# IEC 61674

Edition 3.0 2024-07
COMMENTED VERSION

# INTERNATIONAL STANDARD

colour inside



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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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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

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**This commented version (CMV) of the official standard IEC 61674:2024 edition 3.0 allows the user to identify the changes made to the previous IEC 61674:2012 edition 2.0. Furthermore, comments from IEC SC 62C experts are provided to explain the reasons of the most relevant changes, or to clarify any part of the content.**

**A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text. Experts' comments are identified by a blue-background number. Mouse over a number to display a pop-up note with the comment.**

**This publication contains the CMV and the official standard. The full list of comments is available at the end of the CMV.**

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; **1**

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; **2**

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.

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- reconfirmed,
- withdrawn, or
- revised.

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# 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 ~~must be~~ are of satisfactory quality and ~~must~~ 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, ~~including mammography,~~ RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-RADIATION with generating potentials ~~not greater than~~ 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 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 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*

~~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.

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**
~~ionizing~~ RADIATION DETECTOR ~~consisting of a CHAMBER~~ filled with air, a suitable gas, or a gaseous mixture, in which an electric field ~~insufficient to produce gas multiplication~~ is provided for the total collection, at the electrodes, of charges associated with the ions and the electrons produced in the ~~measuring~~ 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 60731:2011, 3.1.1.1, modified – three new notes to entry have replaced the two original notes.~~ 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 ~~either directly~~ by interaction of the IONIZING RADIATION with the semiconductor material~~, or~~. In the purview of this document 3, 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 ~~charge (or current)~~ 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 term IONIZATION CHAMBER in the original definition has been replaced by the term RADIATION DETECTOR~~ 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 ~~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, 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**
~~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, modified – The note has been deleted.]

**3.11.1**
**RESPONSE**
<~~CHAMBER~~ 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 ~~IONIZATION CHAMBER~~ RADIATION DETECTOR

[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~~

[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]

**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, modified – The note has been deleted.]

**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]

**3.16**
**REFERENCE POINT OF A RADIATION DETECTOR**
**REFERENCE POINT**
point of a RADIATION DETECTOR which, during the calibration of the detector, is brought to coincidence with the point at which the CONVENTIONAL TRUE VALUE is specified

[SOURCE: IEC 60731:2011, 3.16, modified – The term "IONIZATION CHAMBER" has been replaced with "RADIATION DETECTOR" in both the term and the definition.]

**3.17**
**MEDICAL ELECTRICAL EQUIPMENT**
**ME EQUIPMENT**
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and
b) intended by its manufacturer to be used:
    1) in the diagnosis, treatment, or monitoring of a PATIENT; or
    2) for compensation or alleviation of disease, injury or disability

[SOURCE: IEC 60601-1:2005, 3.63, modified – The five notes have not been retained.]

**3.18**
**UNATTENUATED BEAM**
X-ray beam incident on the PATIENT or PHANTOM

**3.18.1**
**UNATTENUATED BEAM QUALITY**
RADIATION QUALITY of the X-ray beam at the location of the entrance surface of the PATIENT or the PHANTOM, determined when the latter are absent

**3.19**
**ATTENUATED BEAM**
X-ray beam exiting the PATIENT or PHANTOM

**3.19.1**
**ATTENUATED BEAM QUALITY**
RADIATION QUALITY of the X-ray beam exiting the PATIENT or PHANTOM

**3.20**
**RATED LENGTH**
length along the axis of the CT DETECTOR within which the DETECTOR performs to its specification

**3.20.1**
**EFFECTIVE LENGTH**
length along the axis of the CT DETECTOR between the two points at which the RESPONSE has fallen to 50 % of its value at its geometrical centre

**3.21**
**AIR KERMA**
***K***
quotient of $dE_{tr}$ by $dm$ where $dE_{tr}$ is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass $dm$

Note 1 to entry: The unit of AIR KERMA is Gy (where 1 Gy = 1 J·kg$^{-1}$).

[SOURCE: IEC 60731:2011, 3.31, modified – The second note has been deleted.]

**3.21.1**
**AIR KERMA RATE**
$\dot{K}$
quotient of $dK$ by $dt$, where $dK$ is the increment of AIR KERMA in the time interval $dt$

Note 1 to entry: The unit of AIR KERMA RATE is Gy·s$^{-1}$ (Gy·min$^{-1}$; Gy·h$^{-1}$).

[SOURCE: IEC 60731:2011, 3.31.1, modified – The second note has been deleted.]

**3.21.2**
**AIR KERMA LENGTH PRODUCT**
$P_{KL}$
line integral of the AIR KERMA $K$ over a length $L$

$$P_{KL} = \int_L K(z)dz \quad (1)$$

Note 1 to entry: The unit of AIR KERMA LENGTH PRODUCT is Gy·m (mGy·m).

**3.22**
**X-RAY TUBE VOLTAGE**
potential difference applied to an X-RAY TUBE between the ANODE and the CATHODE~~. Usually, X-RAY TUBE VOLTAGE is expressed by its peak value in kilovolt (kV)~~ **4**

Note 1 to entry: The unit of this quantity is the volt (V).

Note 2 to entry: The X-RAY TUBE VOLTAGE may vary as a function of time. The PRACTICAL PEAK VOLTAGE is a weighted value of the X-RAY TUBE VOLTAGE over a time period.

[SOURCE: ~~IEC 60601-1-3:2008, 3.88~~ IEC 61676:2023, 3.25, modified – The information about the unit has been moved from the definition to a note to entry, and a second note to entry has been added.]

**3.23**
**COEFFICIENT OF VARIATION**
CV
<positive random variable> STANDARD DEVIATION divided by the MEAN

[SOURCE: ISO 3534-1:2006, 2.38, modified – The example and the notes have not been retained.]

**3.24**
**INSTRUCTIONS FOR USE**
those parts of the ACCOMPANYING DOCUMENTS giving the necessary information for safe and proper use and operation of the equipment

[SOURCE: IEC TR 60788:2004, rm-82-02]

## 4 General requirements

### 4.1 Performance requirements

In Clause 5 and Clause 6, the performance requirements are stated for a complete DIAGNOSTIC DOSIMETER including both the DETECTOR ASSEMBLY and MEASURING ASSEMBLY. For a DOSIMETER designed to operate with one or more DETECTOR ASSEMBLIES, each combination of the MEASURING ASSEMBLY and DETECTOR ASSEMBLY shall comply with the requirements in 4.4, and in Clause 5 and Clause 6 relevant to this combination.

### 4.2 REFERENCE VALUES and STANDARD TEST VALUES

These values are as given in Table 1.

**Table 1 – REFERENCE and STANDARD TEST CONDITIONS**

| INFLUENCE QUANTITY | REFERENCE VALUES | STANDARD TEST VALUES |
|---|---|---|
| Temperature | +20 °C | +15 °C to +25 °C |
| Relative humidity | 50 % | 30 % to 75 % |
| Air pressure | 101,3 kPa | Atmospheric pressure |
| AIR KERMA RATE[a] | As at calibration | REFERENCE VALUE ±10 % |

| INFLUENCE QUANTITY | REFERENCE VALUES | STANDARD TEST VALUES |
|---|---|---|
| RADIATION QUALITY: | | |
| Mammography | As stated by the manufacturer[b] | REFERENCE VALUE |
| ~~– UNATTENUATED BEAM~~ | ~~28 kV~~<br>~~all qualities, defined by a special combination of x-ray tube anode and filtration[b], as stated by the manufacturer~~ | ~~REFERENCE VALUE~~ |
| ~~– ATTENUATED BEAM~~ | ~~28 Kv~~<br>~~all qualities, defined by a special combination of x-ray tube anode and filtration[b], as stated by the manufacturer, and an additional filtration of 2 mm Al~~ | ~~REFERENCE VALUE~~ |
| Conventional diagnostic: | | |
| – UNATTENUATED BEAM | 70 kV (RQR 5 x IEC 61267) | REFERENCE VALUE |
| – ATTENUATED BEAM | 70 kV (RQA 5 x IEC 61267) | REFERENCE VALUE |
| COMPUTED TOMOGRAPHY[c]: | 120 kV (RQT 9 x IEC 61267) | REFERENCE VALUE |
| Copper filtered beam | 70 kV (RQC 5 x IEC 61267) | REFERENCE VALUE |
| Electromagnetic fields | Zero | Insignificant[d] |

[a] AIR KERMA RATE is only an INFLUENCE QUANTITY for AIR KERMA and AIR KERMA LENGTH PRODUCT measurements.

[b] RADIATION QUALITIES used in mammography ~~can~~ shall be ~~based on different~~ stated as combinations of X-RAY TUBE anode materials (e.g., W, Mo, Rh) and filtrations (e.g., Al, Mo, Rh, Pd, Ag). Each such combination may have its own RATED RANGE. If applicable, established radiation qualities should be used as defined in IEC 61267.

[c] The RADIATION DETECTOR shall be irradiated by a radiation field with a diameter not smaller than twice the diameter of the RADIATION DETECTOR. The RADIATION DETECTOR shall be exposed with the beam aligned across the centre of the active length of the RADIATION DETECTOR.

[d] "Insignificant" means that the field is sufficiently small not to have any determinable effect on the RESPONSE of the DOSIMETER, for example as exists in a normal laboratory environment without special shielding.

## 4.3 General test conditions

### 4.3.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 1 shall be met during the test procedure, except:

a) for the INFLUENCE QUANTITY under investigation;

b) where local conditions of temperature and relative humidity are outside the STANDARD TEST CONDITIONS. In this case, the tester shall demonstrate the validity of the test results.

### 4.3.2 Statistical fluctuations

At low AIR KERMA and AIR KERMA RATES, the magnitude of the statistical fluctuations of the instrument's reading due to the random nature of the radiation alone may be a significant fraction of the VARIATION of the mean reading permitted in the test. A sufficient number of readings shall be taken to ensure that the mean value of such readings may be estimated with sufficient precision to demonstrate compliance or non-compliance with the test requirements. Table 2 provides guidance on the number of readings required to determine true differences between two sets of instrument readings at the 95 % confidence level. The number of readings,

*n*, required as a function of the percentage difference Δ of the MEAN values and the COEFFICIENT OF VARIATION, *v*, of the sets of readings (assumed to be equal for each set) are listed.

**Table 2 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings**

| Number of readings required *n* | | | | | | | |
|---|---|---|---|---|---|---|---|
| Δ | COEFFICIENT OF VARIATION *v* | | | | | | |
| | < 0,5 % | 0,5 % | 1 % | 2 % | 3 % | 4 % | 5 % |
| 1 % | [a] | 6 | 25 | 100 | 225 | 400 | 600 |
| 2 % | [a] | [a] | 6 | 25 | 55 | 100 | 150 |
| 3 % | [a] | [a] | [a] | 12 | 25 | 45 | 70 |
| 4 % | [a] | [a] | [a] | 6 | 15 | 25 | 40 |
| 5 % | [a] | [a] | [a] | [a] | 9 | 16 | 25 |

~~NOTE~~ This table has been compiled on the assumption that the probability of stating that there is a difference when there is none and the probability of stating that there is no difference when there is one are both equal to 0,05. In the RATE mode, the interval between the readings shall be at least five times the 63 % RESPONSE TIME of the instrument, in order to ensure that the readings are statistically independent.

[a] At least five repeated readings shall be taken.



#### 4.3.3 STABILIZATION TIME

The instrument shall be switched on for at least the STABILIZATION TIME quoted by the manufacturer, before the start of the compliance test.

In addition, if the RADIATION DETECTOR is an IONIZATION CHAMBER, then it should be allowed to attain thermal equilibrium with the environment and should have the polarizing voltage applied for a period of time equal to or greater than the specified STABILIZATION TIME.

#### 4.3.4 Adjustments during test

Compliance tests shall be performed with the instrument ready for use, after the STABILIZATION TIME and after making any necessary preliminary adjustments. During the tests, adjustments may be repeated at intervals as long as they do not interfere with the effect to be verified. For example, zero setting is not permitted during tests for measuring the LEAKAGE CURRENT.

#### 4.3.5 Batteries

~~Battery-operated instruments shall be equipped with fresh batteries, of the type specified by the MANUFACTURER.~~

Compliance tests shall not be performed while the DOSIMETER indicates a low battery condition. **5**

### 4.4 Constructional requirements as related to performance

#### 4.4.1 Components

If a DIAGNOSTIC DOSIMETER has several ranges or scales or if the DOSIMETER consists of several components, all ranges, scales and components shall be unmistakably and unambiguously identified.

*Compliance with the constructional requirement on components shall be checked by inspection.*

### 4.4.2 Display

#### 4.4.2.1 Units

The indicated unit shall be that of the measuring quantity: AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE, i.e. Gy, Gy·m or Gy/s respectively, possibly with SI prefix, for example m or µ.

*Compliance with the constructional requirement on components shall be checked by inspection.*

~~#### 4.4.2.2 Analogue displays~~

~~Analogue displays shall have a linear scale which is designed such that the ratio of the full-scale values of two subsequent measurement ranges does not exceed 10:3.~~

~~*Compliance with the constructional requirement on components shall be checked by inspection.*~~

#### 4.4.2.2 Digital display

Digital displays whose improper function can result in non-perceptible faults (e.g., no light emission from certain segments of a segment display) shall be provided with a means of reliably checking their proper function.

*Compliance with the constructional requirement on display shall be checked by inspection.*

### 4.4.3 Indication of battery condition

Battery-operated DOSIMETERS shall be provided with a low battery indication for any battery voltage below the RATED RANGE.

*Compliance with the constructional requirement on indication of battery condition shall be checked by inspection.*

### 4.4.4 Indication of polarizing voltage failure

DOSIMETERS intended for use with IONIZATION CHAMBERS shall be provided with a means of indicating if the polarizing voltage does not meet the manufacturer's requirement for satisfactory operation.

*Compliance with the constructional requirement on polarizing voltage shall be checked by inspection.*

### 4.4.5 Over-ranging

When testing for compliance with the requirement on over-ranging, it is not necessary to use REFERENCE CONDITIONS.

The following requirements shall be fulfilled.

a) On all AIR KERMA RATE ranges, the DOSIMETER shall clearly indicate over-range when the full-scale reading is exceeded, and shall remain indicating over-range for all AIR KERMA RATES up to 1 Gy/s.

   *Compliance shall be checked for each allowable combination of AIR KERMA RATE range and DETECTOR ASSEMBLY with a full scale reading of 10 mGy/s or less, by exposing the relevant RADIATION DETECTOR in any suitable X-ray beam at the AIR KERMA RATE, for which the display reads just below the stated full scale, then proceeding to:*

   *1) increase the AIR KERMA RATE slowly but continuously until the display shows over-range;*

2) *increase the AIR KERMA RATE ~~further in discrete decade steps until 10 mGy/s is exceeded~~ up to 1 Gy/s and 10 times the full scale reading, checking that the display indicates over-range for each of these AIR KERMA RATES.*

*Compliance shall be checked for each allowable combination of AIR KERMA RATE range and DETECTOR ASSEMBLY with a full scale reading of more than 10 mGy/s as described above, or by conducting an electrical test on the MEASURING ASSEMBLY and verifying that, for ion currents corresponding to AIR KERMA RATES of up to 1 Gy/s or 10 times the full scale reading, the DOSIMETER clearly indicates an over-range condition.*

b) On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, the DOSIMETER shall clearly indicate over-range when the full scale reading is exceeded.

*Compliance shall be checked on each AIR KERMA and AIR KERMA LENGTH PRODUCT range by exposing the relevant RADIATION DETECTOR until the display reads just below the stated full scale. The irradiation should then be continued in AIR KERMA or AIR KERMA LENGTH PRODUCT steps approximately equal to the display resolution for the range in use, until the display* shows over-range. An equivalent electrical test can be made on the *MEASURING ASSEMBLY*.

c) On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, the DOSIMETER shall clearly indicate over-range when the RATED RANGE of AIR KERMA RATE is exceeded, unless it is able to measure AIR KERMA at an AIR KERMA RATE of at least:

– 1 Gy/s in the conventional diagnostic UNATTENUATED BEAM;
– 10 mGy/s in the conventional diagnostic ATTENUATED BEAM;
– 100 mGy/s in the mammographic UNATTENUATED BEAM;
– 500 mGy/s in the computed tomographic UNATTENUATED BEAM.

*Compliance shall be checked on each AIR KERMA and AIR KERMA LENGTH PRODUCT range by exposing the relevant RADIATION DETECTOR to an AIR KERMA RATE of 10 % above the RATED RANGE and checking that the DOSIMETER clearly indicates an over-range condition.*

d) During any period of time when the DOSIMETER is inactive, for example following the reset procedure, this state shall be indicated.

*Compliance with this constructional requirement shall be checked by inspection.*

#### 4.4.6 MEASURING ASSEMBLIES with multiple DETECTOR ASSEMBLIES

For MEASURING ASSEMBLIES displaying AIR KERMA or AIR KERMA RATE using multiple DETECTOR ASSEMBLIES connected to a single display, ~~only the signal from a single DETECTOR ASSEMBLY shall be displayed on the MEASURING ASSEMBLY at any one time~~ it shall be clearly visible which INDICATED VALUES refer to which DETECTOR ASSEMBLY.

*Compliance with the constructional requirement on MEASURING ASSEMBLIES with multiple DETECTOR ASSEMBLIES shall be checked by inspection.*

#### 4.4.7 Radioactive STABILITY CHECK DEVICE

The half-life of the RADIONUCLIDE of a STABILITY CHECK DEVICE (if provided) shall be greater than five years.

*Compliance shall be checked by inspection.*

### 4.5 UNCERTAINTY of measurement

When measurements of VARIATION are made to verify that equipment complies with specified LIMITS OF VARIATION, the OVERALL UNCERTAINTY of these measurements of VARIATION should be less than one-fifth of the LIMITS OF VARIATION.

If this is not possible and if the OVERALL UNCERTAINTY of the measurement is less than one half of the LIMITS OF VARIATION, the OVERALL UNCERTAINTY of the measurement made in the compliance test procedures shall be taken into account in the evaluation of the equipment under test by adding the OVERALL UNCERTAINTY to the LIMITS OF VARIATION allowed.

If the OVERALL UNCERTAINTY exceeds one-fifth of the LIMITS OF VARIATION for any PERFORMANCE CHARACTERISTIC, then this shall be stated.

In case of DIAGNOSTIC DOSIMETERS, the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a ~~confidence level~~ coverage probability of 95 % (see IEC 60731:2011, Annex A).

## 5 Limits of PERFORMANCE CHARACTERISTICS

### 5.1 Linearity

For AIR KERMA RATE measurements, Formula (2) shall be fulfilled over the whole RATED RANGE of AIR KERMA RATE:

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}02 \tag{2}$$

where

$R_{max}$ is the maximum RESPONSE over the RATED RANGE of AIR KERMA RATE;

$R_{min}$ is the minimum RESPONSE.

*Compliance with this performance requirement shall be checked by measuring the RESPONSE resulting from the minimum to the maximum RATED AIR KERMA RATE, with measurements made at AIR KERMA RATES in steps not greater than one order of magnitude.*

### 5.2 Repeatability

#### 5.2.1 General

When a measurement is repeated with the same DOSIMETER under unaltered conditions, the COEFFICIENT OF VARIATION of the measurement shall not exceed the maximum value given in Table 3 and Table 4.These requirements are generally valid for an AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE which corresponds to approximately two-thirds of the full scale value of analogue indications and a reading with a RESOLUTION of at least 0,25 % in the case of digital displays.

#### 5.2.2 Repeatability in the ATTENUATED BEAM

*Compliance with the requirements for repeatability in the ATTENUATED BEAM stated in Table 3 shall be checked by measuring the COEFFICIENT OF VARIATION near the lowest limit of the EFFECTIVE RANGE of measurement for AIR KERMA, AIR KERMA RATE and AIR KERMA LENGTH PRODUCT stated by the manufacturer. If this lower limit is below 10 µGy for AIR KERMA measurements and/or below 1 µGy/s for AIR KERMA RATE measurements, additional tests shall be made at 10 µGy and 1 µGy/s respectively.*

**Table 3 – Maximum values for the COEFFICIENT OF VARIATION, $v_{max}$, for measurements in the attenuated beam**

| Quantity | Range of measurement | Maximum COEFFICIENT OF VARIATION ($v_{max}$) |
|---|---|---|
| AIR KERMA, $K$ | $K$ < 10 µGy<br>$K$ ≥ 10 µGy | 0,166 7 × (16 – $K$) %[a]<br>1 % |
| AIR KERMA RATE, $\dot{K}$ | $\dot{K}$ < 1 µGy/s<br>$\dot{K}$ ≥ 1 µGy/s | 1,11 × (4,7 – 2 $\dot{K}$) %[b]<br>3 % |
| AIR KERMA LENGTH PRODUCT, $K{\cdot}l$[c] | As specified by manufacturer | 1 % |
| [a] $K$ in µGy.<br>[b] $\dot{K}$ in µGy/s.<br>[c] Approximately 50 % of the RATED LENGTH should be irradiated. | | |

### 5.2.3 Repeatability in the UNATTENUATED BEAM

*Compliance with the requirements for repeatability in the UNATTENUATED BEAM stated in* Table 4 *shall be checked by measuring the COEFFICIENT OF VARIATION near the lowest limit of the EFFECTIVE RANGE of measurement for AIR KERMA, AIR KERMA RATE and AIR KERMA LENGTH PRODUCT stated by the manufacturer. If this lower limit is below 1 000 µGy for AIR KERMA measurements and/or below 100 µGy/s for AIR KERMA RATE measurements, additional tests shall be made at 1 000 µGy and 100 µGy/s respectively.*

NOTE The COEFFICIENT OF VARIATION is assumed to be determined from a set of at least 10 readings.

**Table 4 – Maximum values for the COEFFICIENT OF VARIATION, $v_{max}$, for measurements in the unattenuated beam and mammography**

| Quantity | Range of measurement | Maximum COEFFICIENT OF VARIATION ($v_{max}$) |
|---|---|---|
| AIR KERMA, $K$ | $K$ < 1 000 µGy<br>$K$ ≥ 1 000 µGy | 0,166 7 × (16 – 0,01 $K$) %[a]<br>1 % |
| AIR KERMA RATE, $\dot{K}$ | $\dot{K}$ < 100 µGy/s<br>$\dot{K}$ ≥ 100 µGy/s | 1,11 × (4,7 – 0,02 $\dot{K}$) %[b]<br>3 % |
| AIR KERMA LENGTH PRODUCT, $K{\cdot}l$[c] | As specified by manufacturer | 1 % |
| [a] $K$ in µGy.<br>[b] $\dot{K}$ in µGy/s.<br>[c] Approximately 50 % of the RATED LENGTH should be irradiated. | | |



## 5.3 RESOLUTION of reading

Within the whole EFFECTIVE RANGE OF INDICATED VALUES, the RESOLUTION of the reading shall be less than or equal to 1 %.

*Compliance with this performance requirement shall be checked by inspection.*

## 5.4 STABILIZATION TIME

Fifteen minutes after switching on the instrument, the LIMITS OF VARIATION of RESPONSE shall be within ±2 % of the steady state value of the RESPONSE.

*Compliance with this performance requirement shall be checked by determining the RESPONSE of the instrument under the same conditions as at calibration, 15 min, 30 min, 45 min and 1 h after the DOSIMETER has been switched on.*

### 5.5 Effect of pulsed radiation on AIR KERMA and AIR KERMA LENGTH PRODUCT measurements

If the DOSIMETER is designed for AIR KERMA measurements in the conventional diagnostic beam (or AIR KERMA LENGTH PRODUCT measurements in the CT beam), the MEASURING ASSEMBLY shall be able to indicate AIR KERMA (or AIR KERMA LENGTH PRODUCT) within the limits of error stated in 5.1, when a pulse of radiation of 1 ms duration and an AIR KERMA RATE of

– ~~1 Gy/s or~~ **6** just below the maximum RATED AIR KERMA RATE~~, whichever is the lower,~~ is incident on each DETECTOR ASSEMBLY stated as suitable for use in the conventional diagnostic UNATTENUATED BEAM;

– ~~10 mGy/s or~~ just below the maximum RATED AIR KERMA RATE~~, whichever is the lower,~~ is incident on each DETECTOR ASSEMBLY stated as suitable for use in the conventional diagnostic ATTENUATED BEAM;

– ~~500 mGy/s or~~ just below the maximum RATED AIR KERMA RATE~~, whichever is the lower,~~ is incident on 50 % of each DETECTOR ASSEMBLY stated as suitable for use in the CT UNATTENUATED BEAM.

*Compliance with this performance requirement ~~may~~ shall be checked by ~~testing the measuring ASSEMBLY electrically with pulses corresponding to the AIR KERMA pulses~~ measuring the RESPONSE of the DOSIMETER under the irradiation conditions defined above.*

### ~~5.6 Reset on AIR KERMA and AIR KERMA LENGTH PRODUCT ranges~~ 7

~~On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, after resetting the DOSIMETER once, the reading shall not be greater than 1,0 % of the full scale reading.~~

~~*Compliance with this performance requirement shall be checked on each AIR KERMA range by obtaining a near full scale reading, either by exposing a suitable RADIATION DETECTOR, or by injecting an equivalent electrical signal, then resetting the DOSIMETER once and noting the residual reading.*~~

### ~~5.7 Effects of LEAKAGE CURRENT~~ 8

#### ~~5.7.1 AIR KERMA RATE measurements~~

~~On all AIR KERMA RATE ranges, the LEAKAGE CURRENT of a DOSIMETER shall not exceed 5,0 % of the minimum EFFECTIVE AIR KERMA RATE of the range in use for at least 1 min, after any compensation adjustment has been made.~~

~~*Compliance with this performance requirement shall be checked for each allowable combination of AIR KERMA RATE range and DETECTOR ASSEMBLY, by measuring the LEAKAGE CURRENT in the "measure" condition with the relevant RADIATION DETECTOR connected.*~~

#### ~~5.7.2 AIR KERMA and AIR KERMA LENGTH PRODUCT measurements~~

~~On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, when the DOSIMETER is left in the "measure" condition after being exposed to the maximum EFFECTIVE AIR KERMA or AIR KERMA LENGTH PRODUCT, the INDICATED VALUE shall not change by more than 1,0 % per minute, and after being exposed to the minimum EFFECTIVE AIR KERMA or AIR KERMA LENGTH PRODUCT the INDICATED VALUE shall not change by more than 5,0 % per minute.~~

~~*Compliance with this performance requirement shall be checked for each allowable combination of AIR KERMA (or AIR KERMA LENGTH PRODUCT) range and DETECTOR ASSEMBLY, by exposing the relevant RADIATION DETECTOR until the display reads just below the stated full scale, then*~~

~~*stopping the irradiation and noting the* RATE *of change of reading whilst keeping the* DOSIMETER *in the "measure" condition.*~~

### 5.6 Stability

#### 5.6.1 Long term stability

For all RADIATION QUALITIES within the RATED RANGE, the LIMITS OF VARIATION of RESPONSE when the DETECTOR ASSEMBLY is irradiated in a reproducible field shall not be greater than ±2,0 % per year.

*Compliance with this performance requirement shall be checked by retaining a representative MEASURING ASSEMBLY and DETECTOR ASSEMBLY(IES), stored under STANDARD TEST CONDITIONS, and investigating their combined long-term stability by making measurements under REFERENCE CONDITIONS at one-month intervals over a period of not less than six months and then using linear regression analysis to extrapolate these readings to obtain the change in RESPONSE over one full year. It is permissible to perform the tests on the MEASURING and DETECTOR ASSEMBLIES separately.*

#### 5.6.2 Accumulated dose stability

After the complete DETECTOR ASSEMBLY has been uniformly irradiated at the conventional diagnostic UNATTENUATED BEAM QUALITY of 70 kV to an accumulated AIR KERMA of 40 Gy, using the maximum RATED field length for CT DETECTORS or the maximum RATED field size for all other DETECTORS,

– the DOSIMETER shall still meet the requirements for ~~LEAKAGE CURRENT~~ LINEARITY given in ~~5.7.1 and 5.7.2~~ 5.1, and
– the LIMITS OF VARIATION of RESPONSE of the DOSIMETER due to the effect of accumulated AIR KERMA on the DETECTOR ASSEMBLY shall not be greater than ±1,0 %.

This requirement shall be met for all DETECTOR ASSEMBLIES supplied with the DOSIMETER.

*Compliance with this performance requirement shall be checked by*

– *repeating the test for ~~LEAKAGE CURRENT~~ linearity given in ~~5.7.1 and 5.7.2~~ 5.1, after delivering the specified accumulated air kerma to the DETECTOR ASSEMBLY, and*
– *measuring the RESPONSE of the DOSIMETER in a reproducible radiation field at the RELEVANT REFERENCE RADIATION quality both before and after delivering the specified accumulated AIR KERMA to the DETECTOR ASSEMBLY in "measure" condition* **9** *and noting the difference. For this test, irradiation conditions shall lie within the RATED RANGES given in Table 5.*

### 5.7 Measurements with a radioactive STABILITY CHECK DEVICE

If a DOSIMETER has an associated radioactive STABILITY CHECK DEVICE which can be used to test its function and RESPONSE and if this STABILITY CHECK DEVICE allows the DOSIMETER to be irradiated in a defined geometry and reproducibly produces a certain MEASURED VALUE (check indication or check time), these check values shall be repeatable at constant air density with a COEFFICIENT OF VARIATION of less than 3 %.

Furthermore, the INSTRUCTIONS FOR USE shall contain information which allows the check indication or the check time to be determined for the respective date with an UNCERTAINTY of less than ±1,0 %.

*Compliance with this performance requirement shall be made by making repeated measurements using the STABILITY CHECK DEVICE according to the instructions given by the manufacturer in the ACCOMPANYING DOCUMENTS. The DETECTOR and STABILITY CHECK DEVICE shall be separated and set-up again between measurements.*

NOTE The COEFFICIENT OF VARIATION is assumed to be determined from a set of at least 10 readings.

## 6 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES

### 6.1 General

The LIMITS OF VARIATION $\pm L$ due to the effects of INFLUENCE QUANTITIES are summarized in Table 5. For any change of an INFLUENCE QUANTITY within its RATED RANGE, the change of the DOSIMETERS RESPONSE shall not be greater than the values in column 4 of Table 5.

### 6.2 Energy dependence of RESPONSE

A DIAGNOSTIC DOSIMETER may have several different RATED RANGES for photon energy (see items a) to e) in Table 5). Over each of these RATED RANGES, the LIMITS OF VARIATION of RESPONSE with changes in RADIATION QUALITY shall not be greater than those given in Table 5.

*Compliance with the requirement on the VARIATION of the instruments RESPONSE with RADIATION QUALITY shall be measured under the same irradiation conditions as for calibration. For each energy range for which the DETECTOR under test is designed, at least the RADIATION QUALITIES listed below as a minimum shall be used, covering the whole stated RATED RANGE:*

- *for the conventional diagnostic range, those with 50 kV, 70 kV, 100 kV, 150 kV X-ray TUBE VOLTAGE;*
- *for mammography, the reference point and the minimum and maximum of the rated range ~~those with 25 kV, 28 kV and 35 kV~~;*
- *for the CT range, those with 100 kV, 120 kV and 150 kV;*
- *for copper-filtered beams, those with 50 kV, 70 kV and 100 kV.*

*For these tests the qualities stated in Table 5 shall be used.*

**Table 5 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES**

| INFLUENCE QUANTITY | MINIMUM RATED RANGE | REFERENCE CONDITIONS | LIMITS OF VARIATION *L* | Subclause |
|---|---|---|---|---|
| RADIATION QUALITY | X-RAY TUBE VOLTAGE and qualities | | | 6.2 |
| a) Conventional diagnostic UNATTENUATED BEAM | 50 kV to 150 kV RQR 3 to RQR 10 x IEC 61267 | 70 kV RQR 5 x IEC 61267 | ±5 % | |
| b) Conventional diagnostic ATTENUATED BEAM | 50 to 150 kV RQA 3 to RQA 10 x IEC 61267 | 70 kV RQA 5 x IEC 61267 | ±5 % | |
| ~~c) mammography UNATTENUATED BEAM[a]~~ | ~~25 – 35 kV different anode + filter combinations[b]~~ | ~~28 kV~~ | ~~±5 %~~ | |
| ~~d) mammography ATTENUATED BEAM[a]~~ | ~~25 – 35 kV different anode + filter combinations[b] + added 2 mm Al filter (≥99,9 % purity)~~ | ~~28 kV~~ | ~~±5 %~~ | |
| c) Mammography UNATTENUATED BEAM[a] | As stated by the manufacturer[b] | As stated by the manufacturer[b] | ±5 % | |
| d) COMPUTED TOMOGRAPHY **10** | 100 to 150 kV RQR 8 to RQR 10 x IEC 61267 | 120 kV RQT 9 x IEC 61267 | ±5 % | |
| | 100 to 150 kV RQT 8 to RQT 10 x IEC 61267 | | | |
| | 100 to 120 kV RQA ~~8~~ 5 to RQA 9 x IEC 61267 | | | |
| e) Copper-filtered beams | 50 to 100 kV RQC3 to RQC 8 x IEC 61267 | 70 kV RQC 5 x IEC 61267 | ±5 % | |
| AIR KERMA RATE (in the case of AIR KERMA measurements) | As stated by the manufacturer | As at calibration | ±2 % | 6.3 |
| Incidence of radiation | | | | |
| – non-CT detectors | ±5°[c] | Reference direction | ±3 % | 6.4.1 |
| – CT DETECTORS | ±180°[d] | | ±3 % | 6.4.2 |
| Operating voltage | | | | |
| Mains | –15 % to +10 % | Nominal voltage[e] | ±2 % | 6.5 |
| Batteries | As stated by the manufacturer | | | |
| Air pressure | 80,0 kPa to 106,0 kPa | 101,3 kPa | ±2 % | 6.6 |
| Air pressure EQUILIBRATION TIME | ±10,0 % | Atmospheric pressure | < 20 s | 6.7 |
| Temperature | +15 °C to +35 °C | +20 °C | ±3 % | 6.8 |
| Relative humidity | ≤ 80 % (maximum 20 g/m$^3$) | 50 % | | |
| Electromagnetic compatibility | As in IEC 61000-4 | Without any disturbance | ±5 % | 6.9 |
| Field size | Minimum: as stated by the manufacturer Maximum: not less than 35 cm × 35 cm | As at calibration | ±3 % | 6.10 |

| INFLUENCE QUANTITY | MINIMUM RATED RANGE | REFERENCE CONDITIONS | LIMITS OF VARIATION | Subclause |
|---|---|---|---|---|
| | | | *L* | |
| [a] A beryllium window is assumed. | | | | |
| [b] RADIATION QUALITIES used in mammography can be based on different combinations of X-RAY TUBE anode materials (e.g., W, Mo, Rh) and filtrations (e.g., Al, Mo, Rh, Pd, Ag). Each such combination may have its own RATED RANGE. If applicable, established radiation qualities should be used as defined in IEC 61267. | | | | |
| [c] From the normal direction of incidence. | | | | |
| [d] In the plane perpendicular to the DETECTOR. | | | | |
| [e] The nominal voltage need not be a single value but can be expressed as a range. | | | | |

### 6.3 AIR KERMA RATE dependence of AIR KERMA and AIR KERMA LENGTH PRODUCT measurements

~~#### 6.3.1 MEASURING ASSEMBLY~~

For AIR KERMA (and AIR KERMA LENGTH PRODUCT) measurements, Formula (3) shall be fulfilled over the whole RATED RANGE of AIR KERMA RATE:

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}02 \qquad (3)$$

where

$R_{max}$ is the maximum RESPONSE over the RATED RANGE of AIR KERMA RATE;

$R_{min}$ is the minimum RESPONSE.

*Compliance with this performance requirement shall be checked by measuring the AIR KERMA (or AIR KERMA LENGTH PRODUCT) RESPONSE resulting from the minimum to the maximum RATED AIR KERMA RATE, with measurements made at AIR KERMA RATES in steps not greater than one order of magnitude. The AIR KERMA (or AIR KERMA LENGTH PRODUCT) applied shall be kept approximately constant by varying the irradiation time. It is permissible to make an equivalent electrical test on the MEASURING ASSEMBLY.*

~~#### 6.3.2 IONIZATION CHAMBER – Recombination losses~~ 11

~~The MANUFACTURER shall state:~~

- ~~for conventional DIAGNOSTIC and mammographic IONIZATION CHAMBERS, the AIR KERMA RATE and AIR KERMA per pulse values at which the ion collection efficiency of the IONIZATION CHAMBER falls to 95 % when the normal polarizing voltage is applied;~~
- ~~for COMPUTED TOMOGRAPHY IONIZATION CHAMBERS, for a stated length of volume irradiated, the AIR KERMA LENGTH PRODUCT RATE value at which the ion collection efficiency of the IONIZATION CHAMBER falls to 95 % when the normal polarizing voltage is applied.~~

~~For diagnostic measurements no CORRECTION FACTOR for recombination losses has to be applied, as long as the RADIATION DETECTOR is used within its RATED RANGE of AIR KERMA (LENGTH) PRODUCT RATE. The calculations of recombination losses shall only provide a conservative estimation of the highest measurable AIR KERMA (LENGTH) PRODUCT RATE.~~

~~*Compliance in the case of AIR KERMA RATE shall be checked by irradiating the IONIZATION CHAMBER in continuous radiation at a known AIR KERMA RATE and then measuring the ion collection efficiency by observing changes in the INDICATED VALUE for known changes in the polarizing voltage.*~~

~~*Compliance in the case of AIR KERMA pulse shall be checked either by:*~~

- ~~*irradiating the IONIZATION CHAMBER in pulsed radiation at a known AIR KERMA pulse and then measuring the ion collection efficiency by observing changes in the INDICATED VALUE for known changes in the polarizing voltage, or by*~~
- ~~*extrapolating the result of the measurement made in continuous radiation to the pulsed case.*~~

~~In either the continuous or pulsed case it is allowable to make the measurement of ion collection efficiency at an AIR KERMA RATE (or AIR KERMA per pulse) less than the maximum RATED value using a lower than normal polarizing voltage and then to extrapolate the measurements to the specified conditions.~~

### 6.4 Dependence of DETECTOR RESPONSE on angle of incidence of radiation

#### 6.4.1 Non-CT detectors

For non-CT detectors, the LIMITS OF VARIATION of RESPONSE due to a change in the angle of incidence ~~of ±5°~~ within the RATED RANGE from the normal direction of incidence shall not be greater than those given in Table 5.

*Compliance with this performance requirement shall be checked by measuring the RESPONSE of the DOSIMETER with the DETECTOR of the instrument tilted ~~±5°~~ by the maximum and minimum RATED value in two perpendicular directions from a position with the axis perpendicular to the axis of the beam.*

#### 6.4.2 CT DETECTORS

For CT DETECTORS, the LIMITS OF VARIATION of RESPONSE due to a change in the angle of incidence ~~of ±180°~~ within the RATED RANGE in the plane perpendicular to the DETECTOR axis shall not be greater than those given in Table 5.

Compliance shall be checked in a ~~100 kV~~ RQT-8 x IEC 61267 or RQA-8 x IEC 61267 ATTENUATED BEAM of width 30 % of the RATED LENGTH centred on the RATED LENGTH.

### 6.5 Operating voltage

#### 6.5.1 Mains-operated DOSIMETERS

For mains-operated DOSIMETERS, the LIMIT OF VARIATION of RESPONSE due to VARIATION of the operating voltage between +10 % and –15 % of the nominal voltage shall not be greater than the limit stated in Table 5, over the RATED RANGE of mains voltage stated by the manufacturer.

*Compliance with this performance requirement shall be checked by taking two sets of readings with the voltage of the AC power supply adjusted to the upper and lower boundaries of the RATED RANGE of operating voltage stated by the manufacturer and compared with a reference set of readings at nominal operating voltage.*

*A radioactive check source may be used when carrying out these measurements.*

#### 6.5.2 Battery-operated DOSIMETERS

For battery-operated DOSIMETERS, a low battery condition shall be indicated if the instrument is operating when the battery voltage is outside the RATED RANGE stated by the manufacturer. Over this RATED RANGE of battery voltage, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 5.

*Compliance with this performance requirement shall be checked as follows: ~~the batteries shall be replaced by a stable~~ 12 ~~d.c. power supply producing a voltage equivalent to the voltage~~*

~~*produced by a set of fresh batteries of the type specified by the manufacturer. a set of reference readings shall be taken and the voltage decreased until the battery power indicator begins to show low battery condition. a second set of readings shall then be taken and compared with the reference* VALUE.~~ *the reference reading shall be taken with a set of fresh batteries of the type specified by the manufacturer. In addition, a set of used batteries, which are just spent enough to cause the low battery indication to show, shall be fitted and a second set of readings shall be taken and compared with the reference reading.*

~~In some instruments, connection to an external supply with a cable may compromise the instrument shield, or batteries may not be at chassis ground. In these cases, the MANUFACTURER should provide proper guidance on the test method.~~

*A radioactive check source may be used when carrying out these measurements.*

### 6.5.3 Mains rechargeable, battery-operated DOSIMETERS

For mains rechargeable, battery-operated DOSIMETERS, in addition to the requirements on battery-powered DOSIMETERS, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 5 when the DOSIMETER is operated under the following conditions:

– mains disconnected, battery fresh;
– mains connected, battery fresh;
– mains connected, battery low.

*Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with the mains disconnected and a set of fresh batteries of the type specified by the manufacturer ~~fitted~~. The mains shall then be connected, and a second set of readings taken and compared with the reference reading. Finally, a set of used batteries, which are just spent enough to cause the low battery indication to show, shall be fitted and, with the mains connected, a third set of readings shall be taken and compared with the reference reading.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.6 Air pressure

The LIMITS OF VARIATION of RESPONSE shall not be greater than those given in Table 5 when the air pressure changes over its RATED RANGE. If the RADIATION DETECTOR is a VENTED IONIZATION CHAMBER, it is permissible for the MEASURED VALUE to be corrected for air density, either by manual calculation or automatically by the instrument, before this requirement is met.

*Compliance with this performance requirement shall be checked by making measurements at an ambient air pressure of 80,0 kPa and 106 kPa and comparing these measurements with those for the reference air pressure of 101,3 kPa. For VENTED IONIZATION CHAMBERS, all readings shall be corrected for air density before this comparison is made.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.7 Air pressure EQUILIBRATION TIME of the RADIATION DETECTOR

If the RESPONSE of the RADIATION DETECTOR is influenced by air density, the 90 % EQUILIBRATION TIME for pressure differences (sudden change of air pressure of 10 % within the RATED RANGE of pressure) between the exterior and interior of the RADIATION DETECTOR shall not be greater than that given in Table 5.

*Compliance with this performance requirement shall be checked by irradiating the DETECTOR ASSEMBLY at constant AIR KERMA RATE, then monitoring the change with time of the electrical signal from the DETECTOR ASSEMBLY when the DETECTOR ASSEMBLY is subjected to a sudden*

*change in air pressure of between 8 % and 12 %. The test shall be carried out for pressure changes in both directions.*

*For DOSIMETERS measuring AIR KERMA only, an alternative test method is permitted, as follows: an AIR KERMA measurement of less than 1 s duration shall be made and recorded. A sudden change in air pressure of between 8 % and 12 % shall then be made, followed by a second AIR KERMA measurement 20 s after the pressure change. The second measurement corrected for the change in air density due to the change of pressure shall be compared to the first measurement. The test shall be carried out for pressure changes in both directions.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.8 Temperature and humidity

The LIMITS OF VARIATION of the DOSIMETER's RESPONSE shall not be greater than the value given in Table 5, for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity (absolute humidity not to exceed 20 g/m$^3$). If the RADIATION DETECTOR is a VENTED IONIZATION CHAMBER, it is permissible for the MEASURED VALUE to be corrected for the air density, either by manual calculation or automatically by the instrument, before this requirement is met.

*Compliance with this performance requirement shall be checked by carrying out the following test. The DOSIMETER shall be exposed to varying temperature and air humidity. At least four measurements shall be performed, one under each of the climatic conditions stated* in *Table 6.*

**Table 6 – Climatic conditions**

| Temperature<br>°C | Relative humidity<br>% | Absolute humidity<br>g/m$^3$ |
|---|---|---|
| 20,0 | 50 | 8,5 |
| 15,0 | 80 | 11,5 |
| 26,5 | 80 | 20,0 |
| 35,0 | 50 | 20,0 |

*For VENTED IONIZATION CHAMBERS, all readings shall be corrected for air density before this comparison is made.*

*The DIAGNOSTIC DOSIMETER shall be exposed to each different temperature and humidity condition for at least 24 h before the instrument is tested.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.9 Electromagnetic compatibility

NOTE 1 The "complete equipment" means the MEASURING ASSEMBLY connected to a DETECTOR ASSEMBLY of a type customarily supplied with the MEASURING ASSEMBLY.

NOTE 2 A suitable overall STABILITY CHECK DEVICE can be fitted to the DETECTOR ASSEMBLY to produce a signal current during these measurements.

#### 6.9.1 ELECTROSTATIC DISCHARGE

The maximum spurious indications (both transient and permanent) of the display or data output due to ELECTROSTATIC DISCHARGE shall be less than the limits given in Table 5.

*Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while discharging a suitable test generator as described in IEC 61000-4-2:2008 at least five times to those various external parts of the complete equipment which may be touched by the operator during a normal measurement*

*(i.e. not to those parts of the CHAMBER and MEASURING ASSEMBLY that are normally exposed in the radiation beam), when the instrument is set to the "measure" condition on its most sensitive range (if the ranges are selectable). The ELECTROSTATIC DISCHARGE shall be equivalent to that from a capacitor of 150 pF charged to a voltage of 6 kV and discharged through a resistor of 330 Ω (severity level 3 for contact discharge as described in IEC 61000-4-2:2008). When instruments with insulated surfaces are tested, the air discharge method with a voltage of 8 kV (severity level 3) shall be used.*

A complete "latch-up" of the MEASURING ASSEMBLY which would not lead to an incorrect AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE value being indicated is allowed.

### 6.9.2 Radiated electromagnetic fields

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to electromagnetic fields shall be less than the limits given in Table 5.

*Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals with the DOSIMETER set to the most sensitive range (if the ranges are selectable), while measurements are performed, both with and without the presence of the radio-frequency field around the complete equipment.*

*The electromagnetic field strength shall be 3 V/m in the frequency range of 80 MHz to 1 GHz in steps of 1 % (severity level 2 as described in IEC 61000-4-3:2020). To reduce the amount of measurements needed to show compliance with this requirement, tests at frequencies 80 MHz, 90 MHz, 100 MHz, 110 MHz, 120 MHz, 130 MHz, 140 MHz, 150 MHz, 160 MHz, 180 MHz, 200 MHz, 220 MHz, 240 MHz, 260 MHz, 290 MHz, 320 MHz, 350 MHz, 380 MHz, 420 MHz, 460 MHz, 510 MHz, 560 MHz, 620 MHz, 680 MHz, 750 MHz, 820 MHz, 900 MHz and 1 000 MHz with a field strength of 10 V/m may be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in* Table 5 *is observed at one of these given frequencies, additional tests in the range of ±5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the DOSIMETER in all three orientations as described in IEC 61000-4-3:2020. For battery-operated instruments, for which the requirements of 6.9.3 and 6.9.4 do not apply, tests at 27 MHz shall also be performed.*

### 6.9.3 CONDUCTED DISTURBANCES induced by bursts and radio frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to CONDUCTED DISTURBANCES induced by bursts and radio frequencies shall be less than the limits given in Table 5.

*For mains-operated instruments, compliance shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range (if the ranges are selectable), both with and without the presence of CONDUCTED DISTURBANCES induced by bursts (according to IEC 61000-4-4) and CONDUCTED DISTURBANCES induced by radio-frequency fields (according to IEC 61000-4-6). The severity level shall, in both cases, be level 3 as described in these standards.*

A complete "latch-up" of the MEASURING ASSEMBLY which would not lead to an incorrect AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE value being indicated is allowed.

### 6.9.4 Voltage dips, short interruptions and voltage VARIATIONS

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to voltage dips, short interruptions and voltage VARIATIONS shall be less than the limits given in Table 5.

*For mains-operated instruments, compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range, both with and without the*

*presence of conducted disturbances induced by voltage dips, short interruptions and voltage VARIATIONS as described in IEC 61000-4-11.*

### 6.10 Field size

For all non-CT detectors, the ACCOMPANYING DOCUMENTS shall state the RATED RANGE of field sizes. Over this RATED RANGE, the LIMIT OF VARIATION of RESPONSE shall not be greater than the value given in Table 5. The maximum RATED field size shall not be less than 35 cm × 35 cm.

*Compliance with this performance requirement shall be checked by measuring the percentage VARIATION in the electrical signal from the DETECTOR ASSEMBLY caused by changing the field size from its REFERENCE VALUE to its minimum and maximum RATED values, after making any corrections necessary for the change in AIR KERMA RATE with varying field size.*

### 6.11 EFFECTIVE LENGTH and spatial uniformity of RESPONSE of CT DOSIMETERS

Over the RATED LENGTH, the spatial uniformity of RESPONSE shall not vary by more than ±3 %.

In addition, the manufacturer shall declare the EFFECTIVE LENGTH of the DETECTOR.

*Compliance with this performance requirement shall be checked by employing a reproducible radiation slit field, defined by a lead diaphragm, of width not more than 2 mm and of length (perpendicular to the DETECTOR axis) sufficient to cover the diameter of the DETECTOR.*

*Commencing with the field centred at 5 cm outside the active volume at the end opposite the connectors and from the marking that indicates the limit of the RATED LENGTH of the DETECTOR, measure the RESPONSE several times for each position of the DETECTOR as the DETECTOR is progressively moved under the diaphragm at intervals equal to 2,5 % of the RATED LENGTH of the DETECTOR. Repeat these measurements across the entire RATED LENGTH of the DETECTOR and 5 cm beyond the second marker that indicates the limit of the RATED LENGTH. The EFFECTIVE LENGTH to be quoted is the full-width-half-maximum of the plot of RESPONSE against distance along the DETECTOR axis.*

## 7 Marking

### 7.1 DETECTOR ASSEMBLY

The DETECTOR shall be provided with the following permanently affixed and clearly legible markings:

– indication of origin, i.e. name and/or trade-mark of the manufacturer or supplier responsible for ensuring that the DETECTOR ASSEMBLY complies with this document;

– REFERENCE POINT of the RADIATION DETECTOR;

– type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized;

– for CT DETECTORS, limits of the ~~RATED~~ EFFECTIVE **13** LENGTH shall be clearly marked.

*Compliance shall be checked by inspection.*

### 7.2 MEASURING ASSEMBLY

The MEASURING ASSEMBLY shall be provided with the following permanently affixed and clearly legible markings:

– indication of origin, i.e. name and/or trademark of the manufacturer or supplier responsible for ensuring that the MEASURING ASSEMBLY complies with this document;

– type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized;
– rated mains supply potential or potentials and rated mains supply frequency or frequencies required so that the performance of the instrument complies with Clause 5 and Clause 6;
– for battery-operated DOSIMETERS, type of batteries required so that the performance of the instrument complies with Clause 5 and Clause 6.

Any graphical symbols used shall be in accordance with IEC 60417.

*Compliance shall be checked by inspection.*

### 7.3 Radioactive STABILITY CHECK DEVICE

The radioactive STABILITY CHECK DEVICE shall be provided with the following permanently affixed and clearly legible markings:

– international trefoil symbol on the surface of the carrying case and on the accessible surface of the device immediately surrounding the source;
– name and ACTIVITY of the RADIONUCLIDE;
– date for which the stated ACTIVITY of the source is applicable;
– type number and serial number of the device, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized.

Markings can be required by relevant national and international legislation.

*Compliance shall be checked by inspection.*

## 8 ACCOMPANYING DOCUMENTS

The manufacturer shall provide adequate information describing the correct use of the instrument.

In general, the ACCOMPANYING DOCUMENTS shall comply with IEC 61187.

The ACCOMPANYING DOCUMENTS shall contain a description of the DIAGNOSTIC DOSIMETER, including its type number and manufacturer.

In addition, the ACCOMPANYING DOCUMENTS shall contain the following information applicable to each type of DETECTOR ASSEMBLY supplied:

– dimensions of DETECTOR(S) and construction (a diagram is considered to be useful);
– RATED RANGE OF USE for X-RAY TUBE VOLTAGE/RADIATION QUALITY;
– data giving typical dependence of RESPONSE on RADIATION QUALITY;
– position of REFERENCE POINT of DETECTOR;
– reference direction of incident radiation;
– maximum RATED AIR KERMA RATE and AIR KERMA per pulse;
– EFFECTIVE RANGES of measurement and RESOLUTION in SI units;
– RATED RANGE OF USE for atmospheric pressure;
– RATED RANGE OF USE for angle of incidence of radiation;
– RATED RANGE OF USE for temperature;
– RATED RANGE OF USE for air humidity;

– RATED RANGE OF USE for operating voltage and, for battery-operated instruments, typical battery life;

– RATED RANGE OF USE for field sizes; furthermore, the ACCOMPANYING DOCUMENTS shall recommend that measurements are conducted only with a field size of at least 10 mm greater than the minimum RATED field size, because of the discrepancies between the light and radiation fields that are typical of diagnostic X-ray equipment;

– table, diagram or formula for air density correction (if required);

– handling of radioactive or electric STABILITY CHECK DEVICE (if necessary);

– table or formula for VARIATION of check indication or check time, as a result of decreased ACTIVITY of radioactive source (if necessary);

– when applicable, a warning that introduction of material other than free air behind the RADIATION DETECTOR will cause its RESPONSE to change due to backscatter;

– a warning that, on AIR KERMA ranges, maximum RATED AIR KERMA RATE or AIR KERMA per pulse should not be exceeded;

– a warning that the instrument shall not be used for dose measurements at RADIATION QUALITIES significantly different from those specified in the ACCOMPANYING DOCUMENTS;

– for DOSIMETERS that cannot display either negative readings or negative drift, a warning notice reading as follows: "Warning – This instrument will not display negative readings. Be sure to accumulate a positive reading before attempting to measure the instrument drift";

– for non-CT detectors, those parts of DETECTOR ASSEMBLY that need to be uniformly irradiated to give the correct RESPONSE;

– for CT DETECTORS, the limits on RATED LENGTH, EFFECTIVE LENGTH of the DETECTOR and uniformity of RESPONSE over RATED LENGTH;

– for ionization chambers, statement if air density correction is applied;

– the manufacturer shall state the REFERENCE VALUES and STANDARD TEST VALUES in the INSTRUCTIONS FOR USE or in the test sheets.

*Compliance shall be checked by inspection.*

# Annex A
(informative)

## Combined standard uncertainty for dosimeter performance

The COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical dosimeter operating at the maximum limits of PERFORMANCE CHARACTERISTICS according to Clause 5 and LIMITS OF VARIATION *L* for the effects of INFLUENCE QUANTITIES according to Table 5 was estimated. The uncertainty components and the results are shown in Table A.1.

**Table A.1 – Estimation of COMBINED STANDARD UNCERTAINTY for dosimeter performance**

| PERFORMANCE CHARACTERISTIC | Subclause | Relative STANDARD UNCERTAINTY[a] % |
|---|---|---|
| Calibration factor[b] | | ±2,89 |
| Linearity | 5.1 | ±1,15 |
| Repeatability | 5.2 | ±0,58 |
| RESOLUTION of reading | 5.3 | ±0,58 |
| STABILIZATION TIME | 5.4 | ±1,15 |
| ~~Reset on air kerma range~~ | ~~5.6~~ | ~~±0,58~~ |
| ~~LEAKAGE CURRENT~~ | ~~5.7.2~~ | ~~±0,58~~ |
| Long term stability | 5.6.1 | ±1,15 |
| Accumulated dose stability | 5.6.2 | ±0,58 |
| RADIATION QUALITY | 6.2 | ±2,89 |
| AIR KERMA RATE | 6.3 | ±1,15 |
| Incidence of radiation | 6.4 | ±1,73 |
| Operating voltage | 6.5 | ±1,15 |
| Air pressure | 6.6 | ±1,15 |
| Temperature and humidity | 6.8 | ±1,73 |
| Electromagnetic compatibility | 6.9 | ±2,89 |
| Field size | 6.10 | ±1,73 |
| **COMBINED STANDARD UNCERTAINTY** | | ±6,~~5~~6 |

[a] Relative STANDARD UNCERTAINTY assuming that there is no additional information about the PROBABILITY DISTRIBUTION of the PERFORMANCE CHARACTERISTIC within the allowed interval other than it has an uniform distribution, i.e. 0,577 *L* for symmetric limits.

[b] Although no requirement on the accuracy of the calibration factor is laid down in this document, a maximum error of the calibration factor is included here and assumed to be ±5 %. A uniform distribution is also assumed.

# Bibliography

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IEC 60601-1:2005/AMD1:2012
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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 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61676:2023, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

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*

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# List of comments

1 The large variety of different radiation qualities in mammography made an explicit listing of radiation qualities impractical.

2 Modern devices no longer have analogue displays.

3 This is a practical decision by the authors for this standard only.

4 In related standards, the X-ray tube voltage is usually defined as the practical peak voltage.

5 Modern devices are usually mains rechargeable, battery-operated dosimeters.

6 The explicit dose rate was often misunderstood as a minimum rated range and was therefore removed for clarification.

7 Problems with range resets would become apparent when testing linearity.

8 Problems with leakage currents would become apparent when testing linearity.

9 In the previous edition, it was not clear whether the device should be switched on during the test.

10 Modern CT scanners can be operated at lower energies.

11 Problems with recombination losses would become apparent when testing linearity.

12 This is not possible with many modern devices and therefore cannot be tested in this way.

13 The markers normally show the effective length, this was a mistake in the previous edition.

# 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)

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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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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]

**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**
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, modified – The note has been deleted.]

**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]

**3.16**
**REFERENCE POINT OF A RADIATION DETECTOR**
**REFERENCE POINT**
point of a RADIATION DETECTOR which, during the calibration of the detector, is brought to coincidence with the point at which the CONVENTIONAL TRUE VALUE is specified

[SOURCE: IEC 60731:2011, 3.16, modified – The term "IONIZATION CHAMBER" has been replaced with "RADIATION DETECTOR" in both the term and the definition.]

**3.17**
**MEDICAL ELECTRICAL EQUIPMENT**
**ME EQUIPMENT**
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and
b) intended by its manufacturer to be used:
    1) in the diagnosis, treatment, or monitoring of a PATIENT; or
    2) for compensation or alleviation of disease, injury or disability

[SOURCE: IEC 60601-1:2005, 3.63, modified – The five notes have not been retained.]

**3.18**
**UNATTENUATED BEAM**
X-ray beam incident on the PATIENT or PHANTOM

**3.18.1**
**UNATTENUATED BEAM QUALITY**
RADIATION QUALITY of the X-ray beam at the location of the entrance surface of the PATIENT or the PHANTOM, determined when the latter are absent

**3.19**
**ATTENUATED BEAM**
X-ray beam exiting the PATIENT or PHANTOM

**3.19.1**
**ATTENUATED BEAM QUALITY**
RADIATION QUALITY of the X-ray beam exiting the PATIENT or PHANTOM

**3.20**
**RATED LENGTH**
length along the axis of the CT DETECTOR within which the DETECTOR performs to its specification

**3.20.1**
**EFFECTIVE LENGTH**
length along the axis of the CT DETECTOR between the two points at which the RESPONSE has fallen to 50 % of its value at its geometrical centre

**3.21**
**AIR KERMA**
***K***
quotient of $dE_{tr}$ by $dm$ where $dE_{tr}$ is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass $dm$

Note 1 to entry: The unit of AIR KERMA is Gy (where 1 Gy = 1 $J \cdot kg^{-1}$).

[SOURCE: IEC 60731:2011, 3.31, modified – The second note has been deleted.]

**3.21.1**
**AIR KERMA RATE**
$\dot{K}$
quotient of $dK$ by $dt$, where $dK$ is the increment of AIR KERMA in the time interval $dt$

Note 1 to entry: The unit of AIR KERMA RATE is $Gy \cdot s^{-1}$ ($Gy \cdot min^{-1}$; $Gy \cdot h^{-1}$).

[SOURCE: IEC 60731:2011, 3.31.1, modified – The second note has been deleted.]

**3.21.2**
**AIR KERMA LENGTH PRODUCT**
$P_{KL}$
line integral of the AIR KERMA $K$ over a length $L$

$$P_{KL} = \int_L K(z)dz \quad (1)$$

Note 1 to entry: The unit of AIR KERMA LENGTH PRODUCT is Gy·m (mGy·m).

**3.22**
**X-RAY TUBE VOLTAGE**
potential difference applied to an X-RAY TUBE between the ANODE and the CATHODE

Note 1 to entry: The unit of this quantity is the volt (V).

Note 2 to entry: The X-RAY TUBE VOLTAGE may vary as a function of time. The PRACTICAL PEAK VOLTAGE is a weighted value of the X-RAY TUBE VOLTAGE over a time period.

[SOURCE: IEC 61676:2023, 3.25, modified – The information about the unit has been moved from the definition to a note to entry, and a second note to entry has been added.]

**3.23**
**COEFFICIENT OF VARIATION**
CV
<positive random variable> STANDARD DEVIATION divided by the MEAN

[SOURCE: ISO 3534-1:2006, 2.38, modified – The example and the notes have not been retained.]

**3.24**
**INSTRUCTIONS FOR USE**
those parts of the ACCOMPANYING DOCUMENTS giving the necessary information for safe and proper use and operation of the equipment

[SOURCE: IEC TR 60788:2004, rm-82-02]

# 4 General requirements

## 4.1 Performance requirements

In Clause 5 and Clause 6, the performance requirements are stated for a complete DIAGNOSTIC DOSIMETER including both the DETECTOR ASSEMBLY and MEASURING ASSEMBLY. For a DOSIMETER designed to operate with one or more DETECTOR ASSEMBLIES, each combination of the MEASURING ASSEMBLY and DETECTOR ASSEMBLY shall comply with the requirements in 4.4, and in Clause 5 and Clause 6 relevant to this combination.

## 4.2 REFERENCE VALUES and STANDARD TEST VALUES

These values are as given in Table 1.

**Table 1 – REFERENCE and STANDARD TEST CONDITIONS**

| INFLUENCE QUANTITY | REFERENCE VALUES | STANDARD TEST VALUES |
|---|---|---|
| Temperature | +20 °C | +15 °C to +25 °C |
| Relative humidity | 50 % | 30 % to 75 % |
| Air pressure | 101,3 kPa | Atmospheric pressure |
| AIR KERMA RATE[a] | As at calibration | REFERENCE VALUE ±10 % |
| RADIATION QUALITY: | | |
| Mammography | As stated by the manufacturer[b] | REFERENCE VALUE |
| Conventional diagnostic: | | |
| – UNATTENUATED BEAM | 70 kV (RQR 5 x IEC 61267) | REFERENCE VALUE |
| – ATTENUATED BEAM | 70 kV (RQA 5 x IEC 61267) | REFERENCE VALUE |
| COMPUTED TOMOGRAPHY[c]: | 120 kV (RQT 9 x IEC 61267) | REFERENCE VALUE |
| Copper filtered beam | 70 kV (RQC 5 x IEC 61267) | REFERENCE VALUE |
| Electromagnetic fields | Zero | Insignificant[d] |

[a] AIR KERMA RATE is only an INFLUENCE QUANTITY for AIR KERMA and AIR KERMA LENGTH PRODUCT measurements.

[b] RADIATION QUALITIES used in mammography shall be stated as combinations of X-RAY TUBE anode materials (e.g., W, Mo, Rh) and filtrations (e.g., Al, Mo, Rh, Pd, Ag). Each such combination may have its own RATED RANGE. If applicable, established radiation qualities should be used as defined in IEC 61267.

[c] The RADIATION DETECTOR shall be irradiated by a radiation field with a diameter not smaller than twice the diameter of the RADIATION DETECTOR. The RADIATION DETECTOR shall be exposed with the beam aligned across the centre of the active length of the RADIATION DETECTOR.

[d] "Insignificant" means that the field is sufficiently small not to have any determinable effect on the RESPONSE of the DOSIMETER, for example as exists in a normal laboratory environment without special shielding.

## 4.3 General test conditions

### 4.3.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 1 shall be met during the test procedure, except:

a) for the INFLUENCE QUANTITY under investigation;

b) where local conditions of temperature and relative humidity are outside the STANDARD TEST CONDITIONS. In this case, the tester shall demonstrate the validity of the test results.

### 4.3.2 Statistical fluctuations

At low AIR KERMA and AIR KERMA RATES, the magnitude of the statistical fluctuations of the instrument's reading due to the random nature of the radiation alone may be a significant fraction of the VARIATION of the mean reading permitted in the test. A sufficient number of readings shall be taken to ensure that the mean value of such readings may be estimated with sufficient precision to demonstrate compliance or non-compliance with the test requirements. Table 2 provides guidance on the number of readings required to determine true differences between two sets of instrument readings at the 95 % confidence level. The number of readings, $n$, required as a function of the percentage difference $\Delta$ of the MEAN values and the COEFFICIENT OF VARIATION, $v$, of the sets of readings (assumed to be equal for each set) are listed.

**Table 2 – Number of readings required to detect true differences $\Delta$ (95 % confidence level) between two sets of instrument readings**

| Number of readings required $n$ | | | | | | | |
|---|---|---|---|---|---|---|---|
| $\Delta$ | COEFFICIENT OF VARIATION $v$ | | | | | | |
| | < 0,5 % | 0,5 % | 1 % | 2 % | 3 % | 4 % | 5 % |
| 1 % | [a] | 6 | 25 | 100 | 225 | 400 | 600 |
| 2 % | [a] | [a] | 6 | 25 | 55 | 100 | 150 |
| 3 % | [a] | [a] | [a] | 12 | 25 | 45 | 70 |
| 4 % | [a] | [a] | [a] | 6 | 15 | 25 | 40 |
| 5 % | [a] | [a] | [a] | [a] | 9 | 16 | 25 |

This table has been compiled on the assumption that the probability of stating that there is a difference when there is none and the probability of stating that there is no difference when there is one are both equal to 0,05. In the RATE mode, the interval between the readings shall be at least five times the 63 % RESPONSE TIME of the instrument, in order to ensure that the readings are statistically independent.

[a] At least five repeated readings shall be taken.



### 4.3.3 STABILIZATION TIME

The instrument shall be switched on for at least the STABILIZATION TIME quoted by the manufacturer, before the start of the compliance test.

In addition, if the RADIATION DETECTOR is an IONIZATION CHAMBER, then it should be allowed to attain thermal equilibrium with the environment and should have the polarizing voltage applied for a period of time equal to or greater than the specified STABILIZATION TIME.

#### 4.3.4 Adjustments during test

Compliance tests shall be performed with the instrument ready for use, after the STABILIZATION TIME and after making any necessary preliminary adjustments. During the tests, adjustments may be repeated at intervals as long as they do not interfere with the effect to be verified. For example, zero setting is not permitted during tests for measuring the LEAKAGE CURRENT.

#### 4.3.5 Batteries

Compliance tests shall not be performed while the DOSIMETER indicates a low battery condition.

### 4.4 Constructional requirements as related to performance

#### 4.4.1 Components

If a DIAGNOSTIC DOSIMETER has several ranges or scales or if the DOSIMETER consists of several components, all ranges, scales and components shall be unmistakably and unambiguously identified.

*Compliance with the constructional requirement on components shall be checked by inspection.*

#### 4.4.2 Display

##### 4.4.2.1 Units

The indicated unit shall be that of the measuring quantity: AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE, i.e. Gy, Gy·m or Gy/s respectively, possibly with SI prefix, for example m or µ.

*Compliance with the constructional requirement on components shall be checked by inspection.*

##### 4.4.2.2 Digital display

Digital displays whose improper function can result in non-perceptible faults (e.g., no light emission from certain segments of a segment display) shall be provided with a means of reliably checking their proper function.

*Compliance with the constructional requirement on display shall be checked by inspection.*

#### 4.4.3 Indication of battery condition

Battery-operated DOSIMETERS shall be provided with a low battery indication for any battery voltage below the RATED RANGE.

*Compliance with the constructional requirement on indication of battery condition shall be checked by inspection.*

#### 4.4.4 Indication of polarizing voltage failure

DOSIMETERS intended for use with IONIZATION CHAMBERS shall be provided with a means of indicating if the polarizing voltage does not meet the manufacturer's requirement for satisfactory operation.

*Compliance with the constructional requirement on polarizing voltage shall be checked by inspection.*

### 4.4.5 Over-ranging

When testing for compliance with the requirement on over-ranging, it is not necessary to use REFERENCE CONDITIONS.

The following requirements shall be fulfilled.

a) On all AIR KERMA RATE ranges, the DOSIMETER shall clearly indicate over-range when the full-scale reading is exceeded, and shall remain indicating over-range for all AIR KERMA RATES up to 1 Gy/s.

*Compliance shall be checked for each allowable combination of AIR KERMA RATE range and DETECTOR ASSEMBLY with a full scale reading of 10 mGy/s or less, by exposing the relevant RADIATION DETECTOR in any suitable X-ray beam at the AIR KERMA RATE, for which the display reads just below the stated full scale, then proceeding to:*

*1) increase the AIR KERMA RATE slowly but continuously until the display shows over-range;*

*2) increase the AIR KERMA RATE up to 1 Gy/s and 10 times the full scale reading, checking that the display indicates over-range for each of these AIR KERMA RATES.*

*Compliance shall be checked for each allowable combination of AIR KERMA RATE range and DETECTOR ASSEMBLY with a full scale reading of more than 10 mGy/s as described above, or by conducting an electrical test on the MEASURING ASSEMBLY and verifying that, for ion currents corresponding to AIR KERMA RATES of up to 1 Gy/s or 10 times the full scale reading, the DOSIMETER clearly indicates an over-range condition.*

b) On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, the DOSIMETER shall clearly indicate over-range when the full scale reading is exceeded.

*Compliance shall be checked on each AIR KERMA and AIR KERMA LENGTH PRODUCT range by exposing the relevant RADIATION DETECTOR until the display reads just below the stated full scale. The irradiation should then be continued in AIR KERMA or AIR KERMA LENGTH PRODUCT steps approximately equal to the display resolution for the range in use, until the display* shows over-range. An equivalent electrical test can be made on the *MEASURING ASSEMBLY*.

c) On all AIR KERMA and AIR KERMA LENGTH PRODUCT ranges, the DOSIMETER shall clearly indicate over-range when the RATED RANGE of AIR KERMA RATE is exceeded, unless it is able to measure AIR KERMA at an AIR KERMA RATE of at least:

- 1 Gy/s in the conventional diagnostic UNATTENUATED BEAM;
- 10 mGy/s in the conventional diagnostic ATTENUATED BEAM;
- 100 mGy/s in the mammographic UNATTENUATED BEAM;
- 500 mGy/s in the computed tomographic UNATTENUATED BEAM.

*Compliance shall be checked on each AIR KERMA and AIR KERMA LENGTH PRODUCT range by exposing the relevant RADIATION DETECTOR to an AIR KERMA RATE of 10 % above the RATED RANGE and checking that the DOSIMETER clearly indicates an over-range condition.*

d) During any period of time when the DOSIMETER is inactive, for example following the reset procedure, this state shall be indicated.

*Compliance with this constructional requirement shall be checked by inspection.*

### 4.4.6 MEASURING ASSEMBLIES with multiple DETECTOR ASSEMBLIES

For MEASURING ASSEMBLIES displaying AIR KERMA or AIR KERMA RATE using multiple DETECTOR ASSEMBLIES connected to a single display, it shall be clearly visible which INDICATED VALUES refer to which DETECTOR ASSEMBLY.

*Compliance with the constructional requirement on MEASURING ASSEMBLIES with multiple DETECTOR ASSEMBLIES shall be checked by inspection.*

#### 4.4.7 Radioactive STABILITY CHECK DEVICE

The half-life of the RADIONUCLIDE of a STABILITY CHECK DEVICE (if provided) shall be greater than five years.

*Compliance shall be checked by inspection.*

### 4.5 UNCERTAINTY of measurement

When measurements of VARIATION are made to verify that equipment complies with specified LIMITS OF VARIATION, the OVERALL UNCERTAINTY of these measurements of VARIATION should be less than one-fifth of the LIMITS OF VARIATION.

If this is not possible and if the OVERALL UNCERTAINTY of the measurement is less than one half of the LIMITS OF VARIATION, the OVERALL UNCERTAINTY of the measurement made in the compliance test procedures shall be taken into account in the evaluation of the equipment under test by adding the OVERALL UNCERTAINTY to the LIMITS OF VARIATION allowed.

If the OVERALL UNCERTAINTY exceeds one-fifth of the LIMITS OF VARIATION for any PERFORMANCE CHARACTERISTIC, then this shall be stated.

In case of DIAGNOSTIC DOSIMETERS, the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a coverage probability of 95 % (see IEC 60731:2011, Annex A).

## 5 Limits of PERFORMANCE CHARACTERISTICS

### 5.1 Linearity

For AIR KERMA RATE measurements, Formula (2) shall be fulfilled over the whole RATED RANGE of AIR KERMA RATE:

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}02 \qquad (2)$$

where

$R_{max}$ is the maximum RESPONSE over the RATED RANGE of AIR KERMA RATE;

$R_{min}$ is the minimum RESPONSE.

*Compliance with this performance requirement shall be checked by measuring the RESPONSE resulting from the minimum to the maximum RATED AIR KERMA RATE, with measurements made at AIR KERMA RATES in steps not greater than one order of magnitude.*

### 5.2 Repeatability

#### 5.2.1 General

When a measurement is repeated with the same DOSIMETER under unaltered conditions, the COEFFICIENT OF VARIATION of the measurement shall not exceed the maximum value given in Table 3 and Table 4.These requirements are generally valid for an AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE which corresponds to approximately two-thirds of the full scale value of analogue indications and a reading with a RESOLUTION of at least 0,25 % in the case of digital displays.

### 5.2.2 Repeatability in the ATTENUATED BEAM

*Compliance with the requirements for repeatability in the ATTENUATED BEAM stated in Table 3 shall be checked by measuring the COEFFICIENT OF VARIATION near the lowest limit of the EFFECTIVE RANGE of measurement for AIR KERMA, AIR KERMA RATE and AIR KERMA LENGTH PRODUCT stated by the manufacturer. If this lower limit is below 10 µGy for AIR KERMA measurements and/or below 1 µGy/s for AIR KERMA RATE measurements, additional tests shall be made at 10 µGy and 1 µGy/s respectively.*

**Table 3 – Maximum values for the COEFFICIENT OF VARIATION, $v_{max}$, for measurements in the attenuated beam**

| Quantity | Range of measurement | Maximum COEFFICIENT OF VARIATION ($v_{max}$) |
|---|---|---|
| AIR KERMA, $K$ | $K$ < 10 µGy<br>$K$ ≥ 10 µGy | 0,166 7 × (16 – $K$) %[a]<br>1 % |
| AIR KERMA RATE, $\dot{K}$ | $\dot{K}$ < 1 µGy/s<br>$\dot{K}$ ≥ 1 µGy/s | 1,11 × (4,7 – 2 $\dot{K}$) %[b]<br>3 % |
| AIR KERMA LENGTH PRODUCT, $K{\cdot}l$[c] | As specified by manufacturer | 1 % |

[a] $K$ in µGy.

[b] $\dot{K}$ in µGy/s.

[c] Approximately 50 % of the RATED LENGTH should be irradiated.

### 5.2.3 Repeatability in the UNATTENUATED BEAM

*Compliance with the requirements for repeatability in the UNATTENUATED BEAM stated in* Table 4 *shall be checked by measuring the COEFFICIENT OF VARIATION near the lowest limit of the EFFECTIVE RANGE of measurement for AIR KERMA, AIR KERMA RATE and AIR KERMA LENGTH PRODUCT stated by the manufacturer. If this lower limit is below 1 000 µGy for AIR KERMA measurements and/or below 100 µGy/s for AIR KERMA RATE measurements, additional tests shall be made at 1 000 µGy and 100 µGy/s respectively.*

NOTE The COEFFICIENT OF VARIATION is assumed to be determined from a set of at least 10 readings.

**Table 4 – Maximum values for the COEFFICIENT OF VARIATION, $v_{max}$, for measurements in the unattenuated beam and mammography**

| Quantity | Range of measurement | Maximum COEFFICIENT OF VARIATION ($v_{max}$) |
|---|---|---|
| AIR KERMA, $K$ | $K$ < 1 000 µGy<br>$K$ ≥ 1 000 µGy | 0,166 7 × (16 – 0,01 $K$) %[a]<br>1 % |
| AIR KERMA RATE, $\dot{K}$ | $\dot{K}$ < 100 µGy/s<br>$\dot{K}$ ≥ 100 µGy/s | 1,11 × (4,7 – 0,02 $\dot{K}$) %[b]<br>3 % |
| AIR KERMA LENGTH PRODUCT, $K{\cdot}l$ [c] | As specified by manufacturer | 1 % |

[a] $K$ in µGy.

[b] $\dot{K}$ in µGy/s.

[c] Approximately 50 % of the RATED LENGTH should be irradiated.

### 5.3 RESOLUTION of reading

Within the whole EFFECTIVE RANGE OF INDICATED VALUES, the RESOLUTION of the reading shall be less than or equal to 1 %.

*Compliance with this performance requirement shall be checked by inspection.*

### 5.4 STABILIZATION TIME

Fifteen minutes after switching on the instrument, the LIMITS OF VARIATION of RESPONSE shall be within ±2 % of the steady state value of the RESPONSE.

*Compliance with this performance requirement shall be checked by determining the RESPONSE of the instrument under the same conditions as at calibration, 15 min, 30 min, 45 min and 1 h after the DOSIMETER has been switched on.*

### 5.5 Effect of pulsed radiation on AIR KERMA and AIR KERMA LENGTH PRODUCT measurements

If the DOSIMETER is designed for AIR KERMA measurements in the conventional diagnostic beam (or AIR KERMA LENGTH PRODUCT measurements in the CT beam), the MEASURING ASSEMBLY shall be able to indicate AIR KERMA (or AIR KERMA LENGTH PRODUCT) within the limits of error stated in 5.1, when a pulse of radiation of 1 ms duration and an AIR KERMA RATE of

– just below the maximum RATED AIR KERMA RATE is incident on each DETECTOR ASSEMBLY stated as suitable for use in the conventional diagnostic UNATTENUATED BEAM;

– just below the maximum RATED AIR KERMA RATE is incident on each DETECTOR ASSEMBLY stated as suitable for use in the conventional diagnostic ATTENUATED BEAM;

– just below the maximum RATED AIR KERMA RATE is incident on 50 % of each DETECTOR ASSEMBLY stated as suitable for use in the CT UNATTENUATED BEAM.

*Compliance with this performance requirement shall be checked by measuring the RESPONSE of the DOSIMETER under the irradiation conditions defined above.*

### 5.6 Stability

#### 5.6.1 Long term stability

For all RADIATION QUALITIES within the RATED RANGE, the LIMITS OF VARIATION of RESPONSE when the DETECTOR ASSEMBLY is irradiated in a reproducible field shall not be greater than ±2,0 % per year.

*Compliance with this performance requirement shall be checked by retaining a representative MEASURING ASSEMBLY and DETECTOR ASSEMBLY(IES), stored under STANDARD TEST CONDITIONS, and investigating their combined long-term stability by making measurements under REFERENCE CONDITIONS at one-month intervals over a period of not less than six months and then using linear regression analysis to extrapolate these readings to obtain the change in RESPONSE over one full year. It is permissible to perform the tests on the MEASURING and DETECTOR ASSEMBLIES separately.*

### 5.6.2 Accumulated dose stability

After the complete DETECTOR ASSEMBLY has been uniformly irradiated at the conventional diagnostic UNATTENUATED BEAM QUALITY of 70 kV to an accumulated AIR KERMA of 40 Gy, using the maximum RATED field length for CT DETECTORS or the maximum RATED field size for all other DETECTORS,

– the DOSIMETER shall still meet the requirements for LINEARITY given in 5.1, and
– the LIMITS OF VARIATION of RESPONSE of the DOSIMETER due to the effect of accumulated AIR KERMA on the DETECTOR ASSEMBLY shall not be greater than ±1,0 %.

This requirement shall be met for all DETECTOR ASSEMBLIES supplied with the DOSIMETER.

*Compliance with this performance requirement shall be checked by*

– *repeating the test for linearity given in 5.1, after delivering the specified accumulated air kerma to the DETECTOR ASSEMBLY, and*
– *measuring the RESPONSE of the DOSIMETER in a reproducible radiation field at the RELEVANT REFERENCE RADIATION quality both before and after delivering the specified accumulated AIR KERMA to the DETECTOR ASSEMBLY in "measure" condition and noting the difference. For this test, irradiation conditions shall lie within the RATED RANGES given in Table 5.*

## 5.7 Measurements with a radioactive STABILITY CHECK DEVICE

If a DOSIMETER has an associated radioactive STABILITY CHECK DEVICE which can be used to test its function and RESPONSE and if this STABILITY CHECK DEVICE allows the DOSIMETER to be irradiated in a defined geometry and reproducibly produces a certain MEASURED VALUE (check indication or check time), these check values shall be repeatable at constant air density with a COEFFICIENT OF VARIATION of less than 3 %.

Furthermore, the INSTRUCTIONS FOR USE shall contain information which allows the check indication or the check time to be determined for the respective date with an UNCERTAINTY of less than ±1,0 %.

*Compliance with this performance requirement shall be made by making repeated measurements using the STABILITY CHECK DEVICE according to the instructions given by the manufacturer in the ACCOMPANYING DOCUMENTS. The DETECTOR and STABILITY CHECK DEVICE shall be separated and set-up again between measurements.*

NOTE The COEFFICIENT OF VARIATION is assumed to be determined from a set of at least 10 readings.

# 6 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES

## 6.1 General

The LIMITS OF VARIATION $\pm L$ due to the effects of INFLUENCE QUANTITIES are summarized in Table 5. For any change of an INFLUENCE QUANTITY within its RATED RANGE, the change of the DOSIMETERS RESPONSE shall not be greater than the values in column 4 of Table 5.

## 6.2 Energy dependence of RESPONSE

A DIAGNOSTIC DOSIMETER may have several different RATED RANGES for photon energy (see items a) to e) in Table 5). Over each of these RATED RANGES, the LIMITS OF VARIATION of RESPONSE with changes in RADIATION QUALITY shall not be greater than those given in Table 5.

*Compliance with the requirement on the VARIATION of the instruments RESPONSE with RADIATION QUALITY shall be measured under the same irradiation conditions as for calibration. For each energy range for which the DETECTOR under test is designed, at least the RADIATION QUALITIES listed below as a minimum shall be used, covering the whole stated RATED RANGE:*

– *for the conventional diagnostic range, those with 50 kV, 70 kV, 100 kV, 150 kV X-ray TUBE VOLTAGE;*
– *for mammography, the reference point and the minimum and maximum of the rated range;*
– *for the CT range, those with 100 kV, 120 kV and 150 kV;*
– *for copper-filtered beams, those with 50 kV, 70 kV and 100 kV.*

*For these tests the qualities stated in Table 5 shall be used.*

**Table 5 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES**

| INFLUENCE QUANTITY | MINIMUM RATED RANGE | REFERENCE CONDITIONS | LIMITS OF VARIATION *L* | Subclause |
|---|---|---|---|---|
| RADIATION QUALITY | X-RAY TUBE VOLTAGE and qualities | | | 6.2 |
| a) Conventional diagnostic UNATTENUATED BEAM | 50 kV to 150 kV RQR 3 to RQR 10 x IEC 61267 | 70 kV RQR 5 x IEC 61267 | ±5 % | |
| b) Conventional diagnostic ATTENUATED BEAM | 50 to 150 kV RQA 3 to RQA 10 x IEC 61267 | 70 kV RQA 5 x IEC 61267 | ±5 % | |
| c) Mammography UNATTENUATED BEAM[a] | As stated by the manufacturer[b] | As stated by the manufacturer[b] | ±5 % | |
| d) COMPUTED TOMOGRAPHY | 100 to 150 kV RQR 8 to RQR 10 x IEC 61267 | 120 kV RQT 9 x IEC 61267 | ±5 % | |
| | 100 to 150 kV RQT 8 to RQT 10 x IEC 61267 | | | |
| | 100 to 120 kV RQA 5 to RQA 9 x IEC 61267 | | | |
| e) Copper-filtered beams | 50 to 100 kV RQC3 to RQC 8 x IEC 61267 | 70 kV RQC 5 x IEC 61267 | ±5 % | |
| AIR KERMA RATE (in the case of AIR KERMA measurements) | As stated by the manufacturer | As at calibration | ±2 % | 6.3 |
| Incidence of radiation | | | | |
| – non-CT detectors | ±5°[c] | Reference direction | ±3 % | 6.4.1 |
| – CT DETECTORS | ±180°[d] | | ±3 % | 6.4.2 |
| Operating voltage | | | | |
| Mains | –15 % to +10 % | Nominal voltage[e] | ±2 % | 6.5 |
| Batteries | As stated by the manufacturer | | | |
| Air pressure | 80,0 kPa to 106,0 kPa | 101,3 kPa | ±2 % | 6.6 |
| Air pressure EQUILIBRATION TIME | ±10,0 % | Atmospheric pressure | < 20 s | 6.7 |
| Temperature | +15 °C to +35 °C | +20 °C | ±3 % | 6.8 |
| Relative humidity | ≤ 80 % (maximum 20 g/m$^3$) | 50 % | | |

| INFLUENCE QUANTITY | MINIMUM RATED RANGE | REFERENCE CONDITIONS | LIMITS OF VARIATION | Subclause |
|---|---|---|---|---|
| | | | *L* | |
| Electromagnetic compatibility | As in IEC 61000-4 | Without any disturbance | ±5 % | 6.9 |
| Field size | Minimum: as stated by the manufacturer<br>Maximum: not less than 35 cm × 35 cm | As at calibration | ±3 % | 6.10 |

[a] A beryllium window is assumed.

[b] RADIATION QUALITIES used in mammography can be based on different combinations of X-RAY TUBE anode materials (e.g., W, Mo, Rh) and filtrations (e.g., Al, Mo, Rh, Pd, Ag). Each such combination may have its own RATED RANGE. If applicable, established radiation qualities should be used as defined in IEC 61267.

[c] From the normal direction of incidence.

[d] In the plane perpendicular to the DETECTOR.

[e] The nominal voltage need not be a single value but can be expressed as a range.

### 6.3 AIR KERMA RATE dependence of AIR KERMA and AIR KERMA LENGTH PRODUCT measurements

For AIR KERMA (and AIR KERMA LENGTH PRODUCT) measurements, Formula (3) shall be fulfilled over the whole RATED RANGE of AIR KERMA RATE:

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}02 \tag{3}$$

where

$R_{max}$ is the maximum RESPONSE over the RATED RANGE of AIR KERMA RATE;

$R_{min}$ is the minimum RESPONSE.

*Compliance with this performance requirement shall be checked by measuring the AIR KERMA (or AIR KERMA LENGTH PRODUCT) RESPONSE resulting from the minimum to the maximum RATED AIR KERMA RATE, with measurements made at AIR KERMA RATES in steps not greater than one order of magnitude. The AIR KERMA (or AIR KERMA LENGTH PRODUCT) applied shall be kept approximately constant, by varying the irradiation time. It is permissible to make an equivalent electrical test on the MEASURING ASSEMBLY.*

### 6.4 Dependence of DETECTOR RESPONSE on angle of incidence of radiation

#### 6.4.1 Non-CT detectors

For non-CT detectors, the LIMITS OF VARIATION of RESPONSE due to a change in the angle of incidence within the RATED RANGE from the normal direction of incidence shall not be greater than those given in Table 5.

*Compliance with this performance requirement shall be checked by measuring the RESPONSE of the DOSIMETER with the DETECTOR of the instrument tilted by the maximum and minimum RATED value in two perpendicular directions from a position with the axis perpendicular to the axis of the beam.*

#### 6.4.2 CT DETECTORS

For CT DETECTORS, the LIMITS OF VARIATION of RESPONSE due to a change in the angle of incidence within the RATED RANGE in the plane perpendicular to the DETECTOR axis shall not be greater than those given in Table 5.

Compliance shall be checked in a RQT-8 x IEC 61267 or RQA-8 x IEC 61267 ATTENUATED BEAM of width 30 % of the RATED LENGTH centred on the RATED LENGTH.

### 6.5 Operating voltage

#### 6.5.1 Mains-operated DOSIMETERS

For mains-operated DOSIMETERS, the LIMIT OF VARIATION of RESPONSE due to VARIATION of the operating voltage between +10 % and –15 % of the nominal voltage shall not be greater than the limit stated in Table 5, over the RATED RANGE of mains voltage stated by the manufacturer.

*Compliance with this performance requirement shall be checked by taking two sets of readings with the voltage of the AC power supply adjusted to the upper and lower boundaries of the RATED RANGE of operating voltage stated by the manufacturer and compared with a reference set of readings at nominal operating voltage.*

*A radioactive check source may be used when carrying out these measurements.*

#### 6.5.2 Battery-operated DOSIMETERS

For battery-operated DOSIMETERS, a low battery condition shall be indicated if the instrument is operating when the battery voltage is outside the RATED RANGE stated by the manufacturer. Over this RATED RANGE of battery voltage, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 5.

*Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with a set of fresh batteries of the type specified by the manufacturer. In addition, a set of used batteries, which are just spent enough to cause the low battery indication to show, shall be fitted and a second set of readings shall be taken and compared with the reference reading.*

*A radioactive check source may be used when carrying out these measurements.*

#### 6.5.3 Mains rechargeable, battery-operated DOSIMETERS

For mains rechargeable, battery-operated DOSIMETERS, in addition to the requirements on battery-powered DOSIMETERS, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 5 when the DOSIMETER is operated under the following conditions:

– mains disconnected, battery fresh;
– mains connected, battery fresh;
– mains connected, battery low.

*Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with the mains disconnected and a set of fresh batteries of the type specified by the manufacturer. The mains shall then be connected, and a second set of readings taken and compared with the reference reading. Finally, a set of used batteries, which are just spent enough to cause the low battery indication to show, shall be fitted and, with the mains connected, a third set of readings shall be taken and compared with the reference reading.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.6 Air pressure

The LIMITS OF VARIATION of RESPONSE shall not be greater than those given in Table 5 when the air pressure changes over its RATED RANGE. If the RADIATION DETECTOR is a VENTED IONIZATION CHAMBER, it is permissible for the MEASURED VALUE to be corrected for air density, either by manual calculation or automatically by the instrument, before this requirement is met.

*Compliance with this performance requirement shall be checked by making measurements at an ambient air pressure of 80,0 kPa and 106 kPa and comparing these measurements with those for the reference air pressure of 101,3 kPa. For VENTED IONIZATION CHAMBERS, all readings shall be corrected for air density before this comparison is made.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.7 Air pressure EQUILIBRATION TIME of the RADIATION DETECTOR

If the RESPONSE of the RADIATION DETECTOR is influenced by air density, the 90 % EQUILIBRATION TIME for pressure differences (sudden change of air pressure of 10 % within the RATED RANGE of pressure) between the exterior and interior of the RADIATION DETECTOR shall not be greater than that given in Table 5.

*Compliance with this performance requirement shall be checked by irradiating the DETECTOR ASSEMBLY at constant AIR KERMA RATE, then monitoring the change with time of the electrical signal from the DETECTOR ASSEMBLY when the DETECTOR ASSEMBLY is subjected to a sudden change in air pressure of between 8 % and 12 %. The test shall be carried out for pressure changes in both directions.*

*For DOSIMETERS measuring AIR KERMA only, an alternative test method is permitted, as follows: an AIR KERMA measurement of less than 1 s duration shall be made and recorded. A sudden change in air pressure of between 8 % and 12 % shall then be made, followed by a second AIR KERMA measurement 20 s after the pressure change. The second measurement corrected for the change in air density due to the change of pressure shall be compared to the first measurement. The test shall be carried out for pressure changes in both directions.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.8 Temperature and humidity

The LIMITS OF VARIATION of the DOSIMETER's RESPONSE shall not be greater than the value given in Table 5, for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity (absolute humidity not to exceed 20 g/m$^3$). If the RADIATION DETECTOR is a VENTED IONIZATION CHAMBER, it is permissible for the MEASURED VALUE to be corrected for the air density, either by manual calculation or automatically by the instrument, before this requirement is met.

*Compliance with this performance requirement shall be checked by carrying out the following test. The DOSIMETER shall be exposed to varying temperature and air humidity. At least four measurements shall be performed, one under each of the climatic conditions stated* in *Table 6*.

**Table 6 – Climatic conditions**

| Temperature<br>°C | Relative humidity<br>% | Absolute humidity<br>g/m$^3$ |
|---|---|---|
| 20,0 | 50 | 8,5 |
| 15,0 | 80 | 11,5 |
| 26,5 | 80 | 20,0 |
| 35,0 | 50 | 20,0 |

*For VENTED IONIZATION CHAMBERS, all readings shall be corrected for air density before this comparison is made.*

*The DIAGNOSTIC DOSIMETER shall be exposed to each different temperature and humidity condition for at least 24 h before the instrument is tested.*

*A radioactive check source may be used when carrying out these measurements.*

### 6.9 Electromagnetic compatibility

NOTE 1 The "complete equipment" means the MEASURING ASSEMBLY connected to a DETECTOR ASSEMBLY of a type customarily supplied with the MEASURING ASSEMBLY.

NOTE 2 A suitable overall STABILITY CHECK DEVICE can be fitted to the DETECTOR ASSEMBLY to produce a signal current during these measurements.

#### 6.9.1 ELECTROSTATIC DISCHARGE

The maximum spurious indications (both transient and permanent) of the display or data output due to ELECTROSTATIC DISCHARGE shall be less than the limits given in Table 5.

*Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while discharging a suitable test generator as described in IEC 61000-4-2:2008 at least five times to those various external parts of the complete equipment which may be touched by the operator during a normal measurement (i.e. not to those parts of the CHAMBER and MEASURING ASSEMBLY that are normally exposed in the radiation beam), when the instrument is set to the "measure" condition on its most sensitive range (if the ranges are selectable). The ELECTROSTATIC DISCHARGE shall be equivalent to that from a capacitor of 150 pF charged to a voltage of 6 kV and discharged through a resistor of 330 Ω (severity level 3 for contact discharge as described in IEC 61000-4-2:2008). When instruments with insulated surfaces are tested, the air discharge method with a voltage of 8 kV (severity level 3) shall be used.*

A complete "latch-up" of the MEASURING ASSEMBLY which would not lead to an incorrect AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE value being indicated is allowed.

#### 6.9.2 Radiated electromagnetic fields

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to electromagnetic fields shall be less than the limits given in Table 5.

*Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals with the DOSIMETER set to the most sensitive range (if the ranges are selectable), while measurements are performed, both with and without the presence of the radio-frequency field around the complete equipment.*

*The electromagnetic field strength shall be 3 V/m in the frequency range of 80 MHz to 1 GHz in steps of 1 % (severity level 2 as described in IEC 61000-4-3:2020). To reduce the amount of measurements needed to show compliance with this requirement, tests at frequencies 80 MHz, 90 MHz, 100 MHz, 110 MHz, 120 MHz, 130 MHz, 140 MHz, 150 MHz, 160 MHz, 180 MHz, 200 MHz, 220 MHz, 240 MHz, 260 MHz, 290 MHz, 320 MHz, 350 MHz, 380 MHz, 420 MHz, 460 MHz, 510 MHz, 560 MHz, 620 MHz, 680 MHz, 750 MHz, 820 MHz, 900 MHz and 1 000 MHz with a field strength of 10 V/m may be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in* Table 5 *is observed at one of these given frequencies, additional tests in the range of ±5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the DOSIMETER in all three orientations as described in IEC 61000-4-3:2020. For battery-operated instruments, for which the requirements of 6.9.3 and 6.9.4 do not apply, tests at 27 MHz shall also be performed.*

### 6.9.3 CONDUCTED DISTURBANCES induced by bursts and radio frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to CONDUCTED DISTURBANCES induced by bursts and radio frequencies shall be less than the limits given in Table 5.

*For mains-operated instruments, compliance shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range (if the ranges are selectable), both with and without the presence of CONDUCTED DISTURBANCES induced by bursts (according to IEC 61000-4-4) and CONDUCTED DISTURBANCES induced by radio-frequency fields (according to IEC 61000-4-6). The severity level shall, in both cases, be level 3 as described in these standards.*

A complete "latch-up" of the MEASURING ASSEMBLY which would not lead to an incorrect AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE value being indicated is allowed.

### 6.9.4 Voltage dips, short interruptions and voltage VARIATIONS

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to voltage dips, short interruptions and voltage VARIATIONS shall be less than the limits given in Table 5.

*For mains-operated instruments, compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range, both with and without the presence of conducted disturbances induced by voltage dips, short interruptions and voltage VARIATIONS as described in IEC 61000-4-11.*

## 6.10 Field size

For all non-CT detectors, the ACCOMPANYING DOCUMENTS shall state the RATED RANGE of field sizes. Over this RATED RANGE, the LIMIT OF VARIATION of RESPONSE shall not be greater than the value given in Table 5. The maximum RATED field size shall not be less than 35 cm × 35 cm.

*Compliance with this performance requirement shall be checked by measuring the percentage VARIATION in the electrical signal from the DETECTOR ASSEMBLY caused by changing the field size from its REFERENCE VALUE to its minimum and maximum RATED values, after making any corrections necessary for the change in AIR KERMA RATE with varying field size.*

## 6.11 EFFECTIVE LENGTH and spatial uniformity of RESPONSE of CT DOSIMETERS

Over the RATED LENGTH, the spatial uniformity of RESPONSE shall not vary by more than ±3 %.

In addition, the manufacturer shall declare the EFFECTIVE LENGTH of the DETECTOR.

*Compliance with this performance requirement shall be checked by employing a reproducible radiation slit field, defined by a lead diaphragm, of width not more than 2 mm and of length (perpendicular to the DETECTOR axis) sufficient to cover the diameter of the DETECTOR.*

*Commencing with the field centred at 5 cm outside the active volume at the end opposite the connectors and from the marking that indicates the limit of the RATED LENGTH of the DETECTOR, measure the RESPONSE several times for each position of the DETECTOR as the DETECTOR is progressively moved under the diaphragm at intervals equal to 2,5 % of the RATED LENGTH of the DETECTOR. Repeat these measurements across the entire RATED LENGTH of the DETECTOR and 5 cm beyond the second marker that indicates the limit of the RATED LENGTH. The EFFECTIVE LENGTH to be quoted is the full-width-half-maximum of the plot of RESPONSE against distance along the DETECTOR axis.*

# 7 Marking

## 7.1 DETECTOR ASSEMBLY

The DETECTOR shall be provided with the following permanently affixed and clearly legible markings:

– indication of origin, i.e. name and/or trade-mark of the manufacturer or supplier responsible for ensuring that the DETECTOR ASSEMBLY complies with this document;

– REFERENCE POINT of the RADIATION DETECTOR;

– type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized;

– for CT DETECTORS, limits of the EFFECTIVE LENGTH shall be clearly marked.

*Compliance shall be checked by inspection.*

## 7.2 MEASURING ASSEMBLY

The MEASURING ASSEMBLY shall be provided with the following permanently affixed and clearly legible markings:

– indication of origin, i.e. name and/or trademark of the manufacturer or supplier responsible for ensuring that the MEASURING ASSEMBLY complies with this document;

– type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized;

– rated mains supply potential or potentials and rated mains supply frequency or frequencies required so that the performance of the instrument complies with Clause 5 and Clause 6;

– for battery-operated DOSIMETERS, type of batteries required so that the performance of the instrument complies with Clause 5 and Clause 6.

Any graphical symbols used shall be in accordance with IEC 60417.

*Compliance shall be checked by inspection.*

## 7.3 Radioactive STABILITY CHECK DEVICE

The radioactive STABILITY CHECK DEVICE shall be provided with the following permanently affixed and clearly legible markings:

– international trefoil symbol on the surface of the carrying case and on the accessible surface of the device immediately surrounding the source;

– name and ACTIVITY of the RADIONUCLIDE;

– date for which the stated ACTIVITY of the source is applicable;

– type number and serial number of the device, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized.

Markings can be required by relevant national and international legislation.

*Compliance shall be checked by inspection.*

# 8 ACCOMPANYING DOCUMENTS

The manufacturer shall provide adequate information describing the correct use of the instrument.

In general, the ACCOMPANYING DOCUMENTS shall comply with IEC 61187.

The ACCOMPANYING DOCUMENTS shall contain a description of the DIAGNOSTIC DOSIMETER, including its type number and manufacturer.

In addition, the ACCOMPANYING DOCUMENTS shall contain the following information applicable to each type of DETECTOR ASSEMBLY supplied:

– dimensions of DETECTOR(S) and construction (a diagram is considered to be useful);
– RATED RANGE OF USE for X-RAY TUBE VOLTAGE/RADIATION QUALITY;
– data giving typical dependence of RESPONSE on RADIATION QUALITY;
– position of REFERENCE POINT of DETECTOR;
– reference direction of incident radiation;
– maximum RATED AIR KERMA RATE and AIR KERMA per pulse;
– EFFECTIVE RANGES of measurement and RESOLUTION in SI units;
– RATED RANGE OF USE for atmospheric pressure;
– RATED RANGE OF USE for angle of incidence of radiation;
– RATED RANGE OF USE for temperature;
– RATED RANGE OF USE for air humidity;
– RATED RANGE OF USE for operating voltage and, for battery-operated instruments, typical battery life;
– RATED RANGE OF USE for field sizes; furthermore, the ACCOMPANYING DOCUMENTS shall recommend that measurements are conducted only with a field size of at least 10 mm greater than the minimum RATED field size, because of the discrepancies between the light and radiation fields that are typical of diagnostic X-ray equipment;
– table, diagram or formula for air density correction (if required);
– handling of radioactive or electric STABILITY CHECK DEVICE (if necessary);
– table or formula for VARIATION of check indication or check time, as a result of decreased ACTIVITY of radioactive source (if necessary);
– when applicable, a warning that introduction of material other than free air behind the RADIATION DETECTOR will cause its RESPONSE to change due to backscatter;
– a warning that, on AIR KERMA ranges, maximum RATED AIR KERMA RATE or AIR KERMA per pulse should not be exceeded;
– a warning that the instrument shall not be used for dose measurements at RADIATION QUALITIES significantly different from those specified in the ACCOMPANYING DOCUMENTS;
– for DOSIMETERS that cannot display either negative readings or negative drift, a warning notice reading as follows: "Warning – This instrument will not display negative readings. Be sure to accumulate a positive reading before attempting to measure the instrument drift";
– for non-CT detectors, those parts of DETECTOR ASSEMBLY that need to be uniformly irradiated to give the correct RESPONSE;
– for CT DETECTORS, the limits on RATED LENGTH, EFFECTIVE LENGTH of the DETECTOR and uniformity of RESPONSE over RATED LENGTH;
– for ionization chambers, statement if air density correction is applied;
– the manufacturer shall state the REFERENCE VALUES and STANDARD TEST VALUES in the INSTRUCTIONS FOR USE or in the test sheets.

*Compliance shall be checked by inspection.*

# Annex A
(informative)

## COMBINED STANDARD UNCERTAINTY for dosimeter performance

The COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical dosimeter operating at the maximum limits of PERFORMANCE CHARACTERISTICS according to Clause 5 and LIMITS OF VARIATION *L* for the effects of INFLUENCE QUANTITIES according to Table 5 was estimated. The uncertainty components and the results are shown in Table A.1.

**Table A.1 – Estimation of COMBINED STANDARD UNCERTAINTY for dosimeter performance**

| PERFORMANCE CHARACTERISTIC | Subclause | Relative STANDARD UNCERTAINTY[a] % |
|---|---|---|
| Calibration factor[b] | | ±2,89 |
| Linearity | 5.1 | ±1,15 |
| Repeatability | 5.2 | ±0,58 |
| RESOLUTION of reading | 5.3 | ±0,58 |
| STABILIZATION TIME | 5.4 | ±1,15 |
| Long term stability | 5.6.1 | ±1,15 |
| Accumulated dose stability | 5.6.2 | ±0,58 |
| RADIATION QUALITY | 6.2 | ±2,89 |
| AIR KERMA RATE | 6.3 | ±1,15 |
| Incidence of radiation | 6.4 | ±1,73 |
| Operating voltage | 6.5 | ±1,15 |
| Air pressure | 6.6 | ±1,15 |
| Temperature and humidity | 6.8 | ±1,73 |
| Electromagnetic compatibility | 6.9 | ±2,89 |
| Field size | 6.10 | ±1,73 |
| **COMBINED STANDARD UNCERTAINTY** | | ±6,6 |

[a] Relative STANDARD UNCERTAINTY assuming that there is no additional information about the PROBABILITY DISTRIBUTION of the PERFORMANCE CHARACTERISTIC within the allowed interval other than it has an uniform distribution, i.e. 0,577 *L* for symmetric limits.

[b] Although no requirement on the accuracy of the calibration factor is laid down in this document, a maximum error of the calibration factor is included here and assumed to be ±5 %. A uniform distribution is also assumed.

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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# APPAREILS ÉLECTROMÉDICAUX – DOSIMÈTRES À CHAMBRES D'IONISATION ET/OU À DÉTECTEURS SEMICONDUCTEURS UTILISÉS EN IMAGERIE DE DIAGNOSTIC À RAYONNEMENT X

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L'IEC 61674 a été établie par le sous-comité 62C: Équipements médicaux, logiciels et systèmes pour la radiothérapie, la médecine nucléaire et la radiodosimétrie, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette troisième édition annule et remplace la deuxième édition de l'IEC 61674 parue en 2012. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) pour la mammographie, le fabricant spécifie la VALEUR DE REFERENCE pour la QUALITE DE RAYONNEMENT;

b) pour la mammographie, le fabricant fournit le DOMAINE ASSIGNE MINIMAL des QUALITES DE RAYONNEMENT pour l'essai de conformité pour la DEPENDANCE DE LA REPONSE EN ENERGIE;

c) l'essai de conformité pour les affichages analogiques a été supprimé;

d) les essais de conformité relatifs à la remise à zéro dans les plages, à l'effet du courant de fuite et aux pertes de recombinaison ont été supprimés. Ces essais sont déjà couverts par l'essai de linéarité et ne peuvent pas être réalisés sur les dispositifs modernes. L'estimation de l'INCERTITUDE NORMALISEE COMBINEE a été modifiée en conséquence;

e) l'essai de conformité pour les dosimètres fonctionnant sur batterie rechargeable par le réseau a été mis à jour pour les dispositifs modernes.

Le texte de cette Norme internationale est issu des documents suivants:

| Projet | Rapport de vote |
|---|---|
| 62C/909/FDIS | 62C/913/RVD |

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains.

– *modalités d'essais: caractères italiques.*

– indications de nature informative qui apparaissent hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères romains.

– TERMES DÉFINIS À L'ARTICLE 3 DE L'IEC 60601-1:2005, L'IEC 60601-1:2005/AMD1:2012 et L'IEC 60601-1:2005/AMD2:2020, DE LA PRÉSENTE NORME PARTICULIÈRE OU COMME SIGNALE: PETITES MAJUSCULES.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2:2021. Pour les besoins du présent document:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

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- révisé.

# INTRODUCTION

Le radiodiagnostic fournit le plus important apport de RAYONNEMENT IONISANT provoqué par l'homme auquel le public est exposé. La réduction de l'exposition reçue par les PATIENTS lors des examens radiologiques médicaux est donc devenue ces dernières années une question centrale. La dose reçue par le PATIENT est réduite le plus possible lorsque la qualité de l'image et le débit de dose de rayonnement de l'appareil produisant le rayonnement X sont correctement réglés. Ces réglages exigent de réaliser le mesurage habituel du KERMA DANS L'AIR, du PRODUIT KERMA DANS L'AIR LONGUEUR et/ou du DEBIT DE KERMA DANS L'AIR avec exactitude. Les appareils concernés par le présent document jouent un rôle essentiel pour atteindre l'exactitude exigée. Il est important que les DOSIMETRES utilisés pour les mesurages de réglage et de contrôle soient de qualité satisfaisante et satisfassent donc aux exigences spéciales énoncées dans le présent document.

# APPAREILS ÉLECTROMÉDICAUX – DOSIMÈTRES À CHAMBRES D'IONISATION ET/OU À DÉTECTEURS SEMICONDUCTEURS UTILISÉS EN IMAGERIE DE DIAGNOSTIC À RAYONNEMENT X

## 1 Domaine d'application et objet

### 1.1 Domaine d'application

Le présent document spécifie les exigences de performance, et quelques exigences de construction associées, des DOSIMETRES DE RADIODIAGNOSTIC destinés au mesurage du KERMA DANS L'AIR, du PRODUIT KERMA DANS L'AIR LONGUEUR ou du DEBIT DE KERMA DANS L'AIR, dans des champs de rayonnement de photons utilisés en imagerie médicale à rayonnement X, telle que la RADIOGRAPHIE, la RADIOSCOPIE et la TOMODENSITOMETRIE (CT), pour des RAYONNEMENTS X dont les potentiels se situent dans la plage comprise entre 20 kV et 150 kV.

Le présent document est applicable à la performance des DOSIMETRES à CHAMBRES D'IONISATION OUVERTES et/ou à DETECTEURS SEMICONDUCTEURS utilisés en imagerie de diagnostic à rayonnement X.

### 1.2 Objet

Le présent document a pour objet:

a) d'établir des exigences pour un niveau satisfaisant de performance des DOSIMETRES DE RADIODIAGNOSTIC; et

b) de normaliser les méthodes pour déterminer la conformité à ce niveau de performance.

Le présent document ne s'applique pas aux aspects de sécurité des DOSIMETRES. Les DOSIMETRES DE RADIODIAGNOSTIC couverts par le présent document ne sont pas destinés à être utilisés dans l'ENVIRONNEMENT DU PATIENT et, par conséquent, les exigences de sécurité électrique applicables sont contenues dans l'IEC 61010-1.

## 2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60417, *Symboles graphiques utilisables sur le matériel,* disponible sous: <http://www.graphical-symbols.info/equipment>

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

IEC 61000-4 (toutes les parties), *Compatibilité électromagnétique (CEM) – Partie 4: Techniques d'essai et de mesure*

IEC 61000-4-2:2008, *Compatibilité électromagnétique (CEM) – Partie 4-2: Techniques d'essai et de mesure – Essai d'immunité aux décharges électrostatiques*

IEC 61000-4-3:2020, *Compatibilité électromagnétique (CEM) – Partie 4-3: Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61000-4-4, *Compatibilité électromagnétique (CEM) – Partie 4-4: Techniques d'essai et de mesure – Essais d'immunité aux transitoires électriques rapides en salves*

IEC 61000-4-6, *Compatibilité électromagnétique (CEM) – Partie 4-6: Techniques d'essai et de mesure – Immunité aux perturbations conduites, induites par les champs radioélectriques*

IEC 61000-4-11, *Compatibilité électromagnétique (CEM) – Partie 4-11: Techniques d'essai et de mesure – Essais d'immunité aux creux de tension, coupures brèves et variations de tension pour les appareils à courant d'entrée inférieur ou égal à 16 A par phase*

IEC 61187, *Équipements de mesures électriques et électroniques – Documentation*

IEC 61267:2005, *Équipement de diagnostic médical à rayonnement X – Conditions de rayonnement pour utilisation dans la détermination des caractéristiques*

## 3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC TR 60788:2004 ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

**3.1**
**DOSIMETRE DE RADIODIAGNOSTIC**
**DOSIMETRE**
appareil qui utilise les CHAMBRES D'IONISATION et/ou les DETECTEURS SEMICONDUCTEURS pour le mesurage du KERMA DANS L'AIR, du PRODUIT KERMA DANS L'AIR LONGUEUR et/ou du DEBIT DE KERMA DANS L'AIR dans le faisceau d'un APPAREIL A RAYONNEMENT X utilisé pour les examens radiologiques médicaux de radiodiagnostic

Note 1 à l'article: Un DOSIMETRE DE RADIODIAGNOSTIC contient les éléments suivants:

– un ou plusieurs ENSEMBLES DE DETECTION, pouvant ou non faire partie intégrante de l'ENSEMBLE DE MESURAGE;
– UN ENSEMBLE DE MESURAGE;
– un ou plusieurs CONTROLEURS DE CONSTANCE (facultatif).

**3.1.1**
**ENSEMBLE DE DETECTION**
DETECTEUR DE RAYONNEMENT et toutes les autres parties auxquelles le DETECTEUR DE RAYONNEMENT est relié de façon permanente, sauf l'ENSEMBLE DE MESURAGE

Note 1 à l'article: L'ENSEMBLE DE DETECTION comprend normalement:

– le DETECTEUR DE RAYONNEMENT et le manche (ou le boîtier) sur lequel le DETECTEUR DE RAYONNEMENT est monté de façon permanente (ou encastré);
– l'appareillage électrique et tous les câbles ou préamplificateurs reliés de façon permanente.

**3.1.1.1**
**DETECTEUR DE RAYONNEMENT**
élément qui transpose le KERMA DANS L'AIR, le PRODUIT KERMA DANS L'AIR LONGUEUR ou le DEBIT DE KERMA DANS L'AIR en un signal électrique mesurable

Note 1 à l'article: Un DETECTEUR DE RAYONNEMENT peut être soit une CHAMBRE D'IONISATION, soit un DETECTEUR SEMICONDUCTEUR.

**3.1.1.1.1**
**CHAMBRE D'IONISATION**
**CHAMBRE**
DETECTEUR DE RAYONNEMENT rempli d'air, d'un gaz approprié ou d'un mélange gazeux dans lequel un champ électrique assure la collecte par les électrodes de la totalité des charges associées aux ions et aux ELECTRONS produits dans le volume sensible du détecteur par le RAYONNEMENT IONISANT

Note 1 à l'article: Une CHAMBRE D'IONISATION peut être hermétique ou ouverte.

Note 2 à l'article: Les CHAMBRES D'IONISATION OUVERTES sont construites de façon à permettre la libre circulation de l'air entre le volume de mesurage et l'atmosphère, de sorte qu'il faut apporter des corrections à la REPONSE pour tenir compte des variations de la densité de l'air.

Note 3 à l'article: Les CHAMBRES D'IONISATION hermétiques ne conviennent pas, parce que l'épaisseur de mur nécessaire pour une CHAMBRE hermétique peut entraîner une dépendance en énergie inacceptable de la REPONSE, et parce que la stabilité à long terme des CHAMBRES hermétiques n'est pas garantie.

[SOURCE: IEC 60050-395:2014, 395-03-07, modifié – Deux nouvelles notes à l'article ont été ajoutées.]

**3.1.1.1.2**
**CHAMBRE D'IONISATION OUVERTE**
CHAMBRE D'IONISATION construite de façon à permettre la libre circulation de l'air entre le volume de mesurage et l'atmosphère, de sorte qu'il faut apporter des corrections à la REPONSE pour tenir compte des variations de la densité de l'air

[SOURCE: IEC 60731:2011, 3.1.1.1.3, modifié – Le terme a été modifié de "chambre ouverte" en "CHAMBRE D'IONISATION OUVERTE".]

**3.1.1.1.3**
**DETECTEUR SEMICONDUCTEUR**
dispositif à semiconducteur qui utilise la production et le mouvement de porteurs de paires électron-trou dans une région appauvrie en porteurs de charges du semiconducteur pour la détection et le mesurage du RAYONNEMENT IONISANT

Note 1 à l'article: La production de paires électron-trou est provoquée par interaction du RAYONNEMENT IONISANT avec le matériau semiconducteur, dans le cadre du présent document, les détecteurs sont qualifiés de détecteurs semiconducteurs, même lorsque la production des paires électron-trou est due indirectement, d'abord par conversion de l'énergie du rayonnement incident en lumière dans un matériau scintillateur directement en face d'une photodiode à semiconducteur et couplé optiquement à cette photodiode à semiconducteur, qui produit alors le signal électrique.

**3.1.2**
**ENSEMBLE DE MESURAGE**
dispositif destiné à mesurer le signal électrique du DETECTEUR DE RAYONNEMENT et à le convertir sous une forme convenant à l'affichage des valeurs de la DOSE ou du KERMA, ou de leurs débits correspondants

[SOURCE: IEC 60731:2011, 3.1.2. modifié – Les mots "mesurer la charge (ou le courant) issue de la CHAMBRE D'IONISATION" ont été remplacés par "mesurer le signal électrique du DETECTEUR DE RAYONNEMENT"]

**3.1.3**
**CONTROLEUR DE CONSTANCE**
dispositif qui permet de vérifier la stabilité de la REPONSE de l'ENSEMBLE DE MESURAGE et/ou de l'ENSEMBLE DE CHAMBRE

Note 1 à l'article: Il est admis que le CONTROLEUR DE CONSTANCE soit un dispositif purement électrique, ou une source de rayonnement, ou qu'il combine les deux.

[SOURCE: IEC 60731:2011, 3.1.3]

**3.1.4**
**DOSIMÈTRE EN TOMODENSITOMÉTRIE**
DOSIMETRE DE RADIODIAGNOSTIC qui utilise des CHAMBRES D'IONISATION longues et étroites et/ou des DETECTEURS SEMICONDUCTEURS pour le mesurage du KERMA DANS L'AIR, évalué sur la longueur du DETECTEUR lorsque celui-ci est soumis à un balayage par rayonnement X suivant une section droite d'un tomodensitomètre

Note 1 à l'article: Un DOSIMETRE EN TOMODENSITOMETRIE contient les éléments suivants:

– un ou plusieurs ENSEMBLES DE DETECTION;

– un ENSEMBLE DE MESURAGE.

**3.1.5**
**DÉTECTEUR EN TOMODENSITOMÉTRIE**
DETECTEUR DE RAYONNEMENT utilisé en dosimétrie de TOMODENSITOMETRIE

**3.2**
**VALEUR INDIQUEE**
valeur d'une grandeur dérivée de la valeur lue sur l'échelle d'un instrument en tenant compte de tous les facteurs d'échelle indiqués sur le poste de commande de cet instrument

[SOURCE: IEC 60731:2011, 3.2, modifié – La note a été supprimée]

**3.3**
**VALEUR VRAIE**
valeur de la grandeur physique à mesurer avec un instrument

[SOURCE: IEC 60731:2011, 3.3, modifié – La note a été supprimée]

**3.4**
**VALEUR CONVENTIONNELLEMENT VRAIE**
valeur utilisée à la place de la VALEUR VRAIE pour l'étalonnage ou pour la détermination des performances d'un instrument, puisqu'en pratique la VALEUR VRAIE est inconnue et impossible à connaître

Note 1 à l'article: La VALEUR CONVENTIONNELLEMENT VRAIE est habituellement la valeur déterminée par l'ETALON DE TRAVAIL avec lequel est comparé l'instrument soumis à l'essai.

[SOURCE: IEC 60731:2011, 3.4, modifié – La deuxième note a été supprimée]

**3.5**
**VALEUR MESUREE**
meilleure estimation de la VALEUR VRAIE d'une grandeur, qui est déduite de la VALEUR INDIQUEE par un instrument ainsi que de l'application de tous les FACTEURS DE CORRECTION appropriés et du FACTEUR D'ETALONNAGE

Note 1 à l'article: La VALEUR MESUREE est parfois également désignée par "résultat de mesure".

[SOURCE: IEC 60731:2011, 3.5, modifié – Une nouvelle note à l'article a remplacé la note existante.]

**3.5.1**
**ERREUR DE MESURE**
différence résiduelle entre la VALEUR MESUREE d'une grandeur et la VALEUR VRAIE de cette grandeur

[SOURCE: IEC 60731:2011, 3.5.1]

**3.5.2**
**INCERTITUDE GLOBALE**
INCERTITUDE associée à la VALEUR MESUREE

Note 1 à l'article: C'est-à-dire qui représente les limites entre lesquelles on estime que se trouve l'ERREUR DE MESURE (voir aussi 4.5).

[SOURCE: IEC 60731:2011, 3.5.2, modifié – La parenthèse a été ajoutée à la note à l'article et la seconde note a été supprimée]

**3.5.3**
**INCERTITUDE ELARGIE**
grandeur définissant un intervalle, autour du résultat d'un mesurage, dont on puisse s'attendre à ce qu'il comprenne une fraction élevée de la distribution des valeurs qui pourraient être attribuées raisonnablement au mesurande

[SOURCE: GUIDE ISO/IEC 98-3:2008, 2.3.5, modifié – Les trois notes ont été supprimées.]

**3.6**
**FACTEUR DE CORRECTION**
facteur sans dimensions qui corrige la VALEUR INDIQUEE d'un instrument, de sa valeur en fonctionnement dans des conditions particulières, en sa valeur en fonctionnement dans des CONDITIONS DE REFERENCE spécifiées

[SOURCE: IEC 60731:2011, 3.6]

**3.7**
**GRANDEUR D'INFLUENCE**
grandeur externe susceptible d'affecter les performances d'un instrument

[SOURCE: IEC 60731:2011, 3.7]

**3.8**
**PARAMÈTRE D'INSTRUMENT**
propriété interne d'un instrument qui est susceptible d'affecter ses performances

[SOURCE: IEC 60731:2011, 3.8]

**3.9**
**VALEUR DE RÉFÉRENCE**
valeur particulière d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT choisie pour servir de référence

Note 1 à l'article: C'est-à-dire la valeur d'une GRANDEUR D'INFLUENCE (ou d'un PARAMETRE D'INSTRUMENT) pour laquelle le FACTEUR DE CORRECTION relatif à la dépendance vis-à-vis de cette GRANDEUR d'INFLUENCE (ou de ce PARAMETRE D'INSTRUMENT) est égal à l'unité.

[SOURCE: IEC 60731:2011, 3.9]

**3.9.1**
**CONDITIONS DE RÉFÉRENCE**
conditions dans lesquelles toutes les GRANDEURS D'INFLUENCE et tous les PARAMETRES D'INSTRUMENT prennent leurs VALEURS DE REFERENCE

[SOURCE: IEC 60731:2011, 3.9.1]

**3.10**
**VALEURS D'ESSAI NORMALISÉES**
valeur, ensemble de valeurs ou plage de valeurs d'une GRANDEUR D'INFLUENCE, ou d'un PARAMETRE D'INSTRUMENT, qui sont admises pour effectuer des étalonnages ou des essais sur une autre GRANDEUR D'INFLUENCE ou un autre PARAMETRE D'INSTRUMENT

[SOURCE: IEC 60731:2011, 3.10]

**3.10.1**
**CONDITIONS D'ESSAI NORMALISÉES**
conditions dans lesquelles toutes les GRANDEURS D'INFLUENCE et tous les PARAMETRES D'INSTRUMENT prennent leurs VALEURS D'ESSAI NORMALISEES

[SOURCE: IEC 60731:2011, 3.10.1]

**3.11**
**CARACTÉRISTIQUE DE PERFORMANCE**
une des grandeurs servant à définir la performance d'un instrument

[SOURCE: IEC 60731:2011, 3.11, modifié – La note a été supprimée]

**3.11.1**
**REPONSE**
<ENSEMBLE DE DETECTION avec ENSEMBLE DE MESURAGE> quotient de la VALEUR INDIQUEE par la VALEUR CONVENTIONNELLEMENT VRAIE à l'emplacement du POINT DE REFERENCE du DETECTEUR DE RAYONNEMENT

[SOURCE: IEC 60731:2011, 3.11.1, modifié – Seul le premier alinéa a été maintenu.]

**3.11.2**
**POUVOIR DE RESOLUTION**
<affichage> plus petite variation de valeur lue qui peut être chiffrée numériquement sans interpolation

[SOURCE: IEC 60731:2011, 3.11.2, modifié – Seul le premier alinéa a été maintenu.]

**3.11.2.1**
**POUVOIR DE RESOLUTION**
<affichage numérique > plus petit accroissement significatif de la lecture

[SOURCE: IEC 60731:2011, 3.11.2, modifié – Seul le troisième alinéa a été maintenu.]

**3.11.3**
**TEMPS DE MISE EN EQUILIBRE**
temps nécessaire pour qu'une valeur lue atteigne et se maintienne à l'intérieur d'un écart spécifié autour de sa valeur finale d'équilibre, après qu'un changement brusque de l'une des GRANDEURS D'INFLUENCE a été imposé à l'instrument

[SOURCE: IEC 60731:2011, 3.11.3]

**3.11.4**
**TEMPS DE RÉPONSE**
temps nécessaire pour qu'une valeur lue atteigne et se maintienne à l'intérieur d'un écart spécifié autour de sa valeur finale d'équilibre après un changement brusque de la grandeur à mesurer

[SOURCE: IEC 60731:2011, 3.11.4]

**3.11.5**
**TEMPS DE STABILISATION**
temps nécessaire pour qu'une CARACTERISTIQUE DE PERFORMANCE donnée entre et se maintienne à l'intérieur d'un écart spécifié autour de sa valeur finale d'équilibre, après que l'ENSEMBLE DE MESURAGE a été mis en route et après que la tension de polarisation a été appliquée à la CHAMBRE D'IONISATION

[SOURCE: IEC 60731:2011, 3.11.5]

**3.11.6**
**COURANT DE FUITE DE L'ENSEMBLE DE CHAMBRE**
**COURANT DE FUITE**
tout courant, sur le trajet du signal, qui naît dans l'ENSEMBLE DE CHAMBRE et qui n'est pas dû à l'ionisation dans le volume de mesurage

[SOURCE: IEC 60731:2011, 3.11.6, modifié – La note a été supprimée.]

**3.12**
**VARIATION**
différence relative, $\Delta y/y$, entre les valeurs d'une CARACTERISTIQUE DE PERFORMANCE, $y$, lorsqu'une GRANDEUR D'INFLUENCE (ou un PARAMETRE D'INSTRUMENT) prend successivement deux valeurs spécifiées, les autres GRANDEURS D'INFLUENCE (et les PARAMETRES D'INSTRUMENT) étant maintenues constantes à leurs VALEURS D'ESSAI NORMALISEES (sauf si d'autres valeurs sont spécifiées)

[SOURCE: IEC 60731:2011, 3.12]

**3.13**
**LIMITES DE VARIATION**
VARIATION maximale admise d'une CARACTERISTIQUE DE PERFORMANCE

Note 1 à l'article: Si les LIMITES DE VARIATION sont $\pm L$ %, la VARIATION $\Delta y/y$, exprimée en pourcentage, doit rester dans la plage comprise entre $-L$ % et $+L$ %.

[SOURCE: IEC 60731:2011, 3.13]

**3.14**
**DOMAINE UTILE DES VALEURS INDIQUÉES**
**DOMAINE UTILE**
domaine des VALEURS INDIQUEES à l'intérieur duquel un instrument est conforme à une performance indiquée

Note 1 à l'article: La VALEUR INDIQUEE utile maximale (respectivement minimale) est la valeur la plus élevée (respectivement la plus basse) dans ce domaine.

Note 2 à l'article: Le concept de DOMAINE UTILE peut également, par exemple, s'appliquer à des valeurs lues et à des grandeurs associées non indiquées directement par l'appareil, par exemple le courant d'entrée.

[SOURCE: IEC 60731:2011, 3.14]

**3.15**
**DOMAINE D'UTILISATION ASSIGNÉ**
**DOMAINE ASSIGNÉ**
domaine des valeurs d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT à l'intérieur duquel cet instrument fonctionne dans les LIMITES DE VARIATION

Note 1 à l'article: Ses limites sont les VALEURS ASSIGNEES maximale et minimale.

[SOURCE: IEC 60731:2011, 3.15]

**3.15.1**
**DOMAINE ASSIGNÉ MINIMAL**
plus petit domaine d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT dans lequel l'instrument doit fonctionner à l'intérieur des LIMITES DE VARIATION spécifiées

[SOURCE: IEC 60731:2011, 3.15.1]

**3.16**
**POINT DE REFERENCE D'UN DETECTEUR DE RAYONNEMENT**
**POINT DE REFERENCE**
point d'un DETECTEUR DE RAYONNEMENT qui, pendant l'étalonnage du détecteur, est amené en coïncidence avec le point en lequel la VALEUR CONVENTIONNELLEMENT VRAIE est spécifiée

[SOURCE: IEC 60731:2011, 3.16, modifié – Le terme CHAMBRE D'IONISATION a été remplacé par DETECTEUR DE RAYONNEMENT dans le terme et la définition.]

**3.17**
**APPAREIL ELECTROMEDICAL**
**APPAREIL EM**
appareil électrique qui possède une PARTIE APPLIQUEE ou qui transfère de l'énergie vers le PATIENT ou à partir de celui-ci ou qui détecte un tel transfert d'énergie vers le PATIENT ou à partir de celui-ci et qui est:

a) équipé au plus d'un moyen de raccordement à un RESEAU D'ALIMENTATION donné; et
b) destiné par son FABRICANT à être utilisé:
   1) pour le diagnostic, le traitement ou la surveillance d'un PATIENT; ou
   2) pour la compensation ou l'atténuation d'une maladie, d'une blessure ou d'une incapacité.

[SOURCE: IEC 60601-1:2005, 3.63, modifié – Les cinq notes n'ont pas été maintenues.]

**3.18**
**FAISCEAU NON ATTENUE**
faisceau de rayonnement X incident sur le PATIENT ou le FANTOME

**3.18.1**
**QUALITE DU FAISCEAU NON ATTENUE**
QUALITE DE RAYONNEMENT du faisceau de rayonnement X à l'emplacement de la surface d'entrée du PATIENT ou du FANTOME, déterminée lorsque ces derniers sont absents

**3.19**
**FAISCEAU ATTENUE**
faisceau de rayonnement X qui sort du PATIENT ou du FANTOME

**3.19.1**
**QUALITE DU FAISCEAU ATTENUE**
QUALITE DE RAYONNEMENT du faisceau de rayonnement X sortant du PATIENT ou du FANTOME

**3.20**
**LONGUEUR ASSIGNEE**
partie de l'axe du DETECTEUR EN TOMODENSITOMETRIE pour laquelle le DETECTEUR remplit ses spécifications

**3.20.1**
**LONGUEUR EFFECTIVE**
partie de l'axe du DETECTEUR EN TOMODENSITOMETRIE entre les deux points auxquels la REPONSE s'est affaiblie de 50 % par rapport à sa valeur à son centre géométrique

**3.21**
**KERMA DANS L'AIR**
*K*
quotient de $dE_{tr}$ par d*m*, où $dE_{tr}$ est la somme des énergies cinétiques initiales de toutes les particules ionisantes chargées libérées par des particules ionisantes non chargées dans une masse d'air d*m*

Note 1 à l'article: L'unité de KERMA DANS L'AIR est le Gy (où 1 Gy = 1 $J \cdot kg^{-1}$).

[SOURCE: IEC 60731:2011, 3.31, modifié – La seconde note a été supprimée]

**3.21.1**
**DÉBIT DE KERMA DANS L'AIR**
$\dot{K}$
quotient de d*K* par d*t*, où d*K* est l'accroissement de KERMA DANS L'AIR dans l'intervalle de temps d*t*

Note 1 à l'article: L'unité de DEBIT DE KERMA DANS L'AIR est le $Gy \cdot s^{-1}$ ($Gy \cdot min^{-1}$; $Gy \cdot h^{-1}$).

[SOURCE: IEC 60731:2011, 3.31.1, modifié – La seconde note a été supprimée.]

**3.21.2**
**PRODUIT KERMA DANS L'AIR LONGUEUR**
$P_{KL}$
ligne intégrale du KERMA DANS L'AIR *K* sur une longueur *L*

$$P_{KL} = \int_L K(z)dz \quad (1)$$

Note 1 à l'article: L'unité de PRODUIT KERMA DANS L'AIR LONGUEUR est le Gy·m (mGy·m).

**3.22**
**HAUTE TENSION RADIOGENE**
différence de potentiel appliquée à un TUBE RADIOGENE entre son ANODE et SA CATHODE

Note 1 à l'article: Son unité de grandeur est le volt (V).

Note 2 à l'article: La HAUTE TENSION RADIOGENE peut varier en fonction du temps. La TENSION DE CRETE PRATIQUE est une valeur pondérée de la HAUTE TENSION RADIOGENE sur une certaine durée.

[SOURCE: IEC 61676:2023, 3.25, modifié – L'information concernant l'unité a été déplacée de la définition à une note à l'article et une seconde note à l'article a été ajoutée.]

**3.23**
**COEFFICIENT DE VARIATION**
CV
<variable aléatoire positive> ECART-TYPE divisé par la MOYENNE

[SOURCE: ISO 3534-1:2006, 2.38, modifié – L'exemple et les notes n'ont pas été maintenus.]

**3.24**
**INSTRUCTIONS D'UTILISATION**
parties des DOCUMENTS D'ACCOMPAGNEMENT donnant les renseignements nécessaires pour l'utilisation et le fonctionnement corrects et sûrs de l'appareil

[SOURCE: En anglais, IEC TR 60788:2004, rm-82-02]

# 4 Exigences générales

## 4.1 Exigences de performance

Dans l'Article 5 et l'Article 6, les exigences de performance sont spécifiées pour un DOSIMETRE DE RADIODIAGNOSTIC complet qui comprend à la fois l'ENSEMBLE DE DETECTION et l'ENSEMBLE DE MESURAGE. Pour un DOSIMETRE conçu pour fonctionner avec un ou plusieurs ENSEMBLES DE DETECTION, chaque combinaison d'un ENSEMBLE DE MESURAGE et d'un ENSEMBLE DE DETECTION doit être conforme aux exigences du 4.4 et à celles de l'Article 5 et de l'Article 6 adaptées à cette combinaison.

## 4.2 VALEURS DE REFERENCE et VALEURS D'ESSAI NORMALISEES

Ces valeurs sont indiquées dans le Tableau 1.

**Tableau 1 – Conditions d'essai de référence et normalisées**

| GRANDEUR DE RÉFÉRENCE | VALEURS DE RÉFÉRENCE | VALEURS D'ESSAI NORMALISÉES |
|---|---|---|
| Température | +20 °C | +15 °C à +25 °C |
| Humidité relative | 50 % | 30 % à 75 % |
| Pression de l'air | 101,3 kPa | Pression atmosphérique |
| DEBIT DE KERMA DANS L'AIR[a] | Comme pour l'étalonnage | VALEUR DE RÉFÉRENCE ±10 % |
| QUALITÉ DE RAYONNEMENT: | | |
| Mammographie | Comme cela est indiqué par le fabricant[b] | VALEUR DE RÉFÉRENCE |
| Radiodiagnostic ordinaire: | | |
| – FAISCEAU NON ATTENUE | 70 kV (RQR 5 x IEC 61267) | VALEUR DE REFERENCE |
| – FAISCEAU ATTENUE | 70 kV (RQA 5 x IEC 61267) | VALEUR DE REFERENCE |
| TOMODENSITOMÉTRIE[c]: | 120 kV (RQT 9 x IEC 61267) | VALEUR DE RÉFÉRENCE |
| Faisceau à filtre de cuivre | 70 kV (RQC 5 x IEC 61267) | VALEUR DE RÉFÉRENCE |
| Champs électromagnétiques | Nul | Non significatif[d] |

a LE DEBIT DE KERMA DANS L'AIR n'est qu'une GRANDEUR D'INFLUENCE pour les mesurages de KERMA DANS L'AIR et du PRODUIT KERMA DANS L'AIR LONGUEUR.

b LES QUALITES DE RAYONNEMENT utilisées en mammographie doivent être indiquées comme étant des combinaisons de matériaux de l'anode du TUBE RADIOGENE (par exemple, W, Mo, Rh) et de filtrations (par exemple, Al, Mo, Rh, Pd, Ag). Chacune de ces combinaisons peut avoir son propre DOMAINE ASSIGNE. Le cas échéant, il convient d'utiliser les QUALITES DE RAYONNEMENT établies telles qu'elles sont définies dans l'IEC 61267.

c Le DETECTEUR DE RAYONNEMENT doit être irradié dans un champ de rayonnement de diamètre égal ou supérieur à deux fois le diamètre du DETECTEUR DE RAYONNEMENT. Le DETECTEUR DE RAYONNEMENT doit être exposé avec le faisceau aligné au centre de la longueur active du DETECTEUR DE RAYONNEMENT.

d "Non significatif" signifie que le champ est suffisamment petit pour qu'il n'ait pas d'effet décelable sur la REPONSE du DOSIMETRE, comme cela existe, par exemple, dans un environnement normal de laboratoire sans protection spéciale.