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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy

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Appareils électromédicaux – Dosimètres à chambres d'ionisation utilisés en radiothérapie

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MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

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International Standard IEC 60731 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 third edition cancels and replaces the second edition published in 1997 and its Amendment 1 (2002) and constitutes a technical revision. The technical modifications versus the second edition of this standard concerns performance requirements of RADIOTHERAPY DOSIMETERS intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA in heavy ion RADIATION FIELDS and SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

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

FDIS	Report on voting
62C/506/FDIS	62C/511/RVD

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

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: 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.

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INTRODUCTION

This International Standard is applicable to the performance of RADIOTHERAPY DOSIMETERS with IONIZATION CHAMBERS as used in RADIOTHERAPY.

The effectiveness of treatment of PATIENTS receiving RADIOTHERAPY depends on the accuracy of the dose of radiation received, as well as on the accuracy of their spatial distribution. An excessive dose can lead to excessive tissue damage, while an insufficient dose will not provide the therapeutic benefit sought. The equipment covered by this standard plays an essential part in achieving the required accuracy.

This standard is not concerned with the safety aspects of dosimeters. The relevant IEC standards covering safety depend upon the way in which the dosimeter is used:

– if it is used in the PATIENT environment, the requirements for safety applying to dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 60601-1;
– if it is not used in the PATIENT environment, then the safety requirements for dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 61010-1.

Dosimeters which comply with this standard should nevertheless be used in accordance with the relevant national or international dosimetry protocol (code of practice). In particular, measurements should be made to determine the ion collection efficiency and polarity effect of the chamber under the exact conditions of use.

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MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

1 Scope and object

1.1 Scope

This International Standard specifies the performance requirements of RADIOTHERAPY DOSIMETERS, intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA (and their rates and spatial distributions) in PHOTON, ELECTRON, proton or heavy ion RADIATION FIELDS as used in RADIOTHERAPY.

The DOSE MONITORING SYSTEMS incorporated in RADIOTHERAPY treatment machines are not covered by this standard, neither are the re-entrant IONIZATION CHAMBERS used for BRACHYTHERAPY source calibration and constancy check devices.

This standard is applicable to the following types of dosimeter:

a) FIELD-CLASS DOSIMETERS normally used for
   1) the measurement of KERMA or dose in a RADIATION BEAM, either in air or in a PHANTOM;
   2) in vivo skin surface or intracavitary measurements of dose on PATIENTS.
b) REFERENCE-CLASS DOSIMETERS normally used for the calibration of FIELD-CLASS DOSIMETERS;

   NOTE REFERENCE-CLASS DOSIMETERS may be used as FIELD-CLASS DOSIMETERS.
c) SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

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1.2 Object

The object of this standard is:

– to establish requirements for a satisfactory level of performance for RADIOTHERAPY DOSIMETERS;
– to standardize methods for the determination of compliance with this level of performance.

Three levels of performance are specified:

– a lower level of performance applying to FIELD-CLASS DOSIMETERS;
– a higher level of performance applying to REFERENCE-CLASS DOSIMETERS;
– a specific level of performance applying to SCANNING-CLASS DOSIMETERS.

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 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

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IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

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ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

ISO 3534-1:2006, *Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability*

3 Terms and definitions

For the purpose of this International Standard the terms and definitions listed in index of defined terms and the following apply.

NOTE The definitions given in this standard are generally in agreement with those in IEC TR 60788:2004 and ISO International vocabulary of basic and general terms in metrology, except that some definitions have been made more restricted. Any such special definitions should be regarded as applying only to this standard.

Any terms not defined in this standard have the meanings defined in the above publications or are assumed to be in general scientific usage.

Throughout this standard:

– if no material is specified, the term "ABSORBED DOSE" or "dose" means "ABSORBED DOSE TO WATER (in water)" and the term "KERMA" means "AIR KERMA (in air)";

– when the quantity "AIR KERMA (in air)" in units "Gy" is used, the quantity "EXPOSURE" in units "C/kg" is also allowable;

– the term “heavy ion“ addresses the range of nuclides from 2-He to 18-Ar in accordance with IAEA Technical Report 398 [2][1)].

3.1
RADIOTHERAPY DOSIMETER
equipment, consisting of a MEASURING ASSEMBLY and one ore more CHAMBER ASSEMBLIES, for the measurement of AIR KERMA, ABSORBED DOSE, or their corresponding rates or spatial distributions, in PHOTON, ELECTRON, proton and heavy ion radiation as used in RADIOTHERAPY

NOTE A RADIOTHERAPY DOSIMETER may include the following components:

– one or more STABILITY CHECK DEVICES;

– one or more PHANTOMS or build-up caps.

– one or more extension cables;

3.1.1
CHAMBER ASSEMBLY
IONIZATION CHAMBER and all other parts to which the chamber is permanently attached, except the MEASURING ASSEMBLY

NOTE It includes the electrical fitting and any permanently attached cable.

3.1.1.1
IONIZATION CHAMBER
IONIZING RADIATION detector consisting of a chamber filled with air, in which an electric field insufficient to produce gas multiplication, is provided for the collection at the electrodes of charges associated with the ions and the ELECTRONS produced in the measuring volume of the detector by IONIZING RADIATION

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NOTE 1 For this standard, the IONIZATION CHAMBER is considered to consist of the measuring volume, the collecting electrode, the guard electrode (if any), the outer electrode (which consists of the chamber wall and possibly a conducting coating), those parts of the insulator adjacent to the measuring volume, the build-up cap and water-proof housing (if any).

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NOTE 2 There are several categories of IONIZATION CHAMBER (see 3.1.1.1.1 to 3.1.1.1.7).

3.1.1.1.1
SHELL CHAMBER
IONIZATION CHAMBER with a measuring volume of between 0,1 cm^3 and 1,0 cm^3 bounded by a rigid outer electrode mounted on a supporting stem

NOTE 1 The measuring volume is usually symmetrical about the axis of the stem and the chamber is intended to be used with the axis of symmetry perpendicular to the axis of the RADIATION BEAM.

NOTE 2 There are two types of SHELL CHAMBER: THIMBLE CHAMBER and SPHERICAL CHAMBER (see 3.1.1.1.1.1 and 3.1.1.1.1.2).

3.1.1.1.1.1
THIMBLE CHAMBER
SHELL CHAMBER whose outer electrode takes the form of a rigid cylindrical wall closed at one end and mounted at the other on the supporting stem

3.1.1.1.1.2
SPHERICAL CHAMBER
SHELL CHAMBER whose outer electrode takes the form of a rigid spherical wall mounted on the supporting stem

1) Figures in square brackets refer to the Bibliography.

3.1.1.1.2
PARALLEL-PLATE CHAMBER
IONIZATION CHAMBER with a measuring volume of between approximately 0,01 cm^3 and 0,5 cm^3 bounded by parallel electrodes

NOTE The chamber is intended to be used with the electrodes perpendicular to the axis of the RADIATION BEAM.

3.1.1.1.3
VENTED CHAMBER
IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere such that corrections to the RESPONSE for changes in air density need to be made

3.1.1.1.4
SEALED CHAMBER
IONIZATION CHAMBER constructed in such a way as to restrict the pathway between the air inside the measuring volume and the atmosphere sufficiently to ensure that the RESPONSE of the chamber is independent of changes in ambient conditions over a period of time stated by the MANUFACTURER

3.1.1.1.5
UNGUARDED IONIZATION CHAMBER
IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor terminates in the cable and does not extend into the stem or body of the CHAMBER ASSEMBLY

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3.1.1.1.6
PARTIALLY GUARDED IONIZATION CHAMBER
IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor extends well into the stem or body of the CHAMBER ASSEMBLY but does not enter the air in the chamber

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3.1.1.1.7
GUARDED IONIZATION CHAMBER
IONIZATION CHAMBER in which the guard conductor in the stem or body of the CHAMBER ASSEMBLY is continuous with a guard electrode that is in contact with the air inside the chamber

3.1.2
MEASURING ASSEMBLY
device to measure the charge (or current) from the IONIZATION CHAMBER and convert it into a form suitable for displaying the values of dose or KERMA or their corresponding rates

3.1.3
STABILITY CHECK DEVICE
device which enables the stability of RESPONSE of the MEASURING ASSEMBLY and/or CHAMBER ASSEMBLY to be checked

NOTE The STABILITY CHECK DEVICE may be a purely electrical device, or a RADIATION SOURCE, or it may include both.

3.2
INDICATED VALUE
value of a quantity derived from the reading of an instrument together with any scale factors indicated on the CONTROL PANEL of the instrument

NOTE The INDICATED VALUE is equivalent to the "uncorrected observations" shown in Figure A.1.

3.3
TRUE VALUE
value of the physical quantity to be measured by an instrument

NOTE The TRUE VALUE is equivalent to the "value of MEASURAND" shown in Figure A.1.

3.4
CONVENTIONAL TRUE VALUE
value used instead of the TRUE VALUE when calibrating or determining the performance of an instrument, since in practice the TRUE VALUE is unknown and unknowable

NOTE 1 The CONVENTIONAL TRUE VALUE will usually be the value determined by the WORKING STANDARD with which the instrument under test is being compared.

NOTE 2 The possible bounds within which the CONVENTIONAL TRUE VALUE will lie are equivalent to the "values of MEASURAND due to incomplete definition" shown in Figure A.1.

3.4.1
STANDARD
<metrology> instrument which defines, represents physically, maintains or reproduces the unit of measurement of a quantity (or a multiple or submultiple of that unit) in order to transfer it to other instruments by comparison

3.4.1.1
NATIONAL STANDARD
<metrology> STANDARD recognized by an official national decision as the basis for fixing the values and UNCERTAINTIES in that country of all other STANDARDS of the given quantity

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3.4.1.2
WORKING STANDARD
<metrology> STANDARD which is traceable to the NATIONAL STANDARD

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3.5
MEASURED VALUE
best estimate of the TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS and the CALIBRATION FACTOR

NOTE The MEASURED VALUE is the "final result of measurement" shown in Figure A.1.

3.5.1
ERROR OF MEASUREMENT
difference remaining between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

3.5.2
OVERALL UNCERTAINTY
UNCERTAINTY associated with the MEASURED VALUE

NOTE 1 I.e. it represents the bounds within which the ERROR OF MEASUREMENT is estimated to lie.

NOTE 2 For the purpose of this standard the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a confidence level of 95 % (see Annex A).

3.5.3
EXPANDED UNCERTAINTY
quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the MEASURAND

[ISO/IEC GUIDE 98-3:2008, 2.3.5]