maximum difference shall be expressed as a percentage of calculated value for both X-RADIATION and ELECTRON RADIATION.

When MOVING BEAM RADIOTHERAPY is produced by GANTRY rotation, in which the DOSE MONITOR UNITS per angle is constant, and the DOSE MONITORING SYSTEM TERMINATES IRRADIATION, the ACCOMPANYING DOCUMENTS shall contain the maximum difference between the angle of rotation of the GANTRY and the angle calculated by dividing the set value of DOSE MONITOR UNITS by the set value of DOSE MONITOR UNITS per angle.

The maximum difference shall be expressed in degrees for both X-RADIATION and ELECTRON RADIATION.

The maximum difference shall apply to the full range of the available ABSORBED DOSE RATES and the quotient of DOSE MONITOR UNITS per angle of GANTRY rotation.

7.8.2 Test

For each set of test conditions given in Table 7 the GANTRY rotates through an angle corresponding to approximately

- a) an ABSORBED DOSE of 4 Gy, or
- b) as near as possible if an ABSORBED DOSE of 4 Gy cannot be reached.

**Table 7 – Conditions for testing stability of the DOSE MONITORING SYSTEM
in MOVING BEAM RADIOTHERAPY**

DMU ^a per angle of GANTRY rotation	Angular position of BEAM LIMITING SYSTEM	RADIATION FIELD cm x cm ^c	RADIATION TYPE	NOMINAL ENERGY
	Axis ④ ^b			
Maximum	0°	10 × 10	X-RADIATION	One
Minimum				
Maximum	0°	10 × 10	ELECTRON RADIATION	One
Minimum				
a DOSE MONITOR UNITS.				
b See Figures 2, 3 and 4.				
c 10 cm × 10 cm or MANUFACTURER'S reference field size if not available.				

8 Depth ABSORBED DOSE characteristics

8.1 X-RADIATION

8.1.1 Depth dose charts

8.1.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain charts giving percentage ABSORBED DOSE along the RADIATION BEAM AXIS for a RADIATION FIELD of 10 cm × 10 cm and maximum (see 6.7).

Charts shall be given for each selectable NOMINAL ENERGY of X-RADIATION under standardized test conditions (see Clause 6).

The following information shall be given for each NOMINAL ENERGY:

For X-RAY FIELDS of 10 cm × 10 cm and maximum,

- DEPTH OF DOSE MAXIMUM in centimetres.

For X-RAY FIELDS of 10 cm × 10 cm,

- PENETRATIVE QUALITY in centimetres,
- maximum deviation of any actual value from the specified value of PENETRATIVE QUALITY. The maximum deviation shall be expressed as a percentage of the declared value or shall be given in millimetres,
- QUALITY INDEX.

8.1.1.2 Test

The depth dose distribution along the RADIATION BEAM AXIS is measured in a water PHANTOM under standardized test conditions (see Clause 6) and for the set of test conditions given in Table 8.

The DEPTH OF DOSE MAXIMUM is taken at the midpoint between the 99 % depth dose points.

Table 8 – Conditions for testing depth dose characteristics – X-RADIATION

Angular position of		RADIATION FIELD cm x cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	10 x 10 ^b	One	X-RADIATION	Each
		Maximum			
^a See Figures 2, 3 and 4.					
^b 10 cm x 10 cm or MANUFACTURER'S reference field size if not available.					

8.1.2 SURFACE DOSE

8.1.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the RELATIVE SURFACE DOSE for X-RAY FIELDS of 10 cm × 10 cm and maximum. Results of the tests from Clause 29.2.2 in IEC 60601-2-1:1998 plus amendments may be used.

The RELATIVE SURFACE DOSE shall be expressed as a percentage.

The information should be given for each NOMINAL ENERGY of X-RADIATION under standardized test conditions (see Clause 6).

8.1.2.2 Test

The RELATIVE SURFACE DOSE is measured on the RADIATION BEAM AXIS under standardized test conditions (see Clause 6) and for the set of test conditions given in Table 8.

A flat detector may be used with successive additions of BUILD UP material to obtain point-by-point measurements from 0,5 mm to the DEPTH OF DOSE MAXIMUM in order to calculate the RELATIVE SURFACE DOSE.

8.1.3 Isodose charts

8.1.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain representative isodose charts for one or more planes containing the RADIATION BEAM AXIS and including one of the two major axes for each NOMINAL ENERGY of X-RADIATION under standardized test conditions (see Clause 6).

The contours of the isodose charts shall be given as a percentage relative to the dose maximum (100 %) on the RADIATION BEAM AXIS for each contour spaced by 10 % from the 100 % to the 10 % contour.

Together with each isodose chart a warning shall be given that the values shown are only typical values and must not be used for the planning of the TREATMENT of the PATIENT unless they have been verified by measurements on the individual ELECTRON ACCELERATOR.

Data, in a different format but providing information equivalent to that contained in isodose charts, may be presented instead of isodose charts.

8.1.3.2 Test

The isodose charts are measured in one or more planes containing the RADIATION BEAM AXIS and including one of the two major axes in a water PHANTOM under standardized test conditions and for the set of test conditions given in Table 8.

8.1.4 STEREOTACTIC RADIOTHERAPY (SRT) or STEREOTACTIC RADIOSURGERY (SRS)

8.1.4.1 Information to the USER

For SRT/SRS, the ACCOMPANYING DOCUMENTS shall contain the information required in 8.1.1, 8.1.2, and 8.1.3, for the maximum X-RAY FIELD size, and for either a 1 cm diameter X-RAY FIELD, or as close as can be achieved to a 1 cm × 1 cm square X-RAY FIELD.

8.1.4.2 Test

All tests shall be made along the RADIATION BEAM AXIS and measured in a water PHANTOM under standardized test conditions (see Clause 6) and for the set of test conditions given below:

- angular position of the GANTRY and BEAM LIMITING SYSTEM shall be 0° or 90°. Measurement at a single representative dose rate is required.

8.2 ELECTRON RADIATION

8.2.1 Depth dose charts

8.2.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain charts or equivalent data giving ABSORBED DOSE along the RADIATION BEAM AXIS for a RADIATION FIELD of 10 cm × 10 cm and maximum.

Charts shall be given for each selectable NOMINAL ENERGY of ELECTRON RADIATION under standardized test conditions (see Clause 6).

The following information shall be given for each NOMINAL ENERGY:

For ELECTRON FIELDS of 10 cm × 10 cm and maximum,

- DEPTH OF DOSE MAXIMUM in centimetres;
- ratio of PRACTICAL RANGE and the depth at 80 % of the maximum ABSORBED DOSE.

For ELECTRON FIELDS 10 cm × 10 cm,

- PRACTICAL RANGE in centimetres;
- PENETRATIVE QUALITY in centimetres;
- maximum deviation of any actual value from the specified value of PENETRATIVE QUALITY. The maximum deviation shall be expressed as a percentage or shall be given in millimetres.

8.2.1.2 Test

The depth dose distribution along the RADIATION BEAM AXIS is measured in a water PHANTOM under standardized test conditions (see Clause 6) and for the set of test conditions given in Table 9.

Table 9 – Conditions for testing depth dose characteristics – ELECTRON RADIATION

Angular position of		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	10 × 10 ^b	One	ELECTRON RADIATION	Each
		Maximum			
^a See Figures 2, 3 and 4.					
^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

8.2.2 Stability of PENETRATIVE QUALITY

8.2.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum deviation of PENETRATIVE QUALITY with the angle of rotation of the GANTRY.

The maximum deviation shall be expressed as a percentage of the declared PENETRATIVE QUALITY or shall be given in millimetres.

The maximum deviation shall apply to all angular positions of the GANTRY and throughout the available range of ABSORBED DOSE RATES.

8.2.2.2 Test

Measurements shall be made in a PHANTOM. The PHANTOM shall be suitable for measurement of ABSORBED DOSE at approximately the DEPTH OF DOSE MAXIMUM and depth of 80 % of maximum dose.

Table 10 – Conditions for testing stability of PENETRATIVE QUALITY of ELECTRON RADIATION

Angular position of		RADIATION FIELD cm × cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	10 × 10	Maximum	ELECTRON RADIATION	One
			Minimum		
90°	0°	10 × 10	Maximum	ELECTRON RADIATION	One
			Minimum		
180°	0°	10 × 10	Maximum	ELECTRON RADIATION	One
			Minimum		
270°	0°	10 × 10	Maximum	ELECTRON RADIATION	One
			Minimum		
^a See Figures 2, 3 and 4.					
^b 10 cm × 10 cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

The ratio of ABSORBED DOSE at the two depths is determined for each set of test conditions given in Table 10.

Any change in this ratio is converted to a change in PENETRATIVE QUALITY using the depth dose charts required in 8.2.1.

8.2.3 SURFACE DOSE

8.2.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the RELATIVE SURFACE DOSE for ELECTRON FIELDS of 10 cm × 10 cm and maximum.

The RELATIVE SURFACE DOSE shall be expressed as a percentage.

The information shall be given for each NOMINAL ENERGY of ELECTRON RADIATION under standardized test conditions.

8.2.3.2 Test

The RELATIVE SURFACE DOSE is measured on the RADIATION BEAM AXIS under standardized test conditions (see Clause 6) and for the set of test conditions given in Table 10.

A flat detector is used with successive additions of BUILD UP material to obtain point-by-point measurements from 0,5 mm to the DEPTH OF DOSE MAXIMUM in order to calculate the RELATIVE SURFACE DOSE.

8.2.4 Isodose charts

8.2.4.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain representative isodose charts for one or more planes containing the RADIATION BEAM AXIS and including one of the two major axes for each NOMINAL ENERGY of ELECTRON RADIATION under standardized test conditions (see Clause 6).

The contours of the isodose charts shall be given as a percentage relative to the dose maximum (100 %) on the RADIATION BEAM AXIS for each contour spaced by 10 % from the 100 % contour to the 10 % contour.

Together with each isodose chart a warning shall be given that the values shown are only typical values and must not be used for the planning of the TREATMENT of the PATIENT unless they have been verified by measurements on the individual ELECTRON ACCELERATOR.

Data, in a different format but providing information equivalent to that contained in isodose charts, may be presented instead of isodose charts.

8.2.4.2 Test

The isodose charts are measured in one or more planes containing the RADIATION BEAM AXIS and including one of the two major axes in a water PHANTOM under standardized test conditions and for the set of test conditions given in Table 10.

9 Uniformity of RADIATION FIELDS

9.1 X-RADIATION

9.1.1 Flatness of square X-RAY FIELDS

9.1.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ratio of maximum ABSORBED DOSE (averaged over not more than 1 cm² anywhere in the RADIATION FIELD) to the minimum ABSORBED DOSE (averaged over not more than 1 cm² anywhere in the flattened area).

Subclause 9.1.1 does not apply to machines not intended to produce flattened fields.

The flattened area is defined by straight lines joining points on the major axes and diagonals of square fields as shown in Figure 5 and according to Table 11.

**Table 11 – Flattened area
according to Figure 5**

Square RADIATION FIELD	Dimensions defining the flattened area	
F in cm	d_m	d_d
$5 \leq F \leq 10$	1 cm	2 cm
$10 < F \leq 30$	0,1 F	0,2 F
$30 < F$	3 cm	6 cm

This ratio shall be expressed as a percentage.

The maximum value shall be given for each NOMINAL ENERGY for the angular position of the GANTRY of 0° or 90°. The maximum value shall be given for

- square RADIATION FIELDS from 5 cm × 5 cm up to and including 30 cm × 30 cm and
- square RADIATION FIELDS greater than 30 cm × 30 cm.

The maximum value shall apply to all square X-RAY FIELDS and for all ABSORBED DOSE RATES under standardized test conditions (see Clause 6).

Some typical profiles of ABSORBED DOSE over X-RAY FIELDS are shown in Figure 6.

The ACCOMPANYING DOCUMENTS shall contain a chart showing the ratio of the maximum ABSORBED DOSE in the X-RAY FIELD to the ABSORBED DOSE on the RADIATION BEAM AXIS, both measured in the plane at the STANDARD MEASUREMENT DEPTH as a function of the size of the available square RADIATION FIELDS when the angular positions of the GANTRY and of the BEAM LIMITING SYSTEM are 0°.

9.1.1.2 Test

The ABSORBED DOSE profiles along the major axes and the diagonals of the RADIATION FIELD in a PHANTOM are measured (either continuously or at closely spaced points) by a RADIATION DETECTOR for each set of test conditions given in Table 12.

Table 12 – Conditions for testing flatness and symmetry of X-RAY FIELDS

Angular position of		RADIATION FIELD cm × cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	5 × 5	one	X-RADIATION	Each
		10 × 10			
		30 × 30			
		Maximum			
^a See Figures 2, 3 and 4.					
^b X cm × X cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

9.1.2 Deviation of dose distribution of square X-RAY FIELDS with angular positions

9.1.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum variation in the value of the ratio of ABSORBED DOSE (averaged over not more than 1 cm²) at any point in the flattened area, or equivalent test area where machines are not intended to produce flattened fields, and the corresponding ABSORBED DOSE on the RADIATION BEAM AXIS.

The maximum variation shall be expressed as a percentage difference between the lowest and the highest value of this ratio.

The maximum variation shall apply to all square X-RAY FIELDS of 5 cm × 5 cm and greater under standardized test conditions (see Clause 6) and for all angular positions of the GANTRY and of the BEAM LIMITING SYSTEM.

The maximum variation shall be given for

- NOMINAL ENERGIES less than 30 MeV and
- NOMINAL ENERGIES 30 MeV and above.

9.1.2.2 Test

A PHANTOM which rotates with the BEAM LIMITING SYSTEM is attached to the RADIATION HEAD, or otherwise positioned to maintain the standard test conditions described by Clause 6.

The measurements of ABSORBED DOSE are made on the major axes of the RADIATION FIELD for each set of test conditions given in Table 13:

- at the centre, and
- at two-thirds of the distance from the centre to the edge (defined by the line of 50 % of the ABSORBED DOSE at the RADIATION BEAM AXIS).

**Table 13 – Conditions for testing deviation of dose distribution
of X-RAY FIELDS with angular position**

Angular position of GANTRY		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
Axis ① ^a	BEAM LIMITING SYSTEM				
Axis ④ ^a					
90°	0°	30 × 30 ^b	One	X-RADIATION	Each
	45°				
	90°				
	180°				
	270°				
0°	0°	30 × 30 ^b	One	X-RADIATION	Each
45°					
135°					
180°					
225°					
270°					
315°					
^a See Figures 2, 3 and 4.					
^b Or maximum, whichever is less.					

9.1.3 Symmetry of square X-RAY FIELDS

9.1.3.1 Information to the USER

For square X-RAY FIELDS the ACCOMPANYING DOCUMENTS shall state the maximum value of the ratio of the higher to the lower ABSORBED DOSE (averaged over not more than 1 cm²) at any two positions symmetrical to the RADIATION BEAM AXIS and inside the flattened area.

This ratio shall be expressed as a percentage.

The maximum value shall be given for all X-RAY FIELDS of 5 cm × 5 cm and greater under standardized test conditions (see Clause 6) when the angular positions of the GANTRY and of the BEAM LIMITING SYSTEM are at 0° or 90°.

The maximum ratio shall apply for all NOMINAL ENERGIES.

9.1.3.2 Test

For the test see 9.1.1.2.

9.1.4 Maximum ratio of ABSORBED DOSE

9.1.4.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ratio of the ABSORBED DOSE (averaged over not more than 1 cm²) anywhere in the plane normal to the RADIATION BEAM AXIS at the DEPTH OF DOSE MAXIMUM to the value of the maximum ABSORBED DOSE along the RADIATION BEAM AXIS.

This ratio shall be expressed as a percentage.

The maximum value shall be given for each NOMINAL ENERGY for

- square RADIATION FIELDS up to and including 30 cm × 30 cm, and
- square RADIATION FIELDS greater than 30 cm × 30 cm

when the angular positions of the GANTRY and the BEAM LIMITING SYSTEM are 0° or 90°.

9.1.4.2 Test

The regions of high ABSORBED DOSE at the DEPTH OF DOSE MAXIMUM are determined by means of a RADIOGRAPHIC FILM for each set of test conditions given in Table 14.

Measurements of ABSORBED DOSE are made using a RADIATION DETECTOR in the regions of highest ABSORBED DOSE and along the RADIATION BEAM AXIS.

The highest value of ABSORBED DOSE measured in a region is compared with the maximum ABSORBED DOSE along the RADIATION BEAM AXIS.

Table 14 – Conditions for testing maximum ABSORBED DOSE ratio in the RADIATION FIELD

Angular position of		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	5 x 5	One	X-RADIATION	Each
		10 x 10			
		30 × 30			
		Maximum square			
^a See Figures 2, 3 and 4.					

9.1.5 WEDGE X-RAY FIELDS

9.1.5.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum deviation of any value of WEDGE FACTOR and WEDGE ANGLE (see Figure 1) from the specified value.

The maximum deviation shall be expressed as a percentage of the declared value for the WEDGE FACTOR and in degrees for the WEDGE ANGLE.

For certain WEDGE X-RAY FIELDS the conditions shown in Figure 1 to measure the WEDGE ANGLE may not be achievable. In these cases the ACCOMPANYING DOCUMENTS shall specify the exceptions and explain the measuring method used to measure the WEDGE ANGLE.

The maximum deviation of the WEDGE FACTOR shall apply to all angular positions of the GANTRY and of the BEAM LIMITING SYSTEM.

The ACCOMPANYING DOCUMENTS shall state the minimum and maximum RADIATION FIELD sizes available, both symmetric and asymmetric, for the different WEDGE X-RAY FIELDS possible.

If a PWF capability is provided, the ACCOMPANYING DOCUMENTS shall provide the details specified in 5.5, in addition to those specified above.

9.1.5.2 Test

The ABSORBED DOSE is measured on the RADIATION BEAM AXIS for the WEDGE X-RAY FIELD and a non WEDGE X-RAY FIELD for each set of test conditions given in Table 15.

Table 15 – Conditions for testing WEDGE FACTORS

Angular position of		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	b	One	X-RADIATION	Each for which the WEDGE X-RAY FIELD capability is available
	90°				
90°	0°				
	90°				
^a See Figures 2, 3 and 4.					
^b Maximum for the WEDGE X-RAY FIELD					

The WEDGE ANGLES are derived from the isodose charts measured for each set of test conditions given in Table 16.

Table 16 – Conditions for testing WEDGE ANGLES

Angular position of GANTRY BEAM LIMITING SYSTEM		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	b	One	X-RADIATION	Each for which the WEDGE X-RAY FIELD capability is available
^a See Figures 2, 3 and 4. ^b Maximum for the WEDGE X-RAY FIELD					

If a PWF capability is provided, these tests shall also be repeated with four representative PWF orientations, relative to the BEAM LIMITING SYSTEM coordinate system. These tests shall also be repeated for GANTRY angles of 0° and 90°, and for BLS angles of 0° and 90°.

9.1.6 X-RAY FIELDS with INTENSITY-MODULATED RADIATION THERAPY (IMRT)

9.1.6.1 Information to the USER

If this capability has been provided, the ACCOMPANYING DOCUMENTS shall provide details of any routine quality assurance tests designed to verify the capabilities of the multi-element BLD to produce intensity-modulated RADIATION FIELDS.

In addition to any quality assurance test procedures specified by the equipment MANUFACTURER, the following TYPE TESTS shall also be performed, and typical results made available to the USER.

9.1.6.2 Test

9.1.6.2.1 Beam characteristics and dosimetry system performance for small delivered doses

Where applicable the tests in subclauses 7.2 to 7.5, 7.8, 8.1.1 (QUALITY INDEX only) and 9.1.1 to 9.1.4, shall be undertaken for the smallest number of DOSE MONITOR UNITS specified in subclause 5.12, where applicable the tests in subclauses 7.2 to 7.5, 7.8, 8.1.1 (QUALITY INDEX only) and 9.1.1 to 9.1.4 shall be undertaken for the final 2 % of the largest number of the DOSE MONITOR UNITS specified in subclause 5.12.

The MANUFACTURER may provide additional performance values outside the DOSE MONITOR UNIT range specified in subclause 5.12.

9.2 ELECTRON RADIATION

9.2.1 Flatness of ELECTRON FIELDS

9.2.1.1 Information to the USER

For the purpose of this requirement the geometrical field is projected into the PHANTOM parallel to the RADIATION BEAM AXIS (see Figure 7).

The ACCOMPANYING DOCUMENTS shall state the following information for each set of test conditions given in Table 17 under standardized test conditions (see Clause 6):

- a) the maximum distance A¹⁾ between the 90 % isodose contour and the edge of the projection of the geometrical field on both major axes at the STANDARD MEASUREMENT DEPTH;
- b) the maximum distance B¹⁾ between the 80 % isodose contour and the edge of the projection of the geometrical field on both major axes at the BASE DEPTH;
- c) the maximum distance C¹⁾ between the 90 % isodose contour and the corner of the projection of the geometrical field on the bisectors of the corners at the STANDARD MEASUREMENT DEPTH;
- d) the ratio of the highest ABSORBED DOSE (averaged over 1 cm²) anywhere in the RADIATION FIELD at the STANDARD MEASUREMENT DEPTH with respect to the ABSORBED DOSE on the RADIATION BEAM AXIS at the DEPTH OF DOSE MAXIMUM.

The maximum distances shall be given in millimetres and the ratio shall be expressed as a percentage.

The information shall apply to all NOMINAL ENERGIES and to all ELECTRON FIELDS for which the smaller dimension is equal to or greater than 5 cm.

9.2.1.2 Test

For each set of test conditions given in Table 17 and within a PHANTOM the ABSORBED DOSE profiles along the major axes and diagonals of the RADIATION FIELD are measured at

- the depth of 0,5 mm (see 9.2.4.1 and 9.2.4.2),
- the STANDARD MEASUREMENT DEPTH, and
- the BASE DEPTH.

1) See Figure 7.

Table 17 – Conditions for testing flatness, symmetry, deviation of dose distribution with angular position, and maximum ABSORBED DOSE ratio of ELECTRON FIELDS

Angular position of GANTRY		RADIATION FIELD cm × cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
Axis ① ^a	Axis ④ ^a				
		c			
	0°	5 × 5 ^d			Maximum
0°		10 × 10	One	ELECTRON RADIATION	
		10 × 20			
		20 × 20			Minimum
		Maximum			
		5 × 5 ^d			Maximum
0°	45°	10 × 10	One	ELECTRON RADIATION	
		10 × 20			
		20 × 20			Minimum
		Maximum			
		5 × 5 ^d			
Axis ① ^a	Axis ④ ^a	c			
90°	0°	10 × 10	One	ELECTRON RADIATION	Maximum
		10 × 20			
		20 × 20			Minimum
		Maximum			

^a See Figures 2, 3 and 4.

^b X cm x X cm or MANUFACTURER’S reference field size if not available.

^c If continuously variable; otherwise, with each selectable square and rectangle RADIATION FIELD for which the smaller dimension is equal to or greater than 10 cm. For non–square fields only the major axes are to be measured.

^d For testing symmetry only.

9.2.2 Deviation of dose distribution of ELECTRON FIELDS with angular positions

9.2.2.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum variation in the value of the ratio of ABSORBED DOSE averaged over not more than 1 cm² at any point in the flattened area confined by the line 1 cm inside the 90 % isodose contour at the STANDARD MEASUREMENT DEPTH and the corresponding ABSORBED DOSE on the RADIATION BEAM AXIS.

The maximum variation shall be expressed as a percentage of the maximum ABSORBED DOSE on the RADIATION BEAM AXIS.

The maximum variation shall apply to all ELECTRON FIELDS at the STANDARD MEASUREMENT DEPTH for which the smaller dimension is equal to or greater than 10 cm and to all angular positions of the GANTRY and of the BEAM LIMITING SYSTEM.

9.2.2.2 Test

The test is already included in the test of 9.2.1.2.

9.2.3 Symmetry of ELECTRON FIELDS

9.2.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ratio of the higher to the lower ABSORBED DOSE (averaged over not more than 1 cm^2) at any two positions symmetrical to the RADIATION BEAM AXIS and within the area confined by a line 1 cm inside the 90 % isodose contour at the STANDARD MEASUREMENT DEPTH.

This ratio shall be expressed as a percentage.

The maximum value shall be given for all ELECTRON FIELDS of $5 \text{ cm} \times 5 \text{ cm}$ and greater under standardized test conditions (see Clause 6) when the angular positions of the GANTRY and of the BEAM LIMITING SYSTEM are at 0° or 90° .

9.2.3.2 Test

The test is already included in the test of 9.2.1.2.

9.2.4 Maximum ratio of ABSORBED DOSE

9.2.4.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ratio of the ABSORBED DOSE (averaged over not more than 1 cm^2) anywhere in the RADIATION FIELD at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS.

This ratio shall be expressed as a percentage.

9.2.4.2 Test

For each set of test conditions given in Table 17, the RADIATION FIELD is scanned along the major axes and diagonals using a RADIATION DETECTOR in air. At the point of the highest SCALE READING, measurements are made in a PHANTOM to determine the value of ABSORBED DOSE at the depth of 0,5 mm.

9.3 PENUMBRA of RADIATION FIELDS

9.3.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the width of the PENUMBRA as the maximum distance along the major axes between the 80 % and 20 % points of the ABSORBED DOSE at the STANDARD MEASUREMENT DEPTH.

The 80 % and 20 % points are with reference to the ABSORBED DOSE on the RADIATION BEAM AXIS at the STANDARD MEASUREMENT DEPTH.

The width of the PENUMBRA shall be given in millimetres.

The width of the PENUMBRA shall be given for RADIATION FIELDS of $5 \text{ cm} \times 5 \text{ cm}$, $10 \text{ cm} \times 10 \text{ cm}$ and for the maximum RADIATION FIELD for both X-RADIATION and ELECTRON RADIATION.

The width of the PENUMBRA shall apply under standardized test conditions (see Clause 6) and for all NOMINAL ENERGIES.

For RADIATION FIELDS shaped by a multi-element BLD, the ACCOMPANYING DOCUMENTS shall state the maximum width of the PENUMBRA along the major axes of

- a 10 cm × 10 cm RADIATION FIELD (or MANUFACTURER'S reference field size if 10 cm x 10 cm not available) situated anywhere within the available RADIATION BEAM; and
- the maximum (rectangular or square) multi-element BLD RADIATION FIELD.

For RADIATION FIELDS utilized with SRT/SRS, the ACCOMPANYING DOCUMENTS shall state the maximum width of the PENUMBRA along the major axes of

- either a 1 cm diameter X-RAY FIELD, or as close as can be achieved to a 1 cm × 1 cm square X-RAY FIELD, and
- the maximum SRT/SRS RADIATION FIELD (ref. 8.1.4.1)

9.3.2 Test

The width of the PENUMBRA is determined from the measurements made for the tests

- for X-RADIATION according to 9.1.1.2,
- for ELECTRON RADIATION according to 9.2.1.2

for the sets of test conditions for which the angular position of the GANTRY and of the BEAM LIMITING SYSTEM are 0°.

For RADIATION FIELDS shaped by a multi-element BLD, tests of the width of the PENUMBRA along their major axes shall be made

- for two 10 cm × 10 cm RADIATION FIELDS (or MANUFACTURER'S reference field size if 10 cm × 10 cm not available) placed along the diagonal of the maximum RADIATION FIELD in the manner indicated by Figure 11, and
- for the maximum (rectangular or square) RADIATION FIELD.

For RADIATION FIELDS utilized with SRT/SRS, tests shall be made of the maximum width of the PENUMBRA along the major axes of

- either a 1 cm diameter X-RAY FIELD, or as close as can be achieved to a 1 cm × 1 cm square X-RAY FIELD, and
- the maximum SRT/SRS RADIATION FIELD.

10 Indication of RADIATION FIELDS

10.1 X-RADIATION

10.1.1 Numerical field-indication

10.1.1.1 General

All equipment using static BLDs shall have a numerical field-indicator indicating the dimensions of the X-RAY FIELD at the NORMAL TREATMENT DISTANCE.

For a multi-element BLD (excluding binary BLDs, which are either open or closed) there shall be numerical indications of the coordinates, as defined by IEC 61217, of each element edge position projected to the NORMAL TREATMENT DISTANCE. Additionally, the dimension of the RADIATION FIELD defined by each pair of opposed elements may be indicated.

10.1.1.2 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum difference(s) between the numerical field-indication and the distances along the major axes of the points of 50 % ABSORBED DOSE determined according to 10.1.1.3.

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

The maximum difference(s) shall apply to all RADIATION FIELDS for which the smaller dimension is equal to or greater than 5 cm and for all angular positions of the GANTRY and of the BEAM LIMITING SYSTEM and for all NOMINAL ENERGIES.

For multi-element BLDs, the information required in this subclause shall be provided for the RADIATION FIELDS specified in 9.3.1.

For X-RAY FIELDS provided with SRT/SRS, the ACCOMPANYING DOCUMENTS shall state the maximum difference(s) between the numerical field-indication and the distances along the major axes of the points of 50 % ABSORBED DOSE determined according to 10.1.1.3.

The maximum difference shall be given in millimetres or as a percentage of the size of the RADIATION FIELD, for the smallest and maximum X-RAY FIELDS provided.

10.1.1.3 Test

NOTE The numerical field-indication of the X-RAY FIELD and the LIGHT FIELD are referred to the plane normal to the RADIATION BEAM AXIS at the NORMAL TREATMENT DISTANCE.

Because of the necessity of introducing BUILD UP material to determine the RADIATION FIELD, the LIGHT FIELD is obscured or distorted. Furthermore it is often difficult to make the necessary measurements accurately at angular positions of the GANTRY other than 0° and 90°.

For these reasons the test consists of a number of steps described in steps a) to c), see Figure 9.

a) Dose measurements

A PHANTOM is placed so that dose measurements can be made at the NORMAL TREATMENT DISTANCE under standardized test conditions (see Clause 6) and for angular positions of the GANTRY of 0° or 90° for all NOMINAL ENERGIES.

For each set of test conditions given in Table 18, the X-RAY FIELD is set using the numerical field-indication. For each X-RAY FIELD the RADIATION BEAM is scanned along the two major axes at the NORMAL TREATMENT DISTANCE.

The position of the points at which the ABSORBED DOSE is equal to 50 % of the ABSORBED DOSE on the RADIATION BEAM AXIS is so determined.

Table 18 – Conditions for film calibration

Angular position of GANTRY		RADIATION FIELD cm × cm ^b	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
BEAM LIMITING SYSTEM					
Axis ① ^a	Axis ④ ^a				
0° or 90°	0°	5 × 5	One	X-RADIATION	Each
		10 × 10			
		30 × 30			
^a See Figures 2, 3 and 4.					
^b X cm × X cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

b) Optical density measurements

Following each measurement according to step a) and without any change of RADIATION FIELD and NOMINAL ENERGY a slow RADIOGRAPHIC FILM is exposed under standardized test conditions (see Clause 6). The optical density is measured at the points of 50 % ABSORBED DOSE determined in step a).

c) Measurement of the dimensions of the X-RAY FIELD

The dimensions of the RADIATION FIELD are determined for each set of test conditions given in Table 19 under the following conditions:

- 1) the X-RAY FIELD is set using the numerical field-indication;
- 2) the RADIOGRAPHIC FILM is placed at the NORMAL TREATMENT DISTANCE and the edges of the LIGHT FIELD indicated are marked on the film. At least 5 cm water equivalent material is placed behind the RADIOGRAPHIC FILM;
- 3) the RADIOGRAPHIC FILM is covered by 10 cm water equivalent material to realize the STANDARD MEASUREMENT DEPTH;
- 4) after exposure the points of 50 % ABSORBED DOSE are determined by optical densitometry using the calibration data obtained in steps a) and b).

The measured dimensions of the X-RAY FIELD are compared with the numerical field-indicator and the dimensions of the indicated LIGHT FIELD.

Table 19 – Conditions for testing the numerical field indication and the LIGHT FIELD

Angular position of		RADIATION FIELD cm × cm ^b	Distance source to film	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
90°	0°	5 × 5	NORMAL TREATMENT DISTANCE	X-RADIATION	One
		10 × 10			
		20 × 20			
		30 × 30			
270°	90°	10 × 10	NORMAL TREATMENT DISTANCE	X-RADIATION	Maximum
		30 × 30			
0°	45°	10 × 10	NORMAL TREATMENT DISTANCE	X-RADIATION	Minimum
		Maximum			
180°	180°	10 × 10	NORMAL TREATMENT DISTANCE	X-RADIATION	One
0°	0°	Maximum	1,5 NORMAL TREATMENT DISTANCE	X-RADIATION	One
^a See Figures 2, 3 and 4. ^b X cm x X cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

For multi-element BLDs, the measurements described in this subclause shall be performed for the RADIATION FIELDS specified in 9.3.1, and for the set of other conditions specified in rows 2, and 3 of Table 19.

For SRT/SRS X-RAY FIELDS, tests shall be made for the smallest and maximum RADIATION FIELD sizes provided, according to the other conditions specified in Table 18, and Table 19.

10.1.2 LIGHT FIELD-INDICATOR

10.1.2.1 General

All equipment shall have a LIGHT FIELD-INDICATOR indicating the RADIATION FIELD on the entrance surface by means of light, unless an alternate method is provided to validate the accuracy of placement of the RADIATION FIELD. Such alternative means, as well as demonstration of the accuracy of the alternative means, shall be described in the ACCOMPANYING DOCUMENTS.

10.1.2.2 Information to the USER

The ACCOMPANYING DOCUMENTS shall state

- a) the maximum distance measured along the major axes between any edge of the LIGHT FIELD and the corresponding point of 50 % ABSORBED DOSE determined according to item a) of 10.1.1.3 at the NORMAL TREATMENT DISTANCE and at 1,5 times the NORMAL TREATMENT DISTANCE, and
- b) the maximum distance between the centre of the LIGHT FIELD and the RADIATION BEAM AXIS at the NORMAL TREATMENT DISTANCE and at 1,5 times the NORMAL TREATMENT DISTANCE.

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

The maximum distance(s) shall apply to all RADIATION FIELDS for which the smaller dimension is equal to or greater than 5 cm and for all angular positions of the GANTRY and of the BEAM LIMITING SYSTEM and for all NOMINAL ENERGIES.

For multi-element BLDs, the information required in this subclause shall be performed for the RADIATION FIELDS specified in 9.3.1.

For the smallest and maximum SRT/SRS X-RAY FIELDS provided, the ACCOMPANYING DOCUMENTS shall state the maximum distances for a). These distances shall be given in millimetres or shall be expressed as a percentage of the size of the RADIATION FIELD.

10.1.2.3 Test

For the test see 10.1.1.3 and 11.2.2.

For multi-element BLDs, the measurements described in this subclause shall be performed for the RADIATION FIELDS specified in 9.3.1.

For SRT/SRS X-RAY FIELDS, these tests shall be performed for the smallest and maximum RADIATION FIELDS provided.

10.1.3 Reproducibility

10.1.3.1 Information to the USER

10.1.3.1.1 Variation of size of X-RAY FIELD

The ACCOMPANYING DOCUMENTS shall state the maximum variation of the size of the X-RAY FIELD as determined by the points of 50 % ABSORBED DOSE according to step a) of 10.1.1.3 for repeated settings of the same numerical field-indication.

The maximum variation shall be given in millimetres.

10.1.3.1.2 Light field-indication

Where equipment is fitted with a LIGHT FIELD-INDICATOR the ACCOMPANYING DOCUMENTS shall state the maximum variation of the distance between any edge of LIGHT FIELD and the edge of the X-RAY FIELD for repeated settings of the same numerical field-indication.

The maximum variation of the distance shall be given in millimetres.

For multi-element BLDs the information required in this subclause shall be extended to include repeated numerical selections for the same RADIATION FIELDS specified in 9.3.1.

For SRT/SRS, the information required by this subclause shall be provided for the smallest and maximum symmetric RADIATION FIELDS.

10.1.3.2 Test

The test described in step c) of 10.1.1.3 is carried out six times for the test conditions given in Table 20 approaching the same setting of the numerical field-indicator alternatively from larger and smaller indicated values.

For multi-element BLDs the measurements described in this subclause shall be performed for the RADIATION FIELDS specified in 9.3.1.

Table 20 – Conditions for testing reproducibility of X-RAY FIELDS

Angular position of		RADIATION FIELD cm × cm	Distance RADIATION SOURCE to film	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	5 × 5 ^b	NORMAL TREATMENT DISTANCE	X-RADIATION	One
^a See Figures 2, 3 and 4. ^b 5 cm x 5 cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.					

For SRT/SRS, the measurements described shall be performed for the RADIATION FIELDS specified in 10.1.3.1.

10.1.4 Alignment of an SRS STEREOTACTIC FRAME OF REFERENCE with STEREOTACTIC REGISTRATION POINTS

10.1.4.1 Information to the USER

If the equipment uses a STEREOTACTIC FRAME OF REFERENCE for the purpose of guiding an SRS X-RAY BEAM, the ACCOMPANYING DOCUMENTS shall:

- identify the STEREOTACTIC REGISTRATION POINTS used to fix, or determine the position of, the PATIENT in the STEREOTACTIC FRAME OF REFERENCE;
- describe how the STEREOTACTIC REGISTRATION POINTS are fixed in, or otherwise located relative to, the STEREOTACTIC FRAME OF REFERENCE, during TREATMENT, and also during imaging, if applicable;
- state the accuracy with which the STEREOTACTIC REGISTRATION POINTS shall be located relative to the STEREOTACTIC FRAME OF REFERENCE, in mm.

10.1.4.2 Tests

Location accuracy is determined from 4 measurements of the positions of the anatomical registration points relative to the STEREOTACTIC FRAME OF REFERENCE in each of the longitudinal, lateral, and vertical directions of the PATIENT SUPPORT assembly, using a PHANTOM. Before each measurement (12 in total), the PHANTOM shall be removed and then replaced in the TREATMENT position. For each axis of the STEREOTACTIC FRAME OF REFERENCE, the accuracy is determined as the standard deviation of the 4 measurements made, in mm.

10.1.5 SRS X-RAY BEAM guidance

10.1.5.1 Information to the USER

If the equipment uses hardware and/or software means to guide the SRS X-RAY BEAM relative to the STEREOTACTIC FRAME OF REFERENCE, the ACCOMPANYING DOCUMENTS shall:

- a) describe the method used for guidance;
- b) state the accuracy, in mm, with which the central axis of the SRS X-RAY BEAM shall be located relative to the ISOCENTRE, which is defined in relation to the STEREOTACTIC FRAME OF REFERENCE. (see also 11.2)
- c) state how, during installation, and prior to ACCEPTANCE TESTS at site, the ISOCENTRE shall be tested and adjusted. In the tests described in 10.1.5.2, the coincidence between the X-RAY BEAM central axis and ISOCENTRE shall be measured (see also 12.1).

10.1.5.2 Test

Compliance is tested by inspection of the ACCOMPANYING DOCUMENTS.

10.2 ELECTRON RADIATION

10.2.1 Numerical field-indication

10.2.1.1 General

Where equipment is fitted with a LIGHT FIELD-INDICATOR it shall have a numerical field-indication of the dimensions of the ELECTRON RADIATION field.

For an ELECTRON RADIATION field shaped exclusively by a multi-element BLD, there shall be numerical indications of the coordinates, as defined by IEC 61217, of each element edge position defining the RADIATION FIELD. Additionally, the dimension of the RADIATION FIELD defined by each pair of opposed elements may be indicated.

10.2.1.2 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain information about the difference between the numerical field-indication and the size of the RADIATION FIELD at the STANDARD MEASUREMENT DEPTH as defined by the distances between the points of the 50 % ABSORBED DOSE on the major axes when the entrance surface of the PHANTOM is at the NORMAL TREATMENT DISTANCE.

The difference shall be given in millimetres.

The information shall cover all available RADIATION FIELDS and all NOMINAL ENERGIES.

10.2.1.3 Test

Compare the numerical field-indication with the size of the RADIATION FIELD determined from the test of 9.2.1.2 at the STANDARD MEASUREMENT DEPTH (see 6.6).

10.2.2 LIGHT FIELD-INDICATOR

10.2.2.1 General

All equipment shall have a LIGHT FIELD-INDICATOR indicating the dimensions of the ELECTRON FIELD on a surface.

10.2.2.2 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum difference between the value of the numerical field-indication and the distance between the edges of the LIGHT FIELD on a plane surface at the NORMAL TREATMENT DISTANCE.

The maximum difference shall be given in millimetres.

10.2.2.3 Test

The LIGHT FIELD on a surface at the NORMAL TREATMENT DISTANCE is measured along the two major axes for each set of test conditions given in Table 21.

If this is not possible, the measurement is made on a surface 10 cm beyond the NORMAL TREATMENT DISTANCE and the results of the measurement are corrected to the NORMAL TREATMENT DISTANCE.

**Table 21 – Conditions for testing the LIGHT FIELD-INDICATOR
for ELECTRON RADIATION**

Angular position of		RADIATION FIELD cm x cm	Distance from RADIATION SOURCE to surface
GANTRY	BEAM LIMITING SYSTEM		
Axis ① ^a	Axis ④ ^a		
0°	0°	Minimum	NORMAL TREATMENT DISTANCE ^b
		Maximum	
		Long and narrow	
^a See Figures 2, 3 and 4.			
^b Or 10 cm beyond NORMAL TREATMENT DISTANCE.			

For an ELECTRON RADIATION field shaped exclusively by a multi-element BLD, the measurements described shall be performed for RADIATION FIELDS of 5 cm × 5 cm, 5 cm × maximum, and the maximum (rectangular or square) RADIATION FIELD.

10.3 Geometry and motion speeds of adjustable BLDs for X-RADIATION and ELECTRON RADIATION

10.3.1 Information to the USER

For adjustable BEAM LIMITING SYSTEMS for both X RADIATION and ELECTRON RADIATION the ACCOMPANYING DOCUMENTS shall state:

- the maximum range of motion possible, in centimetres at NORMAL TREATMENT DISTANCE, including corresponding coordinates along axes X and Y (X_b and Y_b, see IEC 61217) for all adjustable RADIATION FIELD-defining BLDs in relation to the REFERENCE AXIS;
- the maximum and minimum speeds, in cm/s at NORMAL TREATMENT DISTANCE, by which any RADIATION FIELD-defining BLD can move;
- for rectangular RADIATION FIELDS defined by BLDs other than the multi-element type:
 - the maximum angular deviation, in degrees, from parallelism of the opposing edges and
 - the maximum angular deviation, in degrees, from the right angle of the adjacent edges;
- for multi-element BLDs:
 - the number of elements and their dimensions projected to the NORMAL TREATMENT DISTANCE (NTD);

NOTE In addition, the USER may require shape information.

- 2) the dimensions of the maximum RADIATION FIELD size at NTD, in centimetres, with coordinates stated along axes Xb and Yb (see IEC 61217);
- 3) the maximum distance, in centimetres at NTD, to which the edges of adjacent and opposed elements can be extended beyond one another;
- 4) the minimum and maximum distance, in centimetres at NTD, between opposed elements;
- 5) range of element-end travel at NTD, in centimetres, and the corresponding field coordinates in ($\pm$) cm;
- 6) with symmetrically opened element pairs, the maximum displacement of the RADIATION FIELD, in millimetres at NTD, when rotating the multi-element BLD through 180 degrees;
- 7) element-end position accuracy at NTD, in millimetres;
- 8) element-end position tolerances at NTD, in millimetres;
- 9) minimum and maximum specified element speed at NTD, in cm/s.

10.3.2 Test

Measurements are made directly on the BEAM LIMITING SYSTEM or on the LIGHT FIELD. For rectangular RADIATION FIELDS defined by BLDs other than the multi-element type, apply each set of test conditions given in Table 22 to determine angular deviations as defined in 10.3.1.

For multi-element BLDs, the test for displacement of the RADIATION FIELD should be performed with a 10 cm $\times$ 10 cm and the maximum (rectangular or square) RADIATION FIELD, with the GANTRY at 90°, and the BEAM LIMITING SYSTEM at 0°, 90°, 180°, and 270° where available.

10.4 Illuminance and PENUMBRA of the LIGHT FIELD

10.4.1 Information to the USER

Where a LIGHT FIELD-INDICATOR is present the ACCOMPANYING DOCUMENTS shall state

- a) the value of average illuminance in lux by the LIGHT FIELD-INDICATOR on a surface normal to the RADIATION BEAM axis at the NORMAL TREATMENT DISTANCE and
- b) the contrast ratio of illuminance along the edges of this indication when corrected for ambient lighting.

**Table 22 – Conditions for testing geometry
of the BEAM LIMITING SYSTEM**

Angular position of		RADIATION FIELD cm × cm
GANTRY	BEAM LIMITING SYSTEM	
Axis ① ^a	Axis ④ ^a	
90°	0°	10 × 10 ^b
	90°	
	180°	
	270°	
90°	0°	Maximum
	90°	
	180°	
	270°	
^a See Figures 2, 3 and 4.		
^b 10 cm x 10 cm or MANUFACTURER'S reference field size if not available. For standardised test condition see Clause 6.		

The contrast ratio is the ratio of the illuminance measured at two points on either side of the apparent edge of the field indicated by light and separated by a distance of 3 mm.

The average illumination shall be given in lux and the contrast ratio shall be expressed as a percentage.

10.4.2 Test

For this test the normal room lighting shall be dimmed.

The illuminance of the LIGHT FIELD is measured with an instrument having an aperture of 1 mm or less calibrated for the light spectrum used.

The average illuminance is determined from measurements made at the approximate centre of each of the quadrants of the field indicated by light.

11 Indication of the RADIATION BEAM AXIS

11.1 General

For RADIATION FIELDS which are symmetrical about the ISOCENTRE, the equipment shall have a device for indicating the RADIATION BEAM AXIS on entry to the PATIENT, for example: lasers, FRONT POINTER, cross hairs.

Devices such as a mechanical or optical BACK POINTER, for example a laser BACK POINTER, may also be provided to indicate the exit position of the beam axis.

Where an ELECTRONIC IMAGING DEVICE (e.g. EPID) is provided, a combination of physical position sensors and associated software algorithms may be used to determine the position of the X-RAY BEAM AXIS, within the range of distance from ISOCENTRE available to the ELECTRONIC IMAGING DEVICE. Another method, the use of a radio-opaque marker, is described in 11.2.2.