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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CONTENTS

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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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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*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

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
RADIATION DETECTOR filled with air, a suitable gas, or a gaseous mixture, in which an electric field is provided for the total collection, at the electrodes, of charges associated with the ions and the electrons produced in the sensitive volume of the detector by the 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 60050-395:2014, 395-03-07, modified – Two new notes to entry were added.]

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 by interaction of the IONIZING RADIATION with the semiconductor material. In the purview of this document, detectors qualify as semiconductor detectors, even when the production of electron-hole pairs is caused 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 words "measure the charge (or current) from the IONIZATION CHAMBER" have been replaced with "measure the electrical signal from the 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, modified – The note has been deleted.]

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

[SOURCE: IEC 60731:2011, 3.3, modified – The note has been deleted.]

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, modified – The second note has been deleted.]

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 – The existing note has been replaced with a new note to entry.]

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, modified – The parenthesis has been added to the note to entry, and the second note has been deleted.]

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 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
external quantity that may affect the performance of an instrument

[SOURCE: IEC 60731:2011, 3.7]

3.8
INSTRUMENT PARAMETER
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, modified – The note has been deleted.]

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

[SOURCE: IEC 60731:2011, 3.11.1, modified – Only the first paragraph has been retained.]

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

[SOURCE: IEC 60731:2011, 3.11.2, modified – Only the first paragraph has been retained.]

3.11.2.1
RESOLUTION
<digital display> smallest significant increment of the reading

[SOURCE: IEC 60731:2011, 3.11.2, modified – Only the third paragraph has been retained.]

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]