IEC 61674

Edition 2.0 2012-11

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 à semi-conducteurs utilisés en imagerie de diagnostic à rayonnement X

IEC 61674:2012

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX
W

ICS 11.040.50
ISBN 978-2-83220-510-5

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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

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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 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

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 charge (or current) 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]

3.1.3
STABILITY CHECK DEVICE
device which enables the stability of RESPONSE of the MEASURING ASSEMBLY and/or CHAMBER ASSEMBLY to be checked

Note 1 to entry: The STABILITY CHECK DEVICE may be a purely electrical device, or a radiation source, or it may include both.

[SOURCE: IEC 60731:2011, 3.1.3]

3.1.4
CT DOSIMETER
DIAGNOSTIC DOSIMETER which uses long narrow IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS for the measurement of AIR KERMA integrated along the length of the DETECTOR when the DETECTOR is exposed to a cross-sectional X-ray scan of a computed tomograph

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

– one or more DETECTOR ASSEMBLIES;

– a MEASURING ASSEMBLY.

3.1.5
CT DETECTOR
RADIATION DETECTOR which is used for CT dosimetry

3.2
INDICATED VALUE
value of a quantity derived from the reading of an instrument together with any scale factors indicated on the control panel of the instrument

[SOURCE: IEC 60731:2011, 3.2]

3.3
TRUE VALUE
value of the physical quantity to be measured by an instrument

[SOURCE: IEC 60731:2011, 3.3]

3.4
CONVENTIONAL TRUE VALUE
value used instead of the TRUE VALUE when calibrating or determining the performance of an instrument, since in practice the TRUE VALUE is unknown and unknowable

Note 1 to entry: The CONVENTIONAL TRUE VALUE will usually be the value determined by the WORKING STANDARD with which the instrument under test is being compared.

[SOURCE: IEC 60731:2011, 3.4]

3.5
MEASURED VALUE
best estimate of the TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS and the CALIBRATION FACTOR

Note 1 to entry: The MEASURED VALUE is sometimes also referred to as result of a measurement

[SOURCE: IEC 60731:2011, 3.5, modified – a new note to entry has been added.]

3.5.1
ERROR OF MEASUREMENT
difference remaining between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

[SOURCE: IEC 60731:2011, 3.5.1]

3.5.2
OVERALL UNCERTAINTY
UNCERTAINTY associated with the MEASURED VALUE

Note 1 to entry: I.e. it represents the bounds within which the ERROR OF MEASUREMENT is estimated to lie (see also 4.5).

[SOURCE: IEC 60731:2011, 3.5.2]

3.5.3
EXPANDED UNCERTAINTY
quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand

[SOURCE: ISO/IEC GUIDE 98-3:2008, 2.3.5, modified – the three notes in the original definition have been deleted.]

3.6
CORRECTION FACTOR
dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS

[SOURCE: IEC 60731:2011, 3.6]

3.7
INFLUENCE QUANTITY
any external quantity that may affect the performance of an instrument

[SOURCE: IEC 60731:2011, 3.7]

3.8
INSTRUMENT PARAMETER
any internal property of an instrument that may affect the performance of this instrument

[SOURCE: IEC 60731:2011, 3.8]

3.9
REFERENCE VALUE
particular value of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER chosen for the purposes of reference

Note 1 to entry: I.e. the value of an influence quantity (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity.

[SOURCE: IEC 60731:2011, 3.9]

3.9.1
REFERENCE CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

[SOURCE: IEC 60731:2011, 3.9.1]

3.10
STANDARD TEST VALUES
value, values, or range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which are permitted when carrying out calibrations or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

[SOURCE: IEC 60731:2011, 3.10]

3.10.1
STANDARD TEST CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

[SOURCE: IEC 60731:2011, 3.10.1]

3.11
PERFORMANCE CHARACTERISTIC
one of the quantities used to define the performance of an instrument

[SOURCE: IEC 60731:2011, 3.11]

3.11.1
RESPONSE
<CHAMBER ASSEMBLY with MEASURING ASSEMBLY> quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the IONIZATION CHAMBER

[SOURCE: IEC 60731:2011, 3.11.1, modified – only the first paragraph of the original definition has been retained.]

3.11.2
RESOLUTION
<display> smallest change of reading to which a numerical value can be assigned without further interpolation

<analogue display> smallest fraction of a scale interval that can be determined by an observer under specified conditions

<digital display> smallest significant increment of the reading

[SOURCE: IEC 60731:2011, 3.11.2,]

3.11.3
EQUILIBRATION TIME
time taken for a reading to reach and remain within a specified deviation from its final steady value after a sudden change in an INFLUENCE QUANTITY has been applied to the instrument

[SOURCE: IEC 60731:2011, 3.11.3,]

3.11.4
RESPONSE TIME
time taken for a reading to reach and remain within a specified deviation from its final steady value after a sudden change in the quantity being measured

[SOURCE: IEC 60731:2011, 3.11.4,]

3.11.5
STABILIZATION TIME
time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value after the MEASURING ASSEMBLY has been switched on and the polarizing voltage has been applied to the IONIZATION CHAMBER

[SOURCE: IEC 60731:2011, 3.11.5]

3.11.6
CHAMBER ASSEMBLY LEAKAGE CURRENT
LEAKAGE CURRENT
any current in the signal path arising in the CHAMBER ASSEMBLY which is not produced by ionization in the measuring volume

[SOURCE: IEC 60731:2011, 3.11.6]

3.12
variation
relative difference, $\Delta y/y$, between the values of a PERFORMANCE CHARACTERISTIC y, when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) assumes successively two specified values, the other INFLUENCE QUANTITIES (and INSTRUMENT PARAMETERS) being kept constant at the STANDARD TEST VALUES (unless other values are specified)

[SOURCE: IEC 60731:2011, 3.12]

3.13
LIMITS OF VARIATION
maximum permitted VARIATION of a PERFORMANCE CHARACTERISTIC

Note 1 to entry: If LIMITS OF VARIATION are stated as $\pm L$ %, the VARIATION $\Delta y/y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ %.

[SOURCE: IEC 60731:2011, 3.13]

3.14
EFFECTIVE RANGE OF INDICATED VALUES
EFFECTIVE RANGE
range of INDICATED VALUES for which an instrument complies with a stated performance

Note 1 to entry: The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range.

Note 2 to entry: The concept of EFFECTIVE RANGE may, for example, also be applied to readings and to related quantities not directly indicated by the instrument e.g. input current.

[SOURCE: IEC 60731:2011, 3.14,]

3.15
RATED RANGE OF USE
RATED RANGE
range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION

Note 1 to entry: Its limits are the maximum and minimum RATED VALUES.

[SOURCE: IEC 60731:2011, 3.15]

3.15.1
MINIMUM RATED RANGE
least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER over which the instrument shall operate within the specified LIMITS OF VARIATION

[SOURCE: IEC 60731:2011, 3.15.1]