

Elektrilised meditsiiniseadmed
Kiiritusravil kasutatavadioonkambriga dosimeetrid

Medical electrical equipment

Dosimeters with ionization chambers as used in radiotherapy

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60731:2012 sisaldab Euroopa standardi EN 60731:2012 ingliskeelset teksti.	This Estonian standard EVS-EN 60731:2012 consists of the English text of the European standard EN 60731:2012.
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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)

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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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-14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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	-

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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.

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*

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*

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

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;