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## **Elektrisk utrustning för medicinskt bruk – Dosimetrar med jonisationskammare för radioterapi**

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

Som svensk standard gäller europastandarden EN 60731:2012. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60731:2012.

### **Nationellt förord**

Europastandarden EN 60731:2012

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60731, Third edition, 2011 - Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60731, utgåva 1, 1998 och SS-EN 60731/A1, utgåva 1, 2002, gäller ej fr o m 2015-03-14.

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

**Management Centre: Avenue Marnix 17, B - 1000 Brussels**

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-14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

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## 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<br>+ corr. December<br>+ corr. December | 2005<br>2006<br>2007 | Medical electrical equipment -<br>Part 1: General requirements for basic safety<br>and essential performance                                                                                       | EN 60601-1<br>+ corr. March<br>+ A11 | 2006<br>2010<br>2011 |
| IEC 60601-1-2<br>(mod)                              | 2007                 | Medical electrical equipment -<br>Part 1-2: General requirements for basic<br>safety and essential performance - Collateral<br>standard: Electromagnetic compatibility -<br>Requirements and tests | EN 60601-1-2<br>+ corr. March        | 2007<br>2010         |
| IEC 60601-1-3                                       | 2008                 | Medical electrical equipment -<br>Part 1-3: General requirements for basic<br>safety and essential performance - Collateral<br>Standard: Radiation protection in diagnostic<br>X-ray equipment     | EN 60601-1-3<br>+ corr. March        | 2008<br>2010         |
| IEC 60601-2-8                                       | 2010                 | Medical electrical equipment -<br>Part 2-8: Particular requirements for basic<br>safety and essential performance of<br>therapeutic X-ray equipment operating in the<br>range 10 kV to 1 MV        | EN 60601-2-8                         | 201X <sup>1)</sup>   |
| IEC/TR 60788                                        | 2004                 | Medical electrical equipment - Glossary of<br>defined terms                                                                                                                                        | -                                    | -                    |
| IEC 60976                                           | 2007                 | Medical electrical equipment - Medical<br>electron accelerators - Functional<br>performance characteristics                                                                                        | EN 60976                             | 2007                 |
| IEC 61010-1<br>+ corr. May                          | 2010<br>2011         | Safety requirements for electrical equipment<br>for measurement, control and laboratory use -<br>Part 1: General requirements                                                                      | EN 61010-1                           | 2010                 |
| IEC 61187                                           | -                    | Electrical and electronic measuring equipment<br>- Documentation                                                                                                                                   | EN 61187                             | -                    |
| IEC 61267                                           | 2005                 | Medical diagnostic X-ray equipment -<br>Radiation conditions for use in the<br>determination of characteristics                                                                                    | EN 61267                             | 2006                 |
| IEC 61676                                           | 2002                 | Medical electrical equipment - Dosimetric<br>instruments used for non-invasive<br>measurement of X-ray tube voltage in<br>diagnostic radiology                                                     | EN 61676                             | 2002                 |
| ISO/IEC Guide 98-3                                  | 2008                 | Uncertainty of measurement -<br>Part 3: Guide to the expression of uncertainty<br>in measurement (GUM:1995)                                                                                        | -                                    | -                    |

<sup>1)</sup> 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*