SLOVENSKI STANDARD
oSIST prEN IEC 60731:2026

01-junij-2026

Medicinska električna oprema - Dozimetri z ionizacijskimi komorami ali trdnimi detektorji za uporabo v radioterapiji

Medical electrical equipment - Dosimeters with ionization chambers or solid-state detectors as used in radiotherapy

Appareils électromédicaux - Dosimètres à chambres d'ionisation ou détecteur à état solide utilisés en radiothérapie

Ta slovenski standard je istoveten z: **prEN IEC 60731:2026**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

oSIST prEN IEC 60731:2026 **en**

62C/979/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60731 ED4**	
DATE OF CIRCULATION: **2026-04-10**	CLOSING DATE FOR VOTING: **2026-07-03**
SUPERSEDES DOCUMENTS: **62C/943/CD, 62C/948B/CC**	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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TITLE:

Medical electrical equipment - Dosimeters with ionization chambers or solid-state detectors as used in radiotherapy

PROPOSED STABILITY DATE: 2038

NOTE FROM TC/SC OFFICERS:

Link to Committee Draft for Vote (CDV) online document:

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How to access

This link leads you to the Online Standards Development (OSD) platform for National Mirror Committee's (NMC) comments. The project draft may be found further down this document.

Resource materials

We recommend NCs to review the available materials to better understand the member commenting on the OSD platform. This includes the:

- OSD NC roles overview
- How to add and submit comments to the IEC

Contact

Should you require any assistance, please contact the IEC IT Helpdesk.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Medical electrical equipment - Dosimeters with ionization chambers or solid-state detectors as used in radiotherapy

FOREWORD

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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 fourth edition of IEC 60731 cancels and replaces IEC 60731:2011/AMD:2016 and is a major update. The number of clauses on detector performance has increased from ~40 to ~60 and many of the existing clauses were updated. For the measuring assembly, a few new clauses were added.

The major changes are:

– Inclusion of solid-state detectors.

– The reference class requirements have been increased to incorporate the new requirements from TG-51 Addendum [1], TRS-398 [2] and TRS-483 [3].

– Allowance of 6 MV as reference beam quality due to the predicted scarcity of Co-60 sources.

Other changes:

– The scanning class has been removed.
– Clauses for charge per pulse and instantaneous current have been added for the measuring assembly.

In this standard, the following print types are used:

a) requirements, compliance with which can be tested, and definitions: in roman type;

b) explanations, advice, general statements, exceptions and notes: in small roman type;

c) *test specifications: in italic type.*

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.

INTRODUCTION

This International Standard is applicable to the performance of radiotherapy dosimeters (3.111) with ionization chambers (3.64) or solid-state detectors (3.136) as used in radiotherapy (3.110).

The effectiveness of treatment of patients (3.93) receiving radiotherapy (3.110) 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 document plays an essential part in achieving the required accuracy.

This document is not concerned with the safety aspects of dosimeters. The requirements for safety applying to dosimeters as used in radiotherapy are contained either in IEC 61010-1 or IEC 60601-1. The international standard to be applied shall be decided by the manufacturer in accordance with the scope of the respective international standard.

This document is not concerned with the electromagnetic compatibility (3.38) aspects of dosimeters. The requirements for electromagnetic compatibility (3.38) applying to dosimeters as used in radiotherapy are contained either in IEC 61326-1 or IEC 60601-1-2. The international standard to be applied shall be decided by the manufacturer in accordance with the scope of the respective international standard.

Irrespective of this choice, this document will define exceptions of tests which are described in the electromagnetic compatibility (3.38) standards mentioned above. These exceptions will either refer to tests of IEC 61326-1 or IEC 60601-1-2. Citing of an internatinoal standard to define an exception does not imply that such an internatnional standard shall be used for testing.

Dosimeters that comply with this document 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.

1 Scope and object

1.1 Scope

This International Standard specifies the performance requirements of radiotherapy dosimeters (3.111), intended for the measurement of absorbed dose to water (3.4) or air kerma (3.8) (and their rates and spatial distributions) in photon (3.98), electron (3.39), proton or light and heavy ion radiation fields (3.105) as used in radiotherapy (3.110).

Specificly, the document outlines general and specific performance requirements for detector assemblies (3.29) (ionization chambers (3.64) and solid-state detectors (3.136)), measuring assemblies (3.75), and stability check devices (3.141). These requirements cover aspects such as stability, leakage current, radiation quality dependence, and more.

The following devices are outside the scope of this document and therefore not covered here:

– Dose monitoring systems (3.35) incorporated in radiotherapy (3.110) treatment machines
– Re-entrant (also known as well-type) ionization chambers (3.64) used for brachytherapy source calibration
– constancy check devices

This document is applicable to the following types of dosimeter:

a) Dosimeters, classified as reference-class dosimeters (3.122) , normally used for
   1) kerma (3.67) or dose determination under reference conditions;
   2) the calibration of field-class dosimeters (3.50) ;

NOTE 1 reference-class dosimeters (3.122) may be used as field-class dosimeters (3.50).

b) Dosimeters, classified as field-class dosimeters (3.50), normally used for
   1) the measurement of kerma (3.67) or dose in a radiation beam (3.104), either in air or in a phantom (3.97);
   2) relative dose distribution measurements with a scanning system (3.130) such as an automatic water phantom (3.97).

NOTE 2 In this document, field-class dosimeters (3.50) and reference-class dosimeters (3.122) employ ionization chambers (3.64) as detector (3.28)

c) Solid-state dosimeters (3.138), where the solid-state detector (3.136) is intended for operation at zero bias voltage, normally used for
   1) relative dose distribution measurements with a scanning system (3.130) such as an automatic water phantom (3.97);
   2) point-dose measurements in a solid-state phantom (3.97) or automatic water phantom (3.97).

NOTE 3 Solid-State detectors that are intended for In-Vivo dosimetry applications are outside the scope of this document.

1.2 Object

The object of this documentis:

– to establish requirements for a satisfactory level of performance for radiotherapy dosimeters (3.111);
– 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 (3.50);
– a higher level of performance applying to reference-class dosimeters (3.122);

– a specific level of performance applying to dosimeters where at least one detector assembly is a Solid-state detector (3.136). This may also be designated as solid-state class

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1-2:2014/AMD1:2020, *Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - 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 60601-1:2005/ISH3:2013, *Interpretation sheet 3 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

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

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 61674:2024, *Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging*

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)*