Irish Standard
I.S. EN 60731:2012

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (IEC 60731:2011 (EQV))

I.S. EN 60731:2012

Incorporating amendments/corrigenda issued since publication:

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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EUROPEAN STANDARD

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EN 60731

April 2012

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Supersedes EN 60731:1997 + A1:2002

English version

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy
(IEC 60731:2011)

Appareils électromédicaux - Dosimètres à chambres d'ionisation utilisés en radiothérapie (CEI 60731:2011)

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern zur Anwendung in der Strahlentherapie (IEC 60731:2011)

This European Standard was approved by CENELEC on 2012-03-14. 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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60731:2012 E

Foreword

The text of document 62C/506/FDIS, future edition 3 of IEC 60731, 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 approved by CENELEC as EN 60731:2012.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-12-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-03-14

This document supersedes EN 60731:1997 + A1:2002.

EN 60731:2012 includes the following significant technical changes with respect to EN 60731:1997 + A1:2002:

The technical modifications versus EN 60731:1997 + A1:2002 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60731:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60051-1:1997 NOTE Harmonized as EN 60051-1:1998 (not modified).

Annex ZA
(normative)
Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 60417	data base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
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	EN 60601-1-3 + corr. March	2008 2010
IEC 60601-2-8	2010	Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	EN 60601-2-8	201X[1)]
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	EN 60976	2007
IEC 61010-1 + corr. May	2010 2011	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	2010
IEC 61187	-	Electrical and electronic measuring equipment - Documentation	EN 61187	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 61676	2002	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN 61676	2002
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

[1)] To be published.

Publication	Year	Title	EN/HD	Year
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	-	-

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

The committee has decided that the contents of this publication 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.

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*