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Elektrisk utrustning för medicinskt bruk – Medicinska elektronacceleratorer – Funktionsegenskaper och prestanda

*Medical electrical equipment –
Medical electron accelerators –
Functional performance characteristics*

Som svensk standard gäller europastandarden EN 60976:2007. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60976:2007.

Nationellt förord

Europastandarden EN 60976:2007

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60976, Second edition, 2007 - Medical electrical equipment - Medical electron accelerators - Functional performance characteristics**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60976, utgåva 1, 1999 och SS-EN 60976/A1, utgåva 1, 2001, gäller ej fr o m 2010-11-01.

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English version

**Medical electrical equipment -
Medical electron accelerators -
Functional performance characteristics
(IEC 60976:2007)**

Appareils électromédicaux -
Accélérateurs médicaux d'électrons -
Caractéristiques fonctionnelles
de performance
(CEI 60976:2007)

Medizinische elektrische Geräte -
Medizinische Elektronenbeschleuniger -
Apparative Qualitätsmerkmale
(IEC 60976:2007)

This European Standard was approved by CENELEC on 2007-11-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

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

Foreword

The text of document 62C/429/FDIS, future edition 2 of IEC 60976, 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 EN 60976 on 2007-11-01.

This European Standard supersedes EN 60976:1999 + A1:2000.

EN 60976:2007 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 (PWF);
- STEREOTACTIC RADIOTHERAPY (SRT) / STEREOTACTIC RADIOSURGERY (SRS);
- use of ELECTRONIC IMAGING DEVICES.

This standard, together with IEC/TR 60977, is to be used in conjunction with EN 60601-2-1.

The following dates were 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) 2008-08-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2010-11-01

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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60976:2007 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60580	2000	Medical electrical equipment - Dose area product meters	EN 60580	2000
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-2-1 A1	1998 2002	Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV	EN 60601-2-1 A1	1998 2002
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	–	–
IEC 60977	– ¹⁾	Medical electrical equipment - Medical electron accelerators in the range of 1 MeV to 50 MeV - Guidelines for functional performance characteristics	–	–
IEC 61217	– ¹⁾	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996 ²⁾
IEC 61223-1	1993	Evaluation and routine testing in medical imaging departments - Part 1: General aspects	–	–

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

CONTENTS

1	Scope.....	9
2	Normative references	10
3	Terms and definitions	10
4	Environmental conditions.....	14
4.1	General.....	14
4.2	Transport and storage	14
4.3	Power supply.....	14
5	General information to the USER	14
5.1	Functional performance characteristics	14
5.2	Available nominal energies and ABSORBED DOSE RATES	14
5.3	Available RADIATION FIELDS	15
5.4	NORMAL TREATMENT DISTANCE.....	15
5.5	Available WEDGE X-RAY FIELDS	15
5.6	Available flattening FILTERS	15
5.7	Availability.....	16
5.8	Influencing quantities	16
5.9	Maintenance.....	16
5.10	Presentation.....	16
5.11	Dimensions, clearances, within the RADIATION HEAD, and in the region RADIATION HEAD to ISOCENTRE, of BEAM LIMITING DEVICES	16
5.12	IMRT	16
6	Standardized test conditions.....	17
6.1	General.....	17
6.2	Angle settings	17
6.3	Properties and positioning of the PHANTOM	17
6.4	Positioning of measuring points.....	17
6.5	RADIATION DETECTORS.....	17
6.6	STANDARD MEASUREMENT DEPTHS.....	18
6.7	RADIATION FIELDS	18
6.8	Adjustments during test.....	18
6.9	Use of RADIOGRAPHIC FILM or alternative imaging method.....	18
7	DOSE MONITORING SYSTEM	18
7.1	General.....	18
7.2	Reproducibility	19
7.3	Proportionality.....	20
7.4	Dependence on angular positions.....	21
7.5	Dependence on GANTRY rotation.....	22
7.6	Dependence on the shape of the RADIATION FIELD	22
7.7	Stability of calibration	23
7.8	Stability in MOVING BEAM RADIOTHERAPY.....	25
8	Depth ABSORBED DOSE characteristics	26
8.1	X-RADIATION	26
8.2	ELECTRON RADIATION	28

9	Uniformity of RADIATION FIELDS	31
9.1	X-RADIATION	31
9.2	ELECTRON RADIATION	36
9.3	PENUMBRA of RADIATION FIELDS.....	38
10	Indication of RADIATION FIELDS.....	39
10.1	X-RADIATION	39
10.2	ELECTRON RADIATION	45
10.3	Geometry and motion speeds of adjustable BLDs for X-RADIATION and ELECTRON RADIATION	46
10.4	Illuminance and PENUMBRA of the LIGHT FIELD.....	47
11	Indication of the RADIATION BEAM AXIS.....	48
11.1	General.....	48
11.2	Indication on entry to the PATIENT	49
11.3	Indication on exit from the PATIENT	51
12	ISOCENTRE	52
12.1	Displacement of the RADIATION BEAM AXIS from the ISOCENTRE	52
12.2	Indication of the ISOCENTRE	53
13	Indication of distance along the RADIATION BEAM AXIS	53
13.1	Indicating device	53
13.2	Additional indicating device for equipment with variable distance between RADIATION SOURCE and ISOCENTRE and for non-isocentric equipment.....	54
14	Zero position of rotational scales	55
14.1	General.....	55
14.2	Information to the USER	55
14.3	Tests.....	55
15	Congruence of opposed RADIATION FIELDS	56
15.1	Information to the USER	56
15.2	Test.....	56
16	Movements of the PATIENT table.....	57
16.1	General.....	57
16.2	Vertical movement of the table	57
16.3	ISOCENTRIC rotation of the table	58
16.4	Parallelism of table rotational axes.....	58
16.5	Rigidity of the table	59
17	ELECTRONIC IMAGING DEVICE (e.g. EPID).....	60
17.1	Information to the USER	60
17.2	Tests.....	62
	Annex A (informative) Format for presentation of functional performances values.....	75
	Index of defined terms	96
	Figure 1 – Explanatory diagram for the definition of wedge	64
	Figure 2 – The rotary GANTRY.....	65
	Figure 3 – The wall- or floor-mounted GANTRY	66
	Figure 4 – The ceiling-mounted GANTRY	67
	Figure 5 – Flattened area (shown hatched) within the RADIATION FIELD	68

Figure 6 – Examples of profiles of ABSORBED DOSE along the major axes or the diagonal axes	69
Figure 7 – Explanatory diagram for flatness of the ELECTRON FIELD	70
Figure 8 – A possible arrangement of equipment for the measurement of the ISOCENTRE described in Clause 12	71
Figure 9 – Test 10.1.1.3.....	72
Figure 10 – RADIATION HEAD showing X-RADIATION BLDs and ACCESSORIES (see 4.11).....	73
Figure 11 – Multi-element BLD RADIATION FIELDS used for measurement of X-RADIATION PENUMBRA (see 8.3.2).....	74
Table 1 – Conditions for testing reproducibility.....	19
Table 2 – Conditions for testing proportionality of the DOSE MONITORING SYSTEM.....	20
Table 3 – Conditions for testing dependence of the DOSE MONITORING SYSTEM on equipment position.....	21
Table 4 – Conditions for testing dependence of the DOSE MONITORING SYSTEM on GANTRY rotation.....	22
Table 5 – Conditions for testing dependence on the shape of the RADIATION FIELD.....	23
Table 6 – Conditions for testing stability of calibration of the DOSE MONITORING SYSTEM.....	24
Table 7 – Conditions for testing stability of the DOSE MONITORING SYSTEM in MOVING BEAM RADIOTHERAPY	26
Table 8 – Conditions for testing depth dose characteristics.....	27
Table 9 – Conditions for testing depth dose characteristics.....	29
Table 10 – Conditions for testing stability of PENETRATIVE QUALITY of ELECTRON RADIATION.....	29
Table 11 – Flattened area according to Figure 5	31
Table 12 – Conditions for testing flatness and symmetry of X-RAY FIELDS	32
Table 13 – Conditions for testing deviation of dose distribution of X-RAY FIELDS with angular position	33
Table 14 – Conditions for testing maximum ABSORBED DOSE ratio in the RADIATION FIELD	34
Table 15 – Conditions for testing WEDGE FACTORS	35
Table 16 – Conditions for testing WEDGE ANGLES	35
Table 17 – Conditions for testing flatness, symmetry, deviation of dose distribution with angular position, and maximum ABSORBED DOSE ratio of ELECTRON FIELDS	37
Table 18 – Conditions for film calibration	41
Table 19 – Conditions for testing the numerical and the LIGHT FIELD-INDICATION.....	42
Table 20 – Conditions for testing reproducibility of X-RAY FIELDS	44
Table 21 – Conditions for testing the LIGHT FIELD-INDICATOR for ELECTRON RADIATION	46
Table 22 – Conditions for testing geometry of the BEAM LIMITING SYSTEM	48
Table 23 – Conditions for testing the indication of the RADIATION BEAM AXIS on entry to the PATIENT	50
Table 24 – Conditions for testing the indication of the RADIATION BEAM AXIS on exit from the PATIENT	51

Table 25 – Conditions for testing indication of the ISOCENTRE.....	53
Table 26 – Conditions for testing vertical movement of the table.....	58
Table 27 – Conditions for testing ISOCENTRIC rotation of the table	58
Table 28 – Conditions for testing the angulation of rotational axes of the table	59
Table 29 – Conditions for testing lateral rigidity of the table	60

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*