ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA December 2024

STN	**Zdravotnícke elektrické prístroje Dozimetre s ionizačnými komorami a/alebo polovodičovými detektormi používané pri röntgenologickom diagnostickom zobrazovaní**	**STN EN IEC 61674** 36 4733

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/24

Obsahuje: EN IEC 61674:2024, IEC 61674:2024

Oznámením tejto normy sa od 13.08.2027 ruší
STN EN 61674 (36 4733) z novembra 2013

139414

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61674

August 2024

ICS 11.040.50

Supersedes EN 61674:2013

English Version

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

Appareils électromédicaux - Dosimètres à chambres d'ionisation et/ou à détecteurs semiconducteurs utilisés en imagerie de diagnostic à rayonnement X (IEC 61674:2024)

Medizinische elektrische Geräte - Dosimeter mit Ionisationskammern und/oder Halbleiterdetektoren für den Einsatz an diagnostischen Röntgeneinrichtungen (IEC 61674:2024)

This European Standard was approved by CENELEC on 2024-08-13. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62C/909/FDIS, future edition 3 of IEC 61674, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61674:2024.

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) 2025-05-13
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-08-13

This document supersedes EN 61674:2013 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61674:2024 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1:2005	NOTE	Approved as EN 60601-1:2006 (not modified) +A11:2011
IEC 60601-1:2005/A1:2012	NOTE	Approved as EN 60601-1:2006/A1:2013 (not modified)
IEC 60601-1:2005/A2:2020	NOTE	Approved as EN 60601-1:2006/A2:2021 (not modified)
IEC 60601-1-3:2008	NOTE	Approved as EN 60601-1-3:2008 (not modified) +A11:2016
IEC 60601-1-3:2008/A1:2013	NOTE	Approved as EN 60601-1-3:2008/A1:2013 (not modified)
IEC 60601-1-3:2008/A2:2021	NOTE	Approved as EN 60601-1-3:2008/A2:2021 (not modified)
IEC 60731:2011	NOTE	Approved as EN 60731:2012 (not modified)
IEC 61010-1	NOTE	Approved as EN 61010-1
IEC 61676:2023	NOTE	Approved as EN IEC 61676:2023 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60417	-	Graphical symbols for use on equipment	-	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61000-4	series	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques	EN IEC 61000-4	series
IEC 61000-4-2	2008	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	2009
IEC 61000-4-3	2020	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN IEC 61000-4-3	2020
IEC 61000-4-4	-	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	-
IEC 61000-4-6	-	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN IEC 61000-4-6	-
IEC 61000-4-11	-	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase	EN IEC 61000-4-11	-
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 61674

Edition 3.0 2024-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

IEC 61674:2024-07(en-fr)

IEC 61674

Edition 3.0 2024-07

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INTERNATIONAL
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INTERNATIONALE

ICS 11.040.50 ISBN 978-2-8322-8971-6

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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

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 61674 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) for mammography, the manufacturer specifies the REFERENCE VALUE for the RADIATION QUALITY;
b) for mammography, the manufacturer provides the MINIMUM RATED RANGE of RADIATION QUALITIES for the compliance test on energy dependence of response;
c) the compliance test for analogue displays was removed;

d) the compliance tests for range reset, the effect of leakage and recombination losses were removed. These tests are already covered by the test on linearity and cannot be conducted for modern devices. The estimation of COMBINED STANDARD UNCERTAINTY was changed accordingly;

e) the compliance test for mains rechargeable and battery-operated dosimeters were updated for modern devices.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/909/FDIS	62C/913/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2:2021. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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 document plays an essential part in achieving the required accuracy. It is important that the DOSIMETERS used for adjustment and control measurements are of satisfactory quality and therefore fulfil the special requirements laid down in this document.

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 document 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 document 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 document 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 document is not concerned with the safety aspects of DOSIMETERS. The DIAGNOSTIC DOSIMETERS covered by this document 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 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,* available at http://www.graphical-symbols.info/equipment

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

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

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3:2020, *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 for equipment with input current up to 16 A per phase*

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*