

**Elektrilised meditsiiniseadmed.
Röntgendiagnostikas kasutatavadioonkambriga
dosimeetrid ja/või pooljuhtdetektorid**

Medical electrical equipment

Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging
(IEC 61674:2012)

EESTI STANDARDI EESSÕNA

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ICS 11.040.50

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**Medical electrical equipment -
Dosimeters with ionization chambers and/or semiconductor detectors as
used in X-ray diagnostic imaging
(IEC 61674:2012)**

Appareils électromédicaux -
Dosimètres à chambres d'ionisation et/ou
à détecteurs à semi-conducteurs utilisés
en imagerie de diagnostic
à rayonnement X
(CEI 61674:2012)

Medizinische elektrische Geräte -
Dosimeter mit Ionisationskammern
und/oder Halbleiterdetektoren für den
Einsatz an diagnostischen
Röntgeneinrichtungen
(IEC 61674:2012)

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

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Foreword

The text of document 62C/551/FDIS, future edition 2 of IEC 61674, prepared by IEC TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61674:2013.

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) 2013-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2016-01-03

This document supersedes EN 61674:1997 + A1:2002.

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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 EN 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.

Endorsement notice

The text of the International Standard IEC 61674:2012 was approved by CENELEC as a European Standard without any modification.

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 60050	Series	International Electrotechnical Vocabulary	-	-
IEC 60417	Data-base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
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	EN 60601-1-3 + corr. March	2008 2010
IEC 60731	2011	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	EN 60731	2012
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 61000-4	Series
IEC 61000-4-2	-	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	-
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	-
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 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	EN 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
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	-	-

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope and object.....	7
1.1 Scope.....	7
1.2 Object	7
2 Normative references	7
3 Terms and definitions	8
4 General requirements	15
4.1 Performance requirements	15
4.2 REFERENCE VALUES and STANDARD TEST VALUES.....	15
4.3 General test conditions.....	16
4.3.1 STANDARD TEST CONDITIONS.....	16
4.3.2 Statistical fluctuations.....	17
4.3.3 STABILIZATION TIME	17
4.3.4 Adjustments during test	17
4.3.5 Batteries.....	17
4.4 Constructional requirements as related to performance	18
4.4.1 Components	18
4.4.2 Display	18
4.4.3 Indication of battery condition.....	18
4.4.4 Indication of polarizing voltage failure.....	18
4.4.5 Over-ranging	18
4.4.6 MEASURING ASSEMBLIES with multiple DETECTOR ASSEMBLIES	19
4.4.7 Radioactive STABILITY CHECK DEVICE.....	19
4.5 UNCERTAINTY of measurement	20
5 Limits of PERFORMANCE CHARACTERISTICS	20
5.1 Linearity	20
5.2 Repeatability	20
5.2.1 General	20
5.2.2 Repeatability in the ATTENUATED BEAM.....	20
5.2.3 Repeatability in the UNATTENUATED BEAM.....	21
5.3 RESOLUTION of reading	21
5.4 STABILIZATION TIME.....	21
5.5 Effect of pulsed radiation on AIR KERMA and AIR KERMA LENGTH PRODUCT measurements.....	22
5.6 Reset on AIR KERMA and AIR KERMA LENGTH PRODUCT ranges	22
5.7 Effects of LEAKAGE CURRENT.....	22
5.7.1 AIR KERMA RATE measurements	22
5.7.2 AIR KERMA and AIR KERMA LENGTH PRODUCT measurements.....	22
5.8 Stability.....	23
5.8.1 Long term stability	23
5.8.2 Accumulated dose stability	23
5.9 Measurements with a radioactive STABILITY CHECK DEVICE	23
6 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES	24
6.1 General.....	24
6.2 Energy dependence of RESPONSE	24

6.3	AIR KERMA RATE dependence of AIR KERMA and AIR KERMA LENGTH PRODUCT measurements.....	25
6.3.1	MEASURING ASSEMBLY.....	25
6.3.2	IONIZATION CHAMBER – Recombination losses.....	26
6.4	Dependence of DETECTOR RESPONSE on angle of incidence of radiation.....	26
6.4.1	Non-CT detectors.....	26
6.4.2	CT DETECTORS.....	26
6.5	Operating voltage.....	27
6.5.1	Mains-operated DOSIMETERS.....	27
6.5.2	Battery-operated DOSIMETERS.....	27
6.5.3	Mains rechargeable, battery-operated DOSIMETERS.....	27
6.6	Air pressure.....	28
6.7	Air pressure EQUILIBRATION TIME of the RADIATION DETECTOR.....	28
6.8	Temperature and humidity.....	28
6.9	Electromagnetic compatibility.....	29
6.9.1	ELECTROSTATIC DISCHARGE.....	29
6.9.2	Radiated electromagnetic fields.....	29
6.9.3	CONDUCTED DISTURBANCES induced by bursts and radio frequencies.....	30
6.9.4	Voltage dips, short interruptions and voltage VARIATIONS.....	30
6.10	Field size.....	30
6.11	EFFECTIVE LENGTH and spatial uniformity of RESPONSE of CT DOSIMETERS.....	30
7	Marking.....	31
7.1	DETECTOR ASSEMBLY.....	31
7.2	MEASURING ASSEMBLY.....	31
7.3	Radioactive STABILITY CHECK DEVICE.....	31
8	ACCOMPANYING DOCUMENTS.....	31
	Annex A (informative) COMBINED STANDARD UNCERTAINTY for dosimeter performance.....	33
	Index of defined terms.....	34
	Table 1 – REFERENCE and STANDARD TEST CONDITIONS.....	16
	Table 2 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings.....	17
	Table 3 – Maximum values for the COEFFICIENT OF VARIATION, v_{\max} , for measurements in the attenuated beam.....	21
	Table 4 – Maximum values for the COEFFICIENT OF VARIATION, v_{\max} , for measurements in the unattenuated beam.....	21
	Table 5 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.....	24
	Table 6 – Climatic conditions.....	28
	Table A.1 – Estimation of COMBINED STANDARD UNCERTAINTY for dosimeter performance.....	33

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 RADIOGRAPHY, including mammography, RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-radiation with generating potentials not greater than 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