SVENSK STANDARD SS-EN 60976

Fastställd	Utgåva	Sida	Ansvarig kommitté
2008-03-25	2	1 (1+97)	SEK TK 62BC

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.

ICS 11.040.50; 13.280

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60976

December 2007

ICS 11.040.50; 13.280

Supersedes EN 60976:1999 + A1:2000

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)

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

Ref. No. EN 60976:2007 E

SEK Svensk Elstandard

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.

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Endorsement notice

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

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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.

Publication	Year	Title	EN/HD	Year
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

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 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*