

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

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EUROPEAN STANDARD

EN IEC 61674

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2024

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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)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

EN IEC 61674:2024 (E)

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.

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- latest date by which the document has to be implemented at national (dop) 2025-05-13 level by publication of an identical national standard or by endorsement
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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.

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



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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

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IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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:

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- 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*

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