National Standards Authority of Ireland
Údarás um Chaighdeáin Náisiúnta na hÉireann

IRISH STANDARD

I.S. EN 60976:2007

ICS 11.040.50
13.280

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland
Tel: +353 1 807 3800
Fax: +353 1 807 3838
http://www.nsai.ie

Sales
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MEDICAL ELECTRICAL EQUIPMENT - MEDICAL ELECTRON ACCELERATORS - FUNCTIONAL PERFORMANCE CHARACTERISTICS (IEC 60976:2007 (EQV))

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
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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)

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

Ref. No. EN 60976:2007 E

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.