Medical electrical equipment - Medical electron accelerators - Functional performance characteristics

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EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60976:2008 sisaldab Euroopa standardi EN 60976:2007 ingliskeelset teksti.	This Estonian standard EVS-EN 60976:2008 consists of the English text of the European standard EN 60976:2007.
Standard on kinnitatud Eesti Standardikeskuse 20.02.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 20.02.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 07.12.2007.	Date of Availability of the European standard text 07.12.2007.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.50, 13.280

Võtmesõnad: characteristics, electron accelerators, functional, medical electrical equipment, performance

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60976

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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

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

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 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.