

Medical electrical equipment — Medical electron accelerators — Functional performance characteristics

The European Standard EN 60976:2001, with the incorporation of amendment A1:2000, has the status of a British Standard.

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BS 5724-3.1:
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(Amendment No. 2
renumbers
BS 5724-3.1:1990 as
BS EN 60976:2001)
and incorporating
Amendment No. 1 to
BS EN 60976:2001*

Committees responsible for this British Standard

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- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Institute of Radiology
- College of Radiographers
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Institute of Physical Sciences in Medicine
- Institution of Electrical Engineers
- National Radiological Protection Board
- Royal College of Radiologists

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National foreword

This British Standard has been prepared by Subcommittee 62C and is the English language version of EN 60976, including amendment A1:2000, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 60976, including amendment 1:2000, published by the International Electrotechnical Commission (IEC).

This standard details procedures by which the functional performance characteristics of MEDICAL ELECTRON ACCELERATORS used in radiotherapy may be determined and specified. Guidance in the application of this standard is given in BS 5724-3.1: Supplement 1.

Attention is drawn to BS 5724-2.1 which specifies the particular requirements for the safety of MEDICAL ELECTRON ACCELERATORS.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index,” or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional information. The following print types are used in this standard. Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice and general statements: in small roman type.

Terms defined in clause 2 of BS 5724-1 and BS 6641: SMALL CAPITALS.

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

In 7.2.1.2, line 3, “1 mm” should be replaced by “0,5 mm” to align the depth with that dimension in 7.2.4.

In 8.1.1.1, paragraph 2, line 2, “difference” should be replaced by “differences”.

In 8.2.1.2, line 1, “or” should be replaced by “of”.

In 9.1.1 (line 1); 9.2.1 (line 2); 10.2.1 (line 2) and 14.4.2.1 (line 1), “contain” should be replaced by “state”.

In the title of Figure 5, line 2, “halfs” should be replaced by “halves”.

In Appendix A.1, page 48, the term and reference “TERMINATION OF IRRADIATION ... A.2.78 should be inserted before “TO TERMINATE IRRADIATION”.

In Appendix B, page 53, at reference 7.2.1 (line 1), “base depth” should be replaced by “BASE DEPTH”.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 66, an inside back cover and a back cover.

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English version

Medical electrical equipment — Medical electron accelerators — Functional performance characteristics

(includes amendment A1:2000)
(IEC 60976:1989 + A1:2000)

Appareils électromédicaux —
Accélérateurs médicaux d'électrons —
Caractéristiques fonctionnelles
(inclut l'amendement A1:2000)
(CEI 60976:1989 + A1:2000)

Medizinische elektrische Geräte —
Medizinische Elektronenbeschleuniger —
Apparative Qualitätsmerkmale
(enthält Änderung A1:2000)
(IEC 60976:1989 + A1:2000)

This European Standard was approved by CENELEC on 1999-04-01. Amendment A1 was approved by CENELEC on 2000-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of the International Standard IEC 60976:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 583 S1 on 1991-03-15.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60976 on 1999-04-01.

The following date was fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2000-04-01

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

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Appendix A and Appendix B are informative.

Annex ZA has been added by CENELEC.

Foreword to amendment A1

The text of document 62C/276/FDIS, future amendment 1 to IEC 60976:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60976:1999 on 2000-11-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-08-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2003-11-01

This European Standard is to be read in conjunction with EN 60601-2-1.

Introduction

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

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

Since this standard does not contain safety requirements it has not been numbered in the IEC 601 publication series. It describes aspects of functional performance of 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 the 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 ELECTRON ACCELERATOR conforms with the declared functional performance during the course of its working lifetime. Guidance on the values which may be expected are given in the Report, IEC Publication 977.

1 Scope and object

1.1 Scope

1.1.1 This standard applies to MEDICAL ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

1.1.2 This standard applies to 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.

1.1.3 The present standard describes a set of measurements requiring two to three months' work to complete. It specifies 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 Publication 977, however, does suggest that many of the test procedures are appropriate for acceptance tests.

1.1.4 The measurement conditions described in the present standard differ from those currently 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 present methods.

1.2 Object

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 an 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 Appendix B.

It is recognized that inaccuracies in the test methods must be allowed for when assessing performance. However, it is 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 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.

1.3 Environmental conditions

1.3.1 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).

1.3.2 Transport and storage

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

1.3.3 Power supply

Sub-clause 1.4b) 2) of IEC Publication 601-1, first edition, 1977, applies.¹⁾

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

2 Terminology

2.1 Definitions

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

New additional terms are listed in Appendix A.

An index of the terms referring to the above-mentioned source is also given in Appendix A.

2.2 Degree of requirements

In this standard the auxiliary verb:

- “shall” implies that compliance with a requirement is mandatory for compliance with the standard;
- “should” implies that compliance with a requirement is strongly recommended but is not mandatory for compliance with the standard;
- “may” implies that compliance with a requirement is permitted to be accomplished in a particular manner for compliance with the standard.

3 General information to the USER

The ACCOMPANYING DOCUMENTS shall state all functional performance characteristics contained in Clauses 5, 6, 7, 8, 9, 10, 11, 12 and 13 and the information required in Sub-clauses 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8.

3.1 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 $\times$ 10 cm RADIATION FIELDS for both X-RADIATION and ELECTRON RADIATION.

¹⁾ See also Sub-clause 10.2.2 in the second edition, 1988.

3.2 Available RADIATION FIELDS

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

For a multi-element BLD, the ACCOMPANYING DOCUMENTS shall state:

- the number of elements;
- their dimensions projected to the NORMAL TREATMENT DISTANCE;
- the dimensions of their minimum and maximum RADIATION FIELD sizes, with coordinates stated along axes Xb and Yb (see IEC 61217); and
- the location of these RADIATION FIELDS in relation to the REFERENCE AXIS.

3.3 NORMAL TREATMENT DISTANCE

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

3.4 Available filters

The ACCOMPANYING DOCUMENTS shall state for X-RADIATION and ELECTRON RADIATION the designation, the NOMINAL ENERGY and the maximum square RADIATION FIELD (square corners) of the available FIELD FLATTENING FILTERS.

For each available WEDGE FILTER for X-RADIATION the ACCOMPANYING DOCUMENTS shall state the:

- designation;
- NOMINAL ENERGY;
- maximum RADIATION FIELD (for which the WEDGE FILTER is designed);
- WEDGE FILTER ANGLE;
- isodose value used for the determination of WEDGE FILTER ANGLE for the specified X-RAY FIELD;
- WEDGE FILTER FACTOR.

The ACCOMPANYING DOCUMENTS shall contain examples of isodose charts measured with the surface of the PHANTOM as indicated in Sub-clause 4.2 obtained using WEDGE FILTERS and FIELD FLATTENING FILTERS of the same design 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.

3.5 Availability

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

3.6 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.

3.7 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.

3.8 Presentation

The information to the USER required by this standard should be provided in the format shown in Appendix B.

3.9 Dimensions, shapes, 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:

- the NORMAL TREATMENT DISTANCE;
- 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;
- the thicknesses of all BLDs; and
- the dimensions and location, relative to the NORMAL TREATMENT DISTANCE or to the X-RADIATION source, of:
 - the fixed RADIATION HEAD surface, proximal to the NORMAL TREATMENT DISTANCE, to which demountable ACCESSORIES may be attached; and
 - 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.

4 Standardized test conditions

In determining functional performance characteristics in accordance with this standard, standardized test conditions given in Sub-clauses 4.1, 4.2, 4.3, 4.4 and 4.5 shall prevail unless otherwise required.

4.1 Angle settings

The angles of:

- the roll of the RADIATION HEAD, Axis ②;
- the pitch of the RADIATION HEAD, Axis ③;
- rotation of the BEAM LIMITING SYSTEM, Axis ④;

are at zero unless otherwise required. See Figure 1, Figure 2 and Figure 3.

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, Axis ④, of 90° only, it is equally acceptable to use the angular position of 270°.

4.2 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 10 cm greater than the depth of the measuring point.

4.3 Positioning of measuring points

Measurements are made unless otherwise required:

- on the RADIATION BEAM AXIS; or
- 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.

4.4 RADIATION DETECTORS

Measurements are made with a RADIATION DETECTOR:

- from whose SCALE READINGS relative ABSORBED DOSE can be determined when corrections for spatial changes of the RADIATION SPECTRUM are made; and
- that has adequate spatial resolution in regions of high dose gradients, for example at the edges of the RADIATION FIELD.

4.5 STANDARD MEASUREMENT DEPTHS

4.5.1 X-RAY BEAMS

The STANDARD MEASUREMENT DEPTH for measurements in the X-RAY BEAM is 10 cm.

4.5.2 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.

4.6 RADIATION FIELDS

Where in the test procedure RADIATION FIELDS of specified sizes are not available, the nearest available RADIATION FIELDS should be used. The sizes of RADIATION FIELDS are quoted for the NORMAL TREATMENT DISTANCE.

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

Except as otherwise indicated, all measurements shall be performed with symmetrical rectangular or square RADIATION FIELDS.

The ACCOMPANYING DOCUMENTS shall state that when asymmetrical and irregular RADIATION FIELDS are considered, the functional performance characteristic under investigation may differ from that obtained from symmetrical rectangular or square RADIATION FIELDS, as in the case, for example, of clauses 5, 6 and 7.

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.

4.7 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.

5 DOSE MONITORING SYSTEM

The ACCOMPANYING DOCUMENTS shall state the information to the USER required in Clause 5:

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

The ACCOMPANYING DOCUMENTS shall state 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.

5.1 Reproducibility

5.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the maximum coefficient of variation of the ratio of the measured values of DOSE MONITOR UNITS and the ABSORBED DOSE 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 shall be expressed as a percentage.

The maximum coefficient of variation shall apply for:

- all NOMINAL ENERGIES;
- all ABSORBED DOSE RATES.

5.1.2 Test

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

$$s = \frac{100}{\bar{R}} \sqrt{\sum_{i=1}^n \frac{(\bar{R} - R_i)^2}{n-1}} \quad \%$$

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 × cm	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 Figure 1, Figure 2 and Figure 3.

5.2 Proportionality

5.2.1 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.

5.2.2 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 Sub-clause 5.2.1.

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.

5.2.3 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 × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
Axis ① ^a	Axis ④ ^a				
0°	0°	10 × 10	Each ^b	X-RADIATION	Each
				ELECTRON RADIATION	

^a See Figure 1, Figure 2 and Figure 3.
^b If continuously variable, with four ABSORBED DOSE RATES over the range from 20 % to maximum.

5.3 Dependence on angular positions

5.3.1 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.

5.3.2 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, 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		RADIATION FIELD cm × cm	ABSORBED DOSE RATE	RADIATION TYPE	NOMINAL ENERGY
GANTRY	BEAM LIMITING SYSTEM				
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 Figure 1, Figure 2 and Figure 3.

5.4 Dependence on GANTRY rotation

5.4.1 Information to the USER

For equipment which has a facility for MOVING BEAM RADIOTHERAPY 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 this full angular range (as for MOVING BEAM RADIOTHERAPY); and
- the mean of the greatest and least values of the ratio $\bar{R}$ determined according to Sub-clause 5.3 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.

5.4.2 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 resulting 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 range of GANTRY	Angular position of BEAM LIMITING SYSTEM	RADIATION FIELD cm × cm	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 Figure 1, Figure 2 and Figure 3.

5.5 Dependence on the shape of the RADIATION FIELD

5.5.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall state the dependence of the calibration of the DOSE MONITORING SYSTEM on 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.

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

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

^b With scale ④ at zero, X ⑭ is the dimension parallel to axis ① or f and Y ⑮ is the perpendicular dimension.

^c See Figure 1, Figure 2 and Figure 3.

5.6 Stability of calibration

5.6.1 Stability after high ABSORBED DOSE delivered

5.6.1.1 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:

- immediately following the ELECTRON ACCELERATOR having reached the READY STATE after an extended period in the STAND-BY STATE; and
- immediately after;
 - the delivery of an ABSORBED DOSE of 100 Gy under standard test conditions; or
 - 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.

5.6.1.2 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:

- immediately following a period of at least 3 h in which the ELECTRON ACCELERATOR is maintained in the STAND-BY STATE; and
- immediately following an IRRADIATION of 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 × cm	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 Figure 1, Figure 2 and Figure 3.

5.6.2 Stability throughout the day

5.6.2.1 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.

5.6.2.2 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 Sub-clause 5.6.2.1.

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

5.6.3 Stability throughout the week

5.6.3.1 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 $\bar{R}$.

5.6.3.2 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.

5.7 Stability in MOVING BEAM RADIOTHERAPY

5.7.1 Information to the USER

If in MOVING BEAM RADIOTHERAPY 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.

If in MOVING BEAM RADIOTHERAPY 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.

5.7.2 Test

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

- an ABSORBED DOSE of 4 Gy; or
- 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 × cm	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 Figure 1, Figure 2 and Figure 3.

6 Depth ABSORBED DOSE characteristics

6.1 X-RADIATION

6.1.1 Depth dose charts

6.1.1.1 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.

Charts shall be given for each selectable NOMINAL ENERGY of X-RADIATION under standardized test conditions (see Clause 4).

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.

6.1.1.2 Test

The depth dose distribution along the RADIATION BEAM AXIS is measured in a water PHANTOM under standardized test conditions (see Clause 4) 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

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 × Maximum	One	X-RADIATION	Each

^a Figure 1, Figure 2 and Figure 3.

6.1.2 SURFACE DOSE

6.1.2.1 Information to the USER

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

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 4).

6.1.2.2 Test

The RELATIVE SURFACE DOSE is measured on the RADIATION BEAM AXIS under standardized test conditions (see Clause 4) and for the set of test conditions given in Table 8.

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.

6.1.3 Isodose charts

6.1.3.1 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 4).

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.

6.1.3.2 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.

6.2 ELECTRON RADIATION

6.2.1 Depth dose charts

6.2.1.1 Information to the USER

The ACCOMPANYING DOCUMENTS shall contain charts 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 4).

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.

6.2.1.2 Test

The depth dose distribution along the RADIATION BEAM AXIS is measured in a water PHANTOM under standardized test conditions (see Clause 4) and for the set of test conditions given in Table 9.

Table 9 — Conditions for testing depth dose characteristics

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	One	ELECTRON RADIATION	Each
		Maximum			

^a See Figure 1, Figure 2 and Figure 3.

6.2.2 Stability of PENETRATIVE QUALITY

6.2.2.1 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.

6.2.2.2 Test

Measurements are made in a solid PHANTOM attached to the RADIATION HEAD. The PHANTOM shall be suitable for measurements of ABSORBED DOSE on the RADIATION BEAM AXIS at approximately DEPTH OF DOSE MAXIMUM and at the depth of 80 % of maximum ABSORBED DOSE.

Table 10 — Conditions for testing stability of PENETRATIVE QUALITY of 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°	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 Figure 1, Figure 2 and Figure 3.

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 Sub-clause 6.2.1.

6.2.3 SURFACE DOSE

6.2.3.1 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.

6.2.3.2 Test

The RELATIVE SURFACE DOSE is measured on the RADIATION BEAM AXIS under standardized test conditions (see Clause 4) 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.

6.2.4 Isodose charts

6.2.4.1 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 4).

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.

6.2.4.2 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.

7 Uniformity of RADIATION FIELDS

7.1 X-RADIATION

7.1.1 Flatness of square X-RAY FIELDS

7.1.1.1 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).

The flattened area is defined by straight lines joining points on the major axes and diagonals of square fields as shown in Figure 4 and according to Table 11.

Table 11 — Flattened area according to Figure 4

Square RADIATION FIELD F in cm	Dimensions defining the flattened area	
	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 4).

Some typical profiles of ABSORBED DOSE over X-RAY FIELDS are shown in Figure 5.

The ACCOMPANYING DOCUMENTS shall contain a chart showing the ratio of the maximum ABSORBED DOSE in the X-RAY FIELD of 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°.

7.1.1.2 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 means of 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	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 Figure 1, Figure 2 and Figure 3.

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

7.1.2.1 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 and the corresponding ABSORBED DOSE on the RADIATION BEAM AXIS.