SLOVENSKI STANDARD
oSIST prEN IEC 61674:2023

01-april-2023

Medicinska električna oprema - Dozimetri z ionizacijskimi komorami oziroma polprevodniški detektorji, kot so uporabljeni pri rentgenskem diagnostičnem slikanju

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

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern und/oder Halbleiterdetektoren für den Einsatz an diagnostischen Röntgeneinrichtungen

Appareils électromédicaux - Dosimètres à chambres d'ionisation et/ou à détecteurs semiconducteurs utilisés en imagerie de diagnostic à rayonnement X

Ta slovenski standard je istoveten z: **prEN IEC 61674:2023**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.240	Merjenje sevanja	Radiation measurements

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62C/865/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61674 ED3**	
DATE OF CIRCULATION: **2023-01-27**	CLOSING DATE FOR VOTING: **2023-04-21**
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IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☒ QUALITY ASSURANCE ☒ 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.	

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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,
- any relevant “in some countries” clauses to be included should this proposal proceed. Recipients are reminded that the enquiry stage is the final stage for submitting "in some countries" clauses. See AC/22/2007.

TITLE:

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

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AND/OR SEMICONDUCTOR DETECTORS AS USED IN X-RAY DIAGNOSTIC IMAGING

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International Standard IEC 61674 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 second edition cancels and replaces the first edition of IEC 61674. This edition constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/551/FDIS	62C/555/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

Diagnostic radiology is the largest contributor to man-made IONIZING RADIATION to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing medical radiological examinations or procedures has therefore become a central issue in recent years. The PATIENT dose will be minimized when the X-ray producing equipment is correctly adjusted for image quality and radiation output. These adjustments require that the routine measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE be made accurately. The equipment covered by this standard plays an essential part in achieving the required accuracy. The DOSIMETERS used for adjustment and control measurements must be of satisfactory quality and must therefore fulfil the special requirements laid down in this standard.

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AND/OR SEMICONDUCTOR DETECTORS AS USED IN X-RAY DIAGNOSTIC IMAGING

1 Scope and object

1.1 Scope

This International Standard specifies the performance and some related constructional requirements of DIAGNOSTIC DOSIMETERS intended for the measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE, in photon radiation fields used in medical X-ray imaging, such as RADIOGRAPHY, RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-radiation with generating potentials in the range of 20 kV to 150 kV.

This International Standard is applicable to the performance of DOSIMETERS with VENTED IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS as used in X-ray diagnostic imaging.

1.2 Object

The object of this standard is:

a) to establish requirements for a satisfactory level of performance for DIAGNOSTIC DOSIMETERS, and

b) to standardize the methods for the determination of compliance with this level of performance.

This standard is not concerned with the safety aspects of DOSIMETERS. The DIAGNOSTIC DOSIMETERS covered by this standard are not intended for use in the PATIENT ENVIRONMENT and, therefore, the requirements for electrical safety applying to them are contained in IEC 61010-1.

2 Normative references

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.

IEC 60050 (all parts), *International Electrotechnical Vocabulary* (available at <http://www.electropedia.org>)

IEC 60601-1:2005*, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 60417, *Graphical symbols for use on equipment* (Available at: <http://www.graphical-symbols.info/equipment>

IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61000-4 (all parts) *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances induced by radio-frequency fields*

IEC 61000-4-11, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests*

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*

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 purposes of this document, the terms and definitions given in IEC/TR 60788:2004 and the following apply.

3.1
DIAGNOSTIC DOSIMETER
DOSIMETER
equipment which uses IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS for the measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for diagnostic medical radiological examinations

Note 1 to entry: A DIAGNOSTIC DOSIMETER contains the following components:

– one or more DETECTOR ASSEMBLIES which may or may not be an integral part of the MEASURING ASSEMBLY;

– a MEASURING ASSEMBLY;

– one or more STABILITY CHECK DEVICES (optional).

3.1.1
DETECTOR ASSEMBLY
RADIATION DETECTOR and all other parts to which the RADIATION DETECTOR is permanently attached, except the MEASURING ASSEMBLY

Note 1 to entry: The DETECTOR ASSEMBLY normally includes:

– the RADIATION DETECTOR and the stem (or body) on which the RADIATION DETECTOR is permanently mounted (or embedded);

– the electrical fitting and any permanently attached cable or pre-amplifier.

3.1.1.1

RADIATION DETECTOR

element which transduces AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE into a measurable electrical signal

Note 1 to entry: A radiation detector may be either an ionization chamber or a semiconductor detector.

3.1.1.1.1

IONIZATION CHAMBER

CHAMBER

ionizing RADIATION DETECTOR consisting of a CHAMBER filled with air, in which an electric field insufficient to produce gas multiplication is provided for the collection at the electrodes of charges associated with the ions and the ELECTRONS produced in the measuring volume of the detector by IONIZING RADIATION

Note 1 to entry: An IONIZATION CHAMBER can be sealed or vented.

Note 2 to entry: Vented IONIZATION CHAMBERS are constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere, so that corrections to the RESPONSE for changes in air density need to be made.

Note 3 to entry: Sealed IONIZATION CHAMBERS are not suitable, because the necessary wall thickness of a sealed CHAMBER may cause an unacceptable energy dependence of the RESPONSE and because the long term stability of sealed CHAMBERS is not guaranteed.

[SOURCE: IEC 60731:2011, 3.1.1.1, modified – three new notes to entry have replaced the two original notes.]

3.1.1.1.2

VENTED IONIZATION CHAMBER

IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere such that corrections to the RESPONSE for changes in air density need to be made

[SOURCE: IEC 60731:2011, 3.1.1.1.3, modified – the term has been changed from "vented chamber" to "VENTED IONIZATION CHAMBER".]

3.1.1.1.3

SEMICONDUCTOR DETECTOR

semiconductor device that utilises the production and motion of electron-hole pairs in a charge carrier depleted region of the semiconductor for the detection and measurement of IONIZING RADIATION

Note 1 to entry: The production of electron-hole pairs is caused either

– directly by interaction of the IONIZING RADIATION with the semiconductor material, or

– indirectly by first converting the incident radiation energy to light in a scintillator material directly in front of and optically coupled to a semiconductor photodiode, which then produces the electrical signal.

3.1.2

MEASURING ASSEMBLY

device to measure the electrical signal from the RADIATION DETECTOR and convert it into a form suitable for displaying the values of DOSE or KERMA or their corresponding rates

[SOURCE: IEC 60731:2011, 3.1.2. modified – the term IONIZATION CHAMBER in the original definition has been replaced by the term RADIATION DETECTOR]