BS EN 61674:2013

BSI Standards Publication

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

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This British Standard is the UK implementation of EN 61674:2013. It is identical to IEC 61674:2013. It supersedes BS EN 61674:1998, which will be withdrawn on 3 January 2016.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2013

ISBN 978 0 580 70786 5

ICS 11.040.50; 17.240

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2013.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61674

February 2013

ICS 11.040.50

Supersedes EN 61674:1997 + A1:2002

English version

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

(IEC 61674:2012)

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

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

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CENELEC

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

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Foreword

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

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-10-03
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-01-03

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

In this standard, the following print types are used:
– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF EN 60601-1, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:
– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Endorsement notice

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050	Series	International Electrotechnical Vocabulary	-	-
IEC 60417	Data-base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 + corr. March	2008 2010
IEC 60731	2011	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	EN 60731	2012
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61000-4	Series	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques	EN 61000-4	Series
IEC 61000-4-2	-	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	-
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	-
IEC 61000-4-4	-	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	-
IEC 61000-4-6	-	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	-

IEC 61000-4-11	-	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	-
IEC 61187	-	Electrical and electronic measuring equipment - Documentation	EN 61187	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-
ISO/IEC Guide 99	2007	International vocabulary of metrology - Basic and general concepts and associated terms (VIM)	-	-
ISO 3534-1	2006	Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability	-	-

CONTENTS

INTRODUCTION

Diagnostic radiology is the largest contributor to man-made IONIZING RADIATION to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing medical radiological examinations or procedures has therefore become a central issue in recent years. The PATIENT dose will be minimized when the X-ray producing equipment is correctly adjusted for image quality and radiation output. These adjustments require that the routine measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE be made accurately. The equipment covered by this standard plays an essential part in achieving the required accuracy. The DOSIMETERS used for adjustment and control measurements must be of satisfactory quality and must therefore fulfil the special requirements laid down in this standard.

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

1 Scope and object

1.1 Scope

This International Standard specifies the performance and some related constructional requirements of DIAGNOSTIC DOSIMETERS intended for the measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE, in photon radiation fields used in RADIOGRAPHY, including mammography, RADIOSCOPY and COMPUTED TOMOGRAPHY (CT), for X-radiation with generating potentials not greater than 150 kV.

This International Standard is applicable to the performance of DOSIMETERS with VENTED IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS as used in X-ray diagnostic imaging.

1.2 Object

The object of this standard is:

a) to establish requirements for a satisfactory level of performance for DIAGNOSTIC DOSIMETERS, and

b) to standardize the methods for the determination of compliance with this level of performance.

This standard is not concerned with the safety aspects of DOSIMETERS. The DIAGNOSTIC DOSIMETERS covered by this standard are not intended for use in the PATIENT ENVIRONMENT and, therefore, the requirements for electrical safety applying to them are contained in IEC 61010-1.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050 (all parts), *International Electrotechnical Vocabulary* (available at <http://www.electropedia.org>)

IEC 60601-1:2005*, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*

IEC 60417, *Graphical symbols for use on equipment* (Available at: <http://www.graphical-symbols.info/equipment>

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

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61000-4 (all parts) *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances induced by radio-frequency fields*

IEC 61000-4-11, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests*

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO/IEC GUIDE 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

ISO 3534-1:2006, *Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability*

3 Terms and definitions

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

3.1
DIAGNOSTIC DOSIMETER
DOSIMETER
equipment which uses IONIZATION CHAMBERS and/or SEMICONDUCTOR DETECTORS for the measurement of AIR KERMA, AIR KERMA LENGTH PRODUCT and/or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for diagnostic medical radiological examinations

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

– one or more DETECTOR ASSEMBLIES which may or may not be an integral part of the MEASURING ASSEMBLY;

– a MEASURING ASSEMBLY;

– one or more STABILITY CHECK DEVICES (optional).

3.1.1
DETECTOR ASSEMBLY
RADIATION DETECTOR and all other parts to which the RADIATION DETECTOR is permanently attached, except the MEASURING ASSEMBLY

Note 1 to entry: The DETECTOR ASSEMBLY normally includes:

– the RADIATION DETECTOR and the stem (or body) on which the RADIATION DETECTOR is permanently mounted (or embedded);

– the electrical fitting and any permanently attached cable or pre-amplifier.

3.1.1.1
RADIATION DETECTOR
element which transduces AIR KERMA, AIR KERMA LENGTH PRODUCT or AIR KERMA RATE into a measurable electrical signal

Note 1 to entry: A radiation detector may be either an ionization chamber or a semiconductor detector.

3.1.1.1.1
IONIZATION CHAMBER
CHAMBER
ionizing RADIATION DETECTOR consisting of a CHAMBER filled with air, in which an electric field insufficient to produce gas multiplication is provided for the collection at the electrodes of charges associated with the ions and the ELECTRONS produced in the measuring volume of the detector by IONIZING RADIATION

Note 1 to entry: An IONIZATION CHAMBER can be sealed or vented.

Note 2 to entry: Vented IONIZATION CHAMBERS are constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere, so that corrections to the RESPONSE for changes in air density need to be made.

Note 3 to entry: Sealed IONIZATION CHAMBERS are not suitable, because the necessary wall thickness of a sealed CHAMBER may cause an unacceptable energy dependence of the RESPONSE and because the long term stability of sealed CHAMBERS is not guaranteed.

[SOURCE: IEC 60731:2011, 3.1.1.1, modified – three new notes to entry have replaced the two original notes.]

3.1.1.1.2
VENTED IONIZATION CHAMBER
IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere such that corrections to the RESPONSE for changes in air density need to be made

[SOURCE: IEC 60731:2011, 3.1.1.1.3, modified – the term has been changed from "vented chamber" to "VENTED IONIZATION CHAMBER".]

3.1.1.1.3
SEMICONDUCTOR DETECTOR
semiconductor device that utilises the production and motion of electron-hole pairs in a charge carrier depleted region of the semiconductor for the detection and measurement of IONIZING RADIATION

Note 1 to entry: The production of electron-hole pairs is caused either

– directly by interaction of the IONIZING RADIATION with the semiconductor material, or

– indirectly by first converting the incident radiation energy to light in a scintillator material directly in front of and optically coupled to a semiconductor photodiode, which then produces the electrical signal.

3.1.2
MEASURING ASSEMBLY
device to measure the charge (or current) from the RADIATION DETECTOR and convert it into a form suitable for displaying the values of DOSE or KERMA or their corresponding rates

[SOURCE: IEC 60731:2011, 3.1.2. modified – the term IONIZATION CHAMBER in the original definition has been replaced by the term RADIATION DETECTOR]

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

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

[SOURCE: IEC 60731:2011, 3.1.3]

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

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

– one or more DETECTOR ASSEMBLIES;

– a MEASURING ASSEMBLY.

3.1.5
CT DETECTOR
RADIATION DETECTOR which is used for CT dosimetry

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

[SOURCE: IEC 60731:2011, 3.2]

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

[SOURCE: IEC 60731:2011, 3.3]

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

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

[SOURCE: IEC 60731:2011, 3.4]

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

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

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

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

[SOURCE: IEC 60731:2011, 3.5.1]

3.5.2
OVERALL UNCERTAINTY
UNCERTAINTY associated with the MEASURED VALUE

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

[SOURCE: IEC 60731:2011, 3.5.2]

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

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

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

[SOURCE: IEC 60731:2011, 3.6]

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

[SOURCE: IEC 60731:2011, 3.7]

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

[SOURCE: IEC 60731:2011, 3.8]

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

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

[SOURCE: IEC 60731:2011, 3.9]

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

[SOURCE: IEC 60731:2011, 3.9.1]

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

[SOURCE: IEC 60731:2011, 3.10]

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

[SOURCE: IEC 60731:2011, 3.10.1]

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

[SOURCE: IEC 60731:2011, 3.11]

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

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

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

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

<digital display> smallest significant increment of the reading

[SOURCE: IEC 60731:2011, 3.11.2,]

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

[SOURCE: IEC 60731:2011, 3.11.3,]

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

[SOURCE: IEC 60731:2011, 3.11.4,]

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

[SOURCE: IEC 60731:2011, 3.11.5]

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

[SOURCE: IEC 60731:2011, 3.11.6]

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

[SOURCE: IEC 60731:2011, 3.12]

3.13
LIMITS OF VARIATION
maximum permitted VARIATION of a PERFORMANCE CHARACTERISTIC

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

[SOURCE: IEC 60731:2011, 3.13]

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

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

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

[SOURCE: IEC 60731:2011, 3.14,]

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

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

[SOURCE: IEC 60731:2011, 3.15]

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

[SOURCE: IEC 60731:2011, 3.15.1]

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 by 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 of the original definition 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]

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]

3.21.2
AIR KERMA LENGTH PRODUCT
PKL
line integral of the AIR KERMA K over a length L.

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

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)

[SOURCE: IEC 60601-1-3:2008, 3.88]

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

[SOURCE: ISO 3534-1:2006, 2.38, modified – the notes of the original definition 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 Clauses 5 and 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 Clauses 5 and 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:		
– UNATTENUATED BEAM	28 kV 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 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 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.

[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, e.g. 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							
	COEFFICIENT OF VARIATION v						
Δ	< 0,5 %	0,5 %	1 %	2 %	3 %	4 %	5 %
1 %	*	6	25	100	225	400	600
2 %	*	*	6	25	55	100	150
3 %	*	*	*	12	25	45	70
4 %	*	*	*	6	15	25	40
5 %	*	*	*	*	9	16	25

For measurements marked * at least five repeated readings shall be taken.

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.

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.

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 e.g. 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.

4.4.2.3 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, 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, e.g. 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.

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 of 95 % (see Annex A of IEC 60731).

5 Limits of PERFORMANCE CHARACTERISTICS

5.1 Linearity

For AIR KERMA RATE measurements, equation (1) shall be fulfilled over the whole RATED RANGE of AIR KERMA RATE:

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}02 \qquad (1)$$

where

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

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 Tables 3 and 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* μ*Gy for* AIR KERMA *measurements and/or below 1* μ*Gy/s for* AIR KERMA RATE *measurements, additional tests shall be made at 10* μ*Gy and 1* μ*Gy/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 $K \geq 10$ μGy	$0{,}1667 \cdot (16 - K)$ %[a] 1 %
AIR KERMA RATE, $\dot{K}$	$\dot{K} < 1$ μGy/s $\dot{K} \geq 1$ μGy/s	$1{,}11 \cdot (4{,}7 - 2\dot{K})$ %[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* μ*Gy for* AIR KERMA *measurements and/or below 100* μ*Gy/s for* AIR KERMA RATE *measurements, additional tests shall be made at 1 000* μ*Gy and 100* μ*Gy/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

Quantity	Range of measurement	Maximum COEFFICIENT OF VARIATION (v_{max})
AIR KERMA, K	$K < 1\,000$ μGy $K \geq 1\,000$ μGy	$0{,}1667 \cdot (16 - 0{,}01\,K)$ %[a] 1 %
AIR KERMA RATE, $\dot{K}$	$\dot{K} < 100$ μGy/s $\dot{K} \geq 100$ μGy/s	$1{,}11 \cdot (4{,}7 - 0{,}02\,\dot{K})$ %[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:

– 1 Gy/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 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 be checked by testing the MEASURING ASSEMBLY *electrically with pulses corresponding to the* AIR KERMA *pulses defined above.*

5.6 Reset on AIR KERMA and AIR KERMA LENGTH PRODUCT ranges

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

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.*

5.8 Stability

5.8.1 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.*

5.8.2 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, then:

– the DOSIMETER shall still meet the requirements for LEAKAGE CURRENT given in 5.7.1 and 5.7.2, 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 tests for LEAKAGE CURRENT given in 5.7.1 and 5.7.2, after delivering the specified accumulated AIR KERMA to the DETECTOR ASSEMBLY;*

– *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, and noting the difference.*

5.9 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 the mammography 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 – 150 kV RQR 3 – RQR 10 x IEC 61267	70 kV RQR 5 x IEC 61267	±5 %	
b) conventional diagnostic ATTENUATED BEAM	50 – 150 kV RQA 3 – 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 %	
e) COMPUTED TOMOGRAPHY	100 – 150 kV RQR 8 – RQR 10 x IEC 61267	120 kV RQT 9 x IEC 61267	±5 %	
	100 – 150 kV RQT 8 – RQT 10 x IEC 61267			
	100 – 120 kV RQA 8 – RQA 9 x IEC 61267			
f) Copper-filtered beams	50 – 100 kV RQC3 – RQC 8	RQC 5	±5 %	

INFLUENCE QUANTITY	MINIMUM RATED RANGE	REFERENCE CONDITIONS	LIMITS OF VARIATION *L*	Subclause
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 % – +10 %	Nominal voltage[e]	±2 %	6.5
Batteries	As stated by the MANUFACTURER			
Air pressure	80,0 kPa – 106,0 kPa	101,3 kPa	±2 %	6.6
Air pressure EQUILIBRATION TIME	±10,0 %	Atmospheric pressure	<20 s	6.7
Temperature	+15 °C – +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

[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.

[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 Equation (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 and

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 allowed to make an equivalent electrical test on the MEASURING ASSEMBLY.

6.3.2 IONIZATION CHAMBER – Recombination losses

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° 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° 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° 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 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 a.c. 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 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.

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 °C	**Relative humidity** %	**Absolute humidity** 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 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). 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). To reduce the amount of measurements needed to show compliance with this requirement, tests at frequencies 80, 90, 100, 110, 120, 130, 140, 150, 160, 180, 200, 220, 240, 260, 290, 320, 350, 380, 420, 460, 510, 560, 620, 680, 750, 820, 900 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. 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 (IEC 61000-4-4) and* CONDUCTED DISTURBANCES *induced by radio-frequency fields (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 standard;

– 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 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 trade-mark of the MANUFACTURER or supplier responsible for ensuring that the MEASURING ASSEMBLY complies with this standard;

– 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 Clauses 5 and 6;

– for battery-operated DOSIMETERS, type of batteries required so that the performance of the instrument complies with Clauses 5 and 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 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 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 the field size 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);
– 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;
– 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.

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
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	5.8.1	±1,15
Accumulated dose stability	5.8.2	±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

[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 standard a maximum error of the calibration factor is included here and assumed to be ±5 %. A uniform distribution is also assumed.

Index of defined terms

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