

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux – Dosimètres à chambres d'ionisation et/ou à détecteurs semiconducteurs utilisés en imagerie de diagnostic à rayonnement X



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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IEC 61674 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) for mammography, the manufacturer specifies the REFERENCE VALUE for the RADIATION QUALITY;
- b) for mammography, the manufacturer provides the MINIMUM RATED RANGE of RADIATION QUALITIES for the compliance test on energy dependence of response;
- c) the compliance test for analogue displays was removed;

- d) the compliance tests for range reset, the effect of leakage and recombination losses were removed. These tests are already covered by the test on linearity and cannot be conducted for modern devices. The estimation of COMBINED STANDARD UNCERTAINTY was changed accordingly;
- e) the compliance test for mains rechargeable and battery-operated dosimeters were updated for modern devices.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/909/FDIS	62C/913/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used.

- requirements and definitions: roman type.
- *test specifications: italic type.*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2:2021. For the purposes of this document, the auxiliary verb:

- "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 $1 \text{ Gy} = 1 \text{ J} \cdot \text{kg}^{-1}$).

[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 $\text{Gy} \cdot \text{s}^{-1}$ ($\text{Gy} \cdot \text{min}^{-1}$; $\text{Gy} \cdot \text{h}^{-1}$).

[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 $\text{Gy} \cdot \text{m}$ ($\text{mGy} \cdot \text{m}$).

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 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
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:

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

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	$K < 10 \mu\text{Gy}$ $K \geq 10 \mu\text{Gy}$	$0,1667 \times (16 - K) \%^a$ 1 %
AIR KERMA RATE, $\dot{K}$	$\dot{K} < 1 \mu\text{Gy/s}$ $\dot{K} \geq 1 \mu\text{Gy/s}$	$1,11 \times (4,7 - 2 \dot{K}) \%^b$ 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	$K < 1\,000 \mu\text{Gy}$ $K \geq 1\,000 \mu\text{Gy}$	$0,1667 \times (16 - 0,01 K) \%^a$ 1 %
AIR KERMA RATE, $\dot{K}$	$\dot{K} < 100 \mu\text{Gy/s}$ $\dot{K} \geq 100 \mu\text{Gy/s}$	$1,11 \times (4,7 - 0,02 \dot{K}) \%^b$ 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 $\pm 2,0$ % 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.