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Edition 2.0 2007-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Medical electron accelerators – Functional performance characteristics

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Appareils électromédicaux – Accélérateurs médicaux d'électrons – Caractéristiques fonctionnelles de performance

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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IEC 60976:2007
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CONTENTS

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60976:2007
https://standards.iteh.ai/catalog/standards/sist/3a0c4e94-e857-42ef-b0e6-3aac6b3f51c2/iec-60976-2007

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60976:2007
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(standards.iteh.ai)
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(standards.iteh.ai)
IEC 60976:2007
https://standards.iteh.ai/catalog/standards/sist/3a0cfe94-c637-42ef-b0c6-3aac6b3f51c2/iec-60976-2007

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MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – FUNCTIONAL PERFORMANCE CHARACTERISTICS

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International standard IEC 60976 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989. It constitutes a technical revision.

This second edition 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;
– STEREOTACTIC RADIOTHERAPY (SRT) / STEREOTACTIC RADIOSURGERY (SRS);

– use of ELECTRONIC IMAGING DEVICES.

This standard, together with IEC TR 60977, should be read in conjunction with IEC 60601-2-1.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/429/FDIS	62C/433/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
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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.

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IEC 60976:2007
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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.

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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.

IEC 60976:2007
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3ea4d3ff1b2/iec-60976-2007

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*

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3 Terms and definitions

IEC 60976:2007
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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.

3.5
ELECTRONIC IMAGING DEVICE
EID
device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

NOTE See also 3.6.

3.6
ELECTRONIC PORTAL IMAGING DEVICE
EPID
device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed normal to the RADIATION BEAM AXIS, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen, using the medical ELECTRON ACCELERATOR'S RADIATION BEAM as the RADIATION SOURCE

NOTE The primary function of an EPID is in verification of PATIENT set-up, and so replaces the need for port-films for this same purpose.

3.7
GEOMETRICAL FIELD SIZE
geometrical projection as seen from the centre of the front surface of the RADIATION SOURCE on a plane perpendicular to the axis of the beam of the distal end of the BEAM LIMITING DEVICE

NOTE The field is thus of the same shape as the aperture of the BEAM LIMITING DEVICE. The GEOMETRICAL FIELD SIZE may be defined at any distance from the VIRTUAL SOURCE.

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3.8
IMAGE-GUIDED RADIOTHERAPY
IGRT
IEC 60976:2007
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RADIOTHERAPY process by which the location of a RADIOTHERAPY BEAM relative to the intended TARGET VOLUME within a PATIENT'S anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of beam to TARGET VOLUME

3.9
INTENSITY-MODULATED RADIATION THERAPY
IMRT
TREATMENT procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the PATIENT, and beam size; either in a continuous or a discrete manner, and as pre-determined by a TREATMENT plan

NOTE The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned TARGET VOLUME, while minimizing dose to surrounding healthy tissue.

3.10
ISOCENTRIC
used in presence of an ISOCENTRE

3.11
ISOCENTRIC EQUIPMENT
equipment for RADIOTHERAPY designed and constructed in such a manner that it has an ISOCENTRE

3.12
ISOCENTRIC TREATMENT
<RADIOTHERAPY> TREATMENT of a PATIENT in which the position of the TARGET VOLUME is referred to the ISOCENTRE

3.13
NOMINAL ENERGY
ENERGY
ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

3.14
NORMAL TREATMENT DISTANCE
NTD
<ELECTRON RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane

<X-RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

3.15
PENETRATIVE QUALITY
depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is 80 % of the dose at the DEPTH OF DOSE MAXIMUM, measured on the RADIATION BEAM AXIS in a SPECIFIED RADIATION FIELD and with the surface of the PHANTOM at a SPECIFIED distance

3.16
PRACTICAL RANGE
<ELECTRON RADIATION> depth in a PHANTOM with its surface at the NORMAL TREATMENT DISTANCE, for which on the depth dose chart the extrapolation of the steepest fall-off section of the ABSORBED DOSE distribution along the RADIATION BEAM AXIS intercepts the extrapolated tail of the ABSORBED DOSE distribution

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3.17
PRIMARY-SECONDARY DOSE MONITORING SYSTEM
combination of two DOSE MONITORING SYSTEMS in which one is arranged to be the PRIMARY DOSE MONITORING SYSTEM and the other is to be the SECONDARY DOSE MONITORING SYSTEM

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3.18
PROGRAMMABLE WEDGE FIELD
PWF
generation of a wedge-shaped dose profile, with or without the use of a fixed metal WEDGE FILTER placed in the X-RAY BEAM, where the programmed wedge DOSE profile may be generated by controlling the relationship between the beam intensity and a moveable BEAM LIMITING DEVICE

3.19
QUALITY INDEX
<X-RADIATION> ratio of the ABSORBED DOSE measured at a depth of 20 cm to that measured at a depth of 10 cm

NOTE The detector is at the NORMAL TREATMENT DISTANCE. The measurement is made in a PHANTOM on the RADIATION BEAM AXIS for a RADIATION FIELD of 10 cm × 10 cm.

3.20
RADIATION TYPE
nature of the waves or corpuscles comprising the RADIATION, for example whether the RADIATION is X-RADIATION or ELECTRON RADIATION

3.21
REDUNDANT DOSE MONITORING SYSTEM
combination of two DOSE MONITORING SYSTEMS in which both systems are arranged to be the PRIMARY DOSE MONITORING SYSTEM

3.22
RELATIVE SURFACE DOSE
ratio of the ABSORBED DOSE on the RADIATION BEAM AXIS at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS both measured in a PHANTOM with its surface at a specified distance

[IEC 60601-2-1:1998, definition 2.1.116, modified]

3.23
SIGNAL-TO-NOISE RATIO
<RADIOTHERAPY> mean value of the signal divided by the standard deviation, of the signal from the image pixels, for a uniform input fluence

NOTE The SIGNAL-TO-NOISE RATIO is expressed as % or decibels.

3.24
STANDARD MEASUREMENT DEPTH
<IONIZING RADIATION> specified depth in a PHANTOM

3.25
STEREOTACTIC FRAME OF REFERENCE
three-dimensional coordinate system for numerical specification of the position of those parts of a PATIENT'S anatomy intended for SRS/SRT TREATMENT

3.26
STEREOTACTIC RADIOSURGERY
SRS
specific version of STEREOTACTIC RADIOTHERAPY, in which a single high dose of RADIATION is delivered to the TARGET VOLUME, using a STEREOTACTIC FRAME OF REFERENCE in conjunction with anatomical registration points

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IEC 60976:2007
https://standards.iteh.ai/catalog/standards/sist/3a0cfe94-c637-42ef-b0c6-3aac6b3f51c2/iec-60976-2007

3.27
STEREOTACTIC RADIOTHERAPY
SRT
TREATMENT procedure in which RADIATION BEAMS of generally small size are oriented from various angles, and precisely positioned relative to a TARGET VOLUME within the PATIENT

NOTE Precise location of the TARGET VOLUME is enabled by use of a three-dimensional frame of reference, which may include anatomical registration points or markers, and immobilisation methods, or imaging techniques.

3.28
STEREOTACTIC REGISTRATION POINT
reference point on the PATIENT'S anatomy, used to establish the STEREOTACTIC FRAME OF REFERENCE for an SRS/SRT TREATMENT

3.29
TERMINATE RADIATION
to stop IRRADIATION without the possibility of restarting without reselection of operating conditions

NOTE That means returning to the PREPARATORY STATE

– when the pre-selected value of DOSE MONITOR UNITS is reached, or

– when the pre-selected value of elapsed time is reached, or

– by deliberate manual act, or

– by the operation of an INTERLOCK, or

– by pre-selected value of GANTRY angular position in MOVING BEAM RADIOTHERAPY.