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

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

IEC 60731:2011-02+AMD1:2016-04 CSV(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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This Consolidated version of IEC 60731 bears the edition number 3.1. It consists of the third edition (2011-02) [documents 62C/506/FDIS and 62C/511/RVD] and its amendment 1 (2016-04) [documents 62C/596A/CDV and 62C/630/RVC]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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.

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.

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.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability 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

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- withdrawn,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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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.

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.

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*