

INTERNATIONAL STANDARD



Medical electrical equipment – Dose area product meters

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IEC 60580

Edition 3.0 2019-11
REDLINE VERSION

INTERNATIONAL STANDARD



Medical electrical equipment – Dose area product meters

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-7605-1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
DOSE AREA PRODUCT METERS**

FOREWORD

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International Standard IEC 60850 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published 2000, and constitutes a technical revision.

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

- a) a second class of devices is introduced with tighter uncertainty tolerances;
- b) this document has been expanded to include detectors other than ionization chambers;
- c) radiation qualities have been updated to the new definitions according to IEC 61267;
- d) a requirement on the linearity of the dose area product rate measurement was added;
- e) changed chamber light transmission requirement from 70 % to 60 %.

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

FDIS	Report on voting
62C/744/FDIS	62C/751/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: small roman type;
- *test specifications: italic type*;
- TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 3 OR LISTED IN THE INDEX: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

Diagnostic radiology is the largest contributor to man-made ionizing radiation to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS or procedures has therefore become a central issue in recent years. The purpose of routine measurement of DOSE AREA PRODUCT is to help in achieving an overall reduction in the radiation received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS. Provided adequate records are kept, it is possible to determine PATIENT doses, to compare different examination techniques, to establish a technique giving minimum RADIATION to a PATIENT, and to ensure a maintenance of that technique; in this respect, such measurements have a place of particular importance in training establishments. Examination of records may also indicate a deterioration in the efficiency of the image-production system.

~~DOSE AREA PRODUCT METERS must be of satisfactory quality and must therefore fulfill the special requirements laid down in this International Standard.~~

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MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

1 ~~Scope and object~~

This document specifies the performance and testing of DOSE AREA PRODUCT METERS ~~with IONIZATION CHAMBERS~~ intended to measure DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE to which the PATIENT is exposed during MEDICAL RADIOLOGICAL EXAMINATIONS.

This document is applicable to the following types of DOSE AREA PRODUCT METERS:

- a) FIELD-CLASS DOSE AREA PRODUCT METERS normally used for the measurement of DOSE AREA PRODUCTS during MEDICAL RADIOLOGICAL EXAMINATIONS;
- b) REFERENCE-CLASS DOSE AREA PRODUCT METERS normally used for the CALIBRATION of FIELD-CLASS DOSIMETERS.

NOTE REFERENCE-CLASS DOSE AREA PRODUCT METERS can be used as FIELD-CLASS DOSE AREA PRODUCT METERS.

The object of this document is

- 1) to establish requirements for a satisfactory level of performance for DOSE AREA PRODUCT METERS, and
- 2) to standardize the methods for the determination of compliance with this level of performance.

Two levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSE AREA PRODUCT METERS;
- a higher level of performance applying to REFERENCE-CLASS DOSE AREA PRODUCT METERS.

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 60601-1:1988/2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

~~IEC 60601-1-1:1992, Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems~~

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility disturbances – Requirements and tests*

~~IEC 60731:1997, Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy~~

IEC TR 60788:~~1984~~2004, ~~Medical radiology – Terminology~~ *Medical electrical equipment – Glossary of defined terms*

~~IEC 60950:1999, Safety of information technology equipment~~

IEC 61000-4-2:~~1995~~, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3:~~1995~~, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test ⁴⁾*

IEC 61000-4-4:~~1995~~, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5:~~1995~~, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6:~~1996~~, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances induced by radio-frequency fields*

IEC 61000-4-11:~~1994~~, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests*

IEC 61187:~~1993~~, *Electrical and electronic measuring equipment – Documentation*

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

IEC 62368-1, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

~~ICRU 60:1998, International Commission on Radiation Units and Measurements, Fundamental Quantities and Units for Ionizing Radiation, Report 60, ICRU Publications, Bethesda MD (1998)~~

~~ISO, International Organization for Standardization, International vocabulary of basic and general terms in metrology, 2nd edition, Geneva (1993)~~

~~ISO, International Organization for Standardization, Guide to the expression of uncertainty in measurement, 1st edition, Geneva (1993)~~

3 Terms and definitions

~~In this International Standard the auxiliary verb~~

~~— "shall" implies that compliance with a requirement is mandatory for compliance with the standard;~~

~~— "may" implies that compliance with a requirement is permitted to be accomplished in a particular manner for compliance with the standard.~~

~~The definitions given in this International Standard are generally in agreement with those in IEC 60788 and ISO: International vocabulary of basic and general terms in metrology;~~

⁴⁾ There exists a consolidated edition 1.1 (1998) that includes IEC 61000-4-3 (1995) and its amendment 1 (1998).

~~uncertainties are evaluated in accordance with ISO: Guide to the expression of uncertainty in measurement.~~

~~Terms not defined in this subclause or listed in the index of defined terms have the meanings defined in the above publications or are assumed to be terms of general scientific usage. An alphabetical list of defined terms is given in the index.~~

~~For the purposes of this International Standard the following definitions apply:~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788:2004 and the following apply.

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

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

NOTE 1 An index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch.

3.1

ACCOMPANYING DOCUMENT

document provided with an installation, equipment, associated equipment or accessory, containing important information for the assembler, installer and user, particularly regarding safety

3.2

AIR KERMA

K

quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Note 1 to entry: Unit: $J\ kg^{-1}$.

Note 2 to entry: The special name for the unit of AIR KERMA is gray (Gy) (ICRU ~~60~~ 85A).

3.3

AIR KERMA RATE

\dot{K}

quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt , thus

$$\dot{K} = \frac{dK}{dt}$$

Note 1 to entry: Unit: $J\ kg^{-1}\ s^{-1}$.

Note 2 to entry: ~~If~~ The special name ~~gray is used~~, for the unit of AIR KERMA rate is gray per second ($Gy\ s^{-1}$) (ICRU ~~60~~ 85A).

3.4

COEFFICIENT OF VARIATION

standard deviation of a set of readings expressed as a percentage of the mean value of these readings

~~3.5~~

~~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 (IEC 60731)~~

~~NOTE The CONVENTIONAL TRUE VALUE will usually be the value determined by the STANDARD with which the instrument under test is compared.~~

3.5

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]

3.6

DOSE AREA PRODUCT

$$K \cdot A$$

product of the area of the USEFUL BEAM and the AIR KERMA over the cross-section of the USEFUL BEAM, both quantities being measured at the same distance from the FOCAL SPOT

Note 1 to entry: The unit of DOSE AREA PRODUCT is $\text{Gy} \cdot \text{m}^2$.

3.7

DOSE AREA PRODUCT METER

equipment ~~which uses IONIZATION CHAMBERS~~ for the measurement of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE in the beam of an X-ray machine used for diagnostic MEDICAL RADIOLOGICAL EXAMINATIONS

Note 1 to entry: A DOSE AREA PRODUCT METER contains the following components:

- ~~— IONIZATION CHAMBER~~
- RADIATION DETECTOR;
- MEASURING ASSEMBLY;
- STABILITY CHECK DEVICE.

3.8

DOSE AREA PRODUCT RATE

$$\dot{K} \cdot A$$

quotient of an increment of DOSE AREA PRODUCT by the corresponding increment of time

Note 1 to entry: The unit of DOSE AREA PRODUCT RATE is $\text{Gy} \cdot \text{m}^2/\text{s}$.

3.9

EFFECTIVE RANGE (of INDICATED VALUES)

range of INDICATED VALUES for which an instrument complies with a stated performance; the maximum (minimum) EFFECTIVE INDICATED VALUE is the highest (lowest) in this range

Note 1 to entry: The concept of EFFECTIVE RANGE ~~may~~ can, for example, also be applied to scale readings and to related quantities that are not directly indicated by the instrument, e.g. input current ~~(IEC 60731)~~. Its limits are the maximum and MINIMUM RATED VALUES.

Note 2 to entry: The EFFECTIVE RANGE of INDICATED VALUES is referred to as EFFECTIVE RANGE in this document.

3.10

FIELD-CLASS DOSE AREA PRODUCT METER

DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to make routine measurements

Note 1 to entry: DOSE AREA PRODUCT METERS built in or permanently connected to the diagnostic X-ray unit are normally field-class instruments, but can also be reference-class instruments.

~~3.14~~~~EXPANDED UNCERTAINTY~~

~~quantity defining the interval about the result of a measurement within which the values that could reasonably be attributed to the measurand may be expected to lie with a higher degree of confidence (IEC 60731)~~

3.11**FILTRATION**

modification of characteristics of ionizing RADIATION on passing through matter

Note 1 to entry: FILTRATION includes:

- modification of the energy spectrum of ionizing RADIATION by preferential absorption of components;
- modification of the spatial distribution of RADIATION intensity over the cross section of a RADIATION beam, by differential ATTENUATION.

3.12**HALF-VALUE LAYER**

thickness of a specified material which under NARROW BEAM CONDITIONS attenuates photon RADIATION according to its energy spectrum to an extent such that the AIR KERMA RATE is reduced to one half of the value that is measured without the material

3.13**INDICATED VALUE**

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

[SOURCE: IEC 60731:2011, 3.2]

3.14**INFLUENCE QUANTITY**

any external quantity that may affect the performance of an instrument (e.g. ambient temperature, RADIATION QUALITY etc.)

[SOURCE: IEC 60731:2011, 3.7, modified – addition of the parenthesis]

3.15**INSTRUMENT PARAMETER**

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

[SOURCE: IEC 60731:2011, 3.8]

~~3.17~~~~INTRINSIC ERROR~~

~~deviation of the MEASURED VALUE (i.e. the INDICATED VALUE, corrected to REFERENCE CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS (IEC 60731)~~

3.16**IONIZATION CHAMBER**

detector consisting of a chamber filled with a suitable medium, usually gaseous, in which an electric field, insufficient to induce charge multiplication, is provided for the collection at the electrodes of charges associated with ions and the electrons produced in the SENSITIVE VOLUME of the detector by ionizing RADIATION

~~NOTE For use with DOSE AREA PRODUCT METERS, IONIZATION CHAMBERS are constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere. Sealed chambers are not suitable for use with DOSE AREA PRODUCT METERS, 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.~~

3.17

IRRADIATION TIME

duration of irradiation determined according to specific methods, usually the time during which the rate of a RADIATION quantity exceeds a specified level

~~**3.20**~~

~~**LEAKAGE CURRENT**~~

~~any current in the signal path arising in the detector and/or MEASURING ASSEMBLY which is not produced by ionization in the IONIZATION CHAMBER~~

3.18

LIMITS OF VARIATION

maximum VARIATION of a PERFORMANCE CHARACTERISTIC, y , permitted by this document

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, modified – addition of " y , permitted by this document".]

3.19

LINEARITY

maximum VARIATION of the RESPONSE of an instrument within the EFFECTIVE RANGE of measurement quantity, permitted by this document

3.20

MANUFACTURER

organization or individual who produces an equipment

3.21

MEASURED VALUE

value of a physical quantity derived by applying all relevant corrections to an INDICATED VALUE

3.22

MEASURING ASSEMBLY

device to convert the output from the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR into a form suitable for the display of the value(s) of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE

3.23

MEDICAL RADIOLOGICAL EXAMINATION

medical examination using ~~effects of~~ ionizing RADIATION

3.24

MINIMUM RATED RANGE

least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this document

[SOURCE: IEC 60731:2011, 3.15.1, modified – addition of "in order to comply with this document".]

3.25

PATIENT

living being (person or animal) undergoing medical investigation or treatment

[SOURCE: IEC 60601-1:2005, 3.76, modified – replacement of "a medical, surgical or dental procedure" by "medical investigation or treatment"]

3.26**PERFORMANCE CHARACTERISTIC**

one of the quantities used to define the performance of an instrument (e.g. RESPONSE, RADIATION DETECTOR LEAKAGE CURRENT)

[SOURCE: IEC 60731:2011, 3.11, modified – modification of the example]

3.27**QUALITY EQUIVALENT FILTRATION**

~~quantity indicating for a material or an object the effect of its FILTRATION, expressed as the thickness of a particular reference material, whose FILTRATION is found to have the same effect on RADIATION QUALITY under specific conditions of measurement~~

quantitative indication of the FILTRATION effected by one or several layer(s) of reference material(s) which, if substituted in a beam of specified RADIATION QUALITY under NARROW BEAM CONDITION for the material or an object under consideration, give(s) the same RADIATION QUALITY as for the material under consideration

3.28**RADIATION DETECTOR**

equipment, generally sub-assembly, or substance which, in the presence of RADIATION, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of the incident RADIATION

3.29**RADIATION DETECTOR LEAKAGE CURRENT**

any current in the signal path arising in the RADIATION DETECTOR system which is not produced by ionizing RADIATION in the measuring volume

3.30**RADIATION QUALITY**

for a specific type of RADIATION, the description of any characteristic that depends on its energy spectrum

Note 1 to entry: For the purposes of this document, a practical approximation of RADIATION QUALITY is expressed as the quotient of the first HALF-VALUE LAYER and the second HALF-VALUE LAYER.

3.31**RATED FIELD SIZE**

size of the USEFUL BEAM at the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR within which the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR performs to its specification

3.32**RATED RANGE (of use)**

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.

Note 2 to entry: The EFFECTIVE RANGE of use is referred to as RATED RANGE in this document.

[SOURCE: IEC 60731:2011, 3.15, modified – Addition of the Note 2 to entry.]

3.33**REFERENCE CONDITIONS**

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

[SOURCE: IEC 60731:2011, 3.9.1]

3.34**REFERENCE-CLASS DOSE AREA PRODUCT METER**

DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to calibrate other DOSE AREA PRODUCT METERS or for higher-precision field use requirements

3.35**REFERENCE VALUE**

particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purpose 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]

3.35**RELATIVE INTRINSIC ERROR**

~~ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE (IEC 60731)~~

3.36**RESPONSE**

quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

[SOURCE: IEC 60731:2011, 3.11.1, modified – "ionization charge or current" was replaced by "indicated value".]

3.37**RESPONSE TIME**

the time taken for a scale 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, modified – "scale" was added to the definition.]

3.38**RESOLUTION OF THE DISPLAY**

smallest change of scale reading to which a numerical value can be assigned without further interpolation

Note 1 to entry: For an analogue display, the RESOLUTION is the smallest fraction of a scale interval that can be determined by an observer under specified conditions.

Note 2 to entry: For a digital display, the RESOLUTION is the smallest significant increment of the reading.

[SOURCE: IEC 60731:2011, 3.11.2, modified – Addition of new notes to entry.]

3.39**STABILITY CHECK DEVICE**

device, either separate or integral part of the DOSE AREA PRODUCT METER, which enables the stability of the RESPONSE of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and/or MEASURING ASSEMBLY to be checked

Note 1 to entry: The STABILITY CHECK DEVICE ~~may~~ can be a purely electrical device.

3.40**STABILIZATION TIME**

time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value, after the DOSE AREA PRODUCT METER has been switched on and after the polarizing voltage, if needed, has been applied to the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR (IEC 60731 modified)

3.41

STANDARD TEST CONDITIONS

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

[SOURCE: IEC 60731:2011, 3.10.1]

3.42

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]

3.43

TRUE VALUE

~~value of the physical quantity to be measured by an instrument (IEC 60731)~~

3.43

USEFUL BEAM

all X-rays which emerge through a cone defined by the focus point and the specified aperture of its PROTECTIVE SHIELDING or of its BEAM-LIMITING DEVICE

3.44

USEFUL FIELD

cross section of the USEFUL BEAM, perpendicular to its specified direction at a specified distance from the FOCAL SPOT or at a specified plane of measurement

3.45

VARIATION

relative difference, $\Delta y/y$, between the values of a PERFORMANCE CHARACTERISTIC, y , when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) successively assumes 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]

4 General requirements

4.1 Performance requirements

In Clauses 5 and 6 the performance requirements are stated for a complete DOSE AREA PRODUCT METER including both the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and MEASURING ASSEMBLY. For a DOSE AREA PRODUCT METER designed to operate with one or more ~~IONIZATION CHAMBERS~~ RADIATION DETECTORS, each combination of the MEASURING ASSEMBLY and ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall comply with the requirements in 4.6, and in Clauses 5 and 6 relevant to this combination.

4.2 Minimum EFFECTIVE RANGES of DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE

The minimum EFFECTIVE RANGES of DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE are listed in Tables 1 and 2.

Table 1 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1,0 - 1,0 \times 10^5) \mu\text{Gym}^2$
Long time fluoro	$(1,0 \times 10^1 - 1,0 \times 10^6) \mu\text{Gym}^2$
Paediatric procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^4) \mu\text{Gym}^2$

Table 2 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT RATE

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$
Paediatric procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}^a$
^a $(1,0 \times 10^{-2} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$ recommended	

4.3 Plane of measurement

The instrument shall be designed so as to indicate the DOSE AREA PRODUCT and/or the DOSE AREA PRODUCT RATE in the USEFUL BEAM for the plane in which the RADIATION is incident on the PATIENT, excluding, as far as practicable, the contribution of back-scattering to the MEASURED VALUE.

4.4 REFERENCE VALUES and STANDARD TEST CONDITIONS

These values are as given in Table 3.

Table 3 – REFERENCE VALUES and STANDARD TEST CONDITIONS

INFLUENCE QUANTITY	REFERENCE VALUES	STANDARD TEST CONDITIONS
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
Air pressure	101,3 kPa	Atmospheric pressure
DOSE AREA PRODUCT RATE ^a	As at CALIBRATION	REFERENCE VALUE ± 10 %
RADIATION QUALITY	100 kV (RQR 8, IEC 61267)	REFERENCE VALUE
IRRADIATION TIME	As at CALIBRATION	REFERENCE VALUE ± 10 %
Field size	As at CALIBRATION	REFERENCE VALUE
Electromagnetic fields	Zero	Insignificant ^b
^a DOSE AREA PRODUCT RATE is only an INFLUENCE QUANTITY for DOSE AREA PRODUCT MEASUREMENTS.		
^b Insignificant means that the field is sufficiently small not to have any determinable effect on the RESPONSE of the DOSE AREA PRODUCT METER, e.g. as exists in a normal laboratory environment without special shielding.		

4.5 General test conditions

4.5.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 3 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.

4.5.2 Test of components

The preferred procedure for verifying that the performance requirements are met is to test the components separately, in which case:

- tests on the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall be performed using a "high-precision" MEASURING ASSEMBLY;
- tests on the MEASURING ASSEMBLY shall be carried out using a "high-precision" current or charge source, as required, connected to the input.

In this context, "high precision" means that the PERFORMANCE CHARACTERISTICS of the test equipment shall be such that they perturb the value of the particular PERFORMANCE CHARACTERISTIC being measured by less than one-quarter of the LIMITS OF VARIATION.

Any tests may be carried out using the complete DOSE AREA PRODUCT METER; in particular, this is the preferred method for investigating the effects of high-frequency electromagnetic fields and electrostatic discharges on a cable-connected ~~IONIZATION CHAMBER~~ RADIATION DETECTOR supplied with a MEASURING ASSEMBLY as a system. Some tests performed with the whole system cannot give information as to whether the origin of the VARIATION lies in the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR or in the MEASURING ASSEMBLY (e.g. RADIATION DETECTOR LEAKAGE CURRENT and ZERO DRIFT). If a complete system is tested and the relevant INFLUENCE QUANTITY affects both parts, the quadratic sum of the separate LIMITS OF VARIATION may be taken as an overall LIMIT OF VARIATION.

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

4.5.4 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 RADIATION DETECTOR LEAKAGE CURRENT.

4.5.5 Uniformity of RADIATION field

The uniformity over the part of the USEFUL FIELD used for the compliance test shall be checked, for example, by scanning the RADIATION field with a small ~~IONIZATION CHAMBER~~ RADIATION DETECTOR compared with the size of the USEFUL FIELD. Appropriate corrections shall be made to ensure an uncertainty of the test results of not more than one-fifth of the LIMITS OF VARIATION under test.

NOTE The field uniformity of any X-RAY TUBE is subject to deterioration in use; regular checks ~~should therefore be~~ are made.

4.6 Statistical fluctuations

At low DOSE AREA PRODUCT and DOSE AREA PRODUCT 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 4 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 , and the COEFFICIENT OF VARIATION, v , of the sets of readings (assumed to be equal for each set) is listed.

Table 4 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings

Δ	Number of readings required, n							
	COEFFICIENT OF VARIATION, v							
	< 0,5 %	0,5 %	1 %	2 %	3 %	4 %	5 %	10 %
1 %	*	6	25	100	250	400	600	2 500
2 %	*	*	6	25	55	100	150	550
3 %	*	*	*	12	25	45	70	250
4 %	*	*	*	6	15	25	40	150
5 %	*	*	*	*	9	16	25	100
10 %	*	*	*	*	*	*	7	25

NOTE 1 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.

NOTE 2 For measurements marked * at least five repeated readings shall be taken.

4.7 Uncertainty of measurement

When measurements of VARIATION are made to verify that an equipment complies with specified LIMITS OF VARIATION, the COMBINED STANDARD 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 COMBINED STANDARD UNCERTAINTY of the measurement is less than one half of the LIMITS OF VARIATION, the COMBINED STANDARD 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 COMBINED STANDARD UNCERTAINTY to the LIMITS OF VARIATION allowed.

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

NOTE For the purposes of this document, the COMBINED STANDARD UNCERTAINTY may can be taken as the relative EXPANDED UNCERTAINTY expanded with a coverage factor of two.

4.8 Constructional requirements as related to performance

4.8.1 Display

4.8.1.1 Units

The SI unit of DOSE AREA PRODUCT is Gym^2 . The SI unit of DOSE AREA PRODUCT RATE is Gym^2/s . The indicated unit shall be that of the measuring quantity: DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE (i.e. Gym^2 or Gym^2/s , SI prefixes are allowed).

NOTE Units such as mGycm^2 or mGycm^2/s comply with SI rules.

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

4.8.1.2 Digital displays

DOSE AREA PRODUCT METERS shall have a digital display, which may be also realized by means of a digital interface. 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 concerning display shall be checked by inspection.

4.8.2 Indication of polarizing voltage failure

DOSE AREA PRODUCT METERS shall be provided with a means of indicating if the polarizing voltage, if needed, does not meet the MANUFACTURER's requirement for satisfactory operation.

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

4.8.3 Over-ranging

On all DOSE AREA PRODUCT RATE ranges, the DOSE AREA PRODUCT METER shall clearly indicate over-range when the full scale reading is exceeded.

Compliance shall be checked by increasing the DOSE AREA PRODUCT RATE slowly but continuously until the display shows over-range. An equivalent electrical test can be made on the MEASURING ASSEMBLY.

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

On all DOSE AREA PRODUCT ranges, the DOSE AREA PRODUCT METER shall clearly indicate over-range when the full scale reading is exceeded.

Compliance shall be checked on each DOSE AREA PRODUCT range by exposing the relevant DOSE AREA PRODUCT METER until the display reads just below the stated full scale. The irradiation should then be continued in DOSE AREA PRODUCT steps approximately equal to the RESOLUTION of the display for the range in use, until the display shows over-range. An equivalent electrical test can be made on the MEASURING ASSEMBLY.

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

4.8.4 Indication of reset or other inactive condition

During any period of time when the DOSE AREA PRODUCT METER is inactive, e.g. following the reset procedure, this state shall be indicated.

Compliance with this constructional requirement shall be checked by inspection.

4.8.5 ~~IONIZATION CHAMBER~~ RADIATION DETECTOR

The ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall be capable of being situated between the BEAM-LIMITING DEVICE and the PATIENT (see 4.3).

The SENSITIVE VOLUME of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall be capable of being positioned so that for VARIATIONS in the area of a uniform USEFUL FIELD the output current of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is proportional to the area of the USEFUL FIELD, all other conditions being constant.

If the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is specified for use with a light beam diaphragm, the transparency of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR to visible light shall be such as to transmit at least ~~70~~ 60 % of the luminous flux.

The presence of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall not displace ~~the~~ any edge of the indicated area in the plane of the exit surface of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR by more than 2 mm due to refraction or similar effects.

The QUALITY EQUIVALENT FILTRATION of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR shall not exceed 0,5 mm aluminium of a purity of not less than 99 %.

The QUALITY EQUIVALENT FILTRATION shall be marked in thickness of aluminium on the outside of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR.

~~The QUALITY EQUIVALENT FILTRATION shall be measured using an X-radiation generated by an X-RAY TUBE VOLTAGE of 70 kV, a PERCENTAGE RIPPLE not exceeding 10% and a TOTAL FILTRATION of 2 mm aluminium the RADIATION QUALITY RQR 5.~~

4.9 STABILITY CHECK DEVICE

The MEASURING ASSEMBLY shall contain a STABILITY CHECK DEVICE which can be brought into operation by a change-over switch and by means of which the user may check the electrical stability of the MEASURING ASSEMBLY in a simple manner.

The VARIATION in the output signal from the STABILITY CHECK DEVICE shall be less than ±2 %. On a digital display the mean value of the readings created by the STABILITY CHECK DEVICE shall be at least 50.

Compliance with this requirement shall be checked over the MINIMUM RATED RANGE of the INFLUENCE QUANTITIES: operating voltage, air pressure, temperature, relative humidity and electromagnetic compatibility, as listed in Table 5.

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

INFLUENCE QUANTITY	MINIMUM RATED RANGE	REFERENCE CONDITIONS	LIMITS OF VARIATION L	Sub-clause
RADIATION QUALITY	(50 – 150) kV, TOTAL FILTRATION 2,5 mm	100 kV, TOTAL FILTRATION 2,5 mm Al	±8 %	6.1
DOSE AREA PRODUCT RATE (in the case of DOSE AREA PRODUCT measurements)	(1,0 · 10 ⁻¹ – 1,5 · 10 ⁴) µGym ² /s Paediatric procedures: (1,0 · 10 ⁻² – 1,5 · 10 ⁴) µGym ² /s	As at calibration	±5 %	6.2.1
AIR KERMA RATE	As stated by the MANUFACTURER	As at calibration	10 %	6.2.2
IRRADIATION TIME	1 ms – 1 h	As at calibration	±5 %	6.3
Field size	As stated by the MANUFACTURER	As at calibration	±5 %	6.4
Operating voltage	-10% – +10%	Nominal voltage ^a	±2 %	6.5
Air pressure	80,0 – 106,0 kPa	101,3 kPa	±2 %	6.6
Temperature	+15 – +40 °C	+20 °C	±3 %	6.7
Relative humidity	≤ 80 % (maximum 20 g/m ³)	50 %		
Electromagnetic compatibility	As in IEC 61000-4	Without any disturbance	±5 % ^b	6.9
^a The nominal voltage need not be a single value but may be expressed as a range. ^b Of minimum EFFECTIVE DOSE AREA PRODUCT or minimum EFFECTIVE DOSE AREA PRODUCT RATE, respectively.				

INFLUENCE QUANTITY	MINIMUM RATED RANGE	REFERENCE CONDITIONS	LIMITS OF VARIATION <i>L</i>		SUB- CLAUSE
			REFERENCE- CLASS	FIELD- CLASS	
RADIATION QUALITY	50 kV to 150 kV RQR 3 to RQR 10 x IEC 61267	100 kV RQR 8 x IEC 61267	±8 %	±8 %	6.2
DOSE AREA PRODUCT RATE (in the case of DOSE AREA PRODUCT measurements)	($1,0 \times 10^{-1}$ to $1,5 \times 10^4$) $\mu\text{Gym}^2/\text{s}$ Paediatric procedures: ($1,0 \times 10^{-2}$ to $1,5 \times 10^4$) $\mu\text{Gym}^2/\text{s}$	As at CALIBRATION	±3 %	±5 %	6.3.1
AIR KERMA RATE	As stated by the MANUFACTURER	As at CALIBRATION	±5 %	±10 %	6.3.2
IRRADIATION TIME	1 ms to 1 h	As at CALIBRATION	±3 %	±5 %	6.4
Field size	As stated by the MANUFACTURER	As at CALIBRATION	±2 %	±5 %	6.5
Operating voltage	−10 % to +10 %	Nominal voltage ^a	±1 %	±2 %	6.6
Air pressure	80,0 kPa to 106,0 kPa	101,3 kPa	±1 %	±2 %	6.7
Temperature	+15 °C to +40 °C	+20 °C	±2 %	±3 %	6.8
Relative humidity	≤ 80 % (maximum 20 g/m ³)	50 %			
Electromagnetic compatibility	See 6.10	Without any disturbance	±1 % ^b	±5 % ^b	6.10
Drift of indicated values			±2 %	±10 %	5.8
Long term stability			±2 %	±5	5.9
Air density fluctuation, pressure ^c		As at CALIBRATION	±5 % ^b	±5 % ^b	6.9
Air density fluctuation, temperature ^c		As at CALIBRATION	±7,5 %	±7,5 % ^b	6.9

^a The nominal voltage need not be a single value but may be expressed as a range.

^b Of minimum EFFECTIVE DOSE AREA PRODUCT or minimum EFFECTIVE DOSE AREA PRODUCT RATE, respectively.

^c Devices may be calibrated at installation against local conditions.

4.10 Adjustment

A means of adjustment shall be provided so that the DOSE AREA PRODUCT for the plane in which the RADIATION is incident on the PATIENT can be indicated with the accuracy required by Clauses 5 and 6 in cases where absorbing materials are permanently present between the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and the PATIENT; e.g. the backboard of a fluoroscopic stand or the table top of an equipment with under-table X-RAY TUBE.

This adjustment shall be capable of being locked to prevent inadvertent or incompetent alteration and shall be described sufficiently in the ACCOMPANYING DOCUMENTS for a necessary adjustment to be correctly made.

4.11 Electrical safety

DOSE AREA PRODUCT METERS shall comply with IEC 60601-1 ~~and IEC 60601-1-1~~.

NOTE Connected peripheral devices (computers, printers) ~~must~~ shall comply with IEC 60601-1 if they are placed in the PATIENT ENVIRONMENT, otherwise they ~~must~~ shall comply with ~~IEC 60950~~ IEC 62368-1.

5 Limits of PERFORMANCE CHARACTERISTICS under STANDARD TEST CONDITIONS

5.1 RELATIVE INTRINSIC ERROR

~~The RELATIVE INTRINSIC ERROR, I , for DOSE AREA PRODUCT $K \cdot A$ and DOSE AREA PRODUCT RATE $\dot{K} \cdot A$ measurements made under STANDARD TEST CONDITIONS (as defined in Table 2) shall not exceed the values given in Table 4.~~

~~Compliance with this performance requirement shall be checked by exposing the IONIZATION CHAMBER in a radiation beam of reproducible geometry and field size. The RELATIVE INTRINSIC ERROR shall be measured for one or more points in each decade over the EFFECTIVE RANGE (i.e. the whole stated measurement range) of DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE and at the limits of the EFFECTIVE RANGE. If the DOSE AREA PRODUCT METER is designed to measure DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE, these measurements shall be performed in both operating modes. It is allowed to make an equivalent electrical test on the MEASURING ASSEMBLY and to compute recombination losses in the IONIZATION CHAMBER as described in 6.2.2.~~

~~For DOSE AREA PRODUCT measurements the average of at least five readings of the instrument shall be taken as the MEASURED VALUE. If the DOSE AREA PRODUCT RATE cannot be kept constant for all measurements over the EFFECTIVE RANGE of DOSE AREA PRODUCT, the different DOSE AREA PRODUCT ranges with different but constant DOSE AREA PRODUCT RATES shall overlap at their ends for at least one measurement point, to obtain CORRECTION FACTORS for those measurements with DOSE AREA PRODUCT RATES different from those stated for the STANDARD TEST CONDITIONS.~~

~~For DOSE AREA PRODUCT RATE measurements the average of at least 10 readings of the instrument shall be taken as the MEASURED VALUE. For ranges of DOSE AREA PRODUCT RATES which cannot be produced under STANDARD TEST CONDITIONS, other RADIATION QUALITIES may be used. These DOSE AREA PRODUCT RATE ranges shall overlap at least at one measurement point with the range under STANDARD TEST CONDITIONS, to obtain CORRECTION FACTORS for those measurements with RADIATION QUALITIES different from the STANDARD TEST CONDITIONS.~~

Table 4 — RELATIVE INTRINSIC ERROR, I

Quantity	Range of measurement	RELATIVE INTRINSIC ERROR, I
DOSE AREA PRODUCT, $K \cdot A$	$K \cdot A < 10,0 \mu\text{Gym}^2$ $K \cdot A \geq 10,0 \mu\text{Gym}^2$	$I = \pm (10 \% + 1 \text{ digit})$ $I = \pm 10 \%$
DOSE AREA PRODUCT RATE, $\dot{K} \cdot A$	$\dot{K} \cdot A < 1,0 \mu\text{Gym}^2/\text{s}$ $\dot{K} \cdot A \geq 1,0 \mu\text{Gym}^2/\text{s}$	$I = \pm (10 \% + 1 \text{ digit})$ $I = \pm 10 \%$

5.1 Classification of DOSE AREA PRODUCT METERS according to LIMITS OF VARIATION

5.1.1 REFERENCE-CLASS DOSE AREA PRODUCT METERS

A DOSE AREA PRODUCT METER may be classified as REFERENCE-CLASS if the performance requirements listed in Table 5 Column 4 are met.

5.1.2 FIELD-CLASS DOSE AREA PRODUCT METERS

A DOSE AREA PRODUCT METER shall be classified as FIELD-CLASS if the performance requirements listed in Table 5 Column 5 are met.

5.2 LINEARITY

For DOSE AREA PRODUCT RATE measurements, the Equation (1) shall be fulfilled over the whole RATED RANGE OF DOSE AREA PRODUCT RATE.

$$\frac{R_{\max} - R_{\min}}{R_{\max} + R_{\min}} \leq a \quad (1)$$

where

R_{\max} is the maximum RESPONSE over the RATED RANGE of DOSE AREA PRODUCT RATE, and

R_{\min} is the minimum RESPONSE,

$a = 0,03$ for REFERENCE CLASS DOSE AREA PRODUCT METERS, and

$a = 0,05$ for FIELD CLASS DOSE AREA PRODUCT METERS.

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

5.3 Warning function

If the instrument features a warning function such as graphical or audible level settings, the warning function ~~should have~~ shall be activated when a DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE is reached that corresponds to the ~~same RELATIVE INTRINSIC ERROR as the device~~ set level within $\pm 10\%$. The warning function ~~must~~ shall be activated within 3 s after the level setting is reached.

Compliance with this ~~constructional~~ requirement shall be checked by setting levels at one or more points in each decade over the EFFECTIVE RANGE of DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE and at the limits of the EFFECTIVE RANGE. On DOSE AREA PRODUCT ranges a constant input signal shall be applied. The warning function shall be activated when a DOSE AREA PRODUCT is reached that corresponds to the set level within $\pm 10\%$. On DOSE AREA PRODUCT RATE ranges an increasing input signal shall be applied. The warning function shall be activated when a DOSE AREA PRODUCT RATE is reached that corresponds to the set level within $\pm 10\%$. Then the input signal shall be decreased; the warning function shall be inactivated when a DOSE AREA PRODUCT RATE is reached that corresponds to the set level within $\pm 10\%$. It is allowed that the warning function is activated/deactivated with a delay of up to 3 s.

5.4 Repeatability

When a measurement is repeated with the same DOSE AREA PRODUCT METER under unaltered conditions, the COEFFICIENT OF VARIATION of the measurement shall not exceed the maximum value given in Table 6.

Compliance with this performance requirement shall be checked by measuring the COEFFICIENT OF VARIATION for a DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE which corresponds approximately to a reading with a RESOLUTION of at least 0,25 %.

Table 6 – Maximum values for the COEFFICIENT OF VARIATION, V_{\max}

Quantity	Range of measurement	Maximum COEFFICIENT OF VARIATION V_{\max}
DOSE AREA PRODUCT, $K \cdot A$	$K \cdot A < 10,0 \mu\text{Gym}^2$	5 %
	$K \cdot A \geq 10,0 \mu\text{Gym}^2$	2 %
DOSE AREA PRODUCT RATE, $\dot{K} \cdot A$	$\dot{K} \cdot A < 1,0 \mu\text{Gym}^2/\text{s}$	5 %
	$\dot{K} \cdot A \geq 1,0 \mu\text{Gym}^2/\text{s}$	2 %

5.5 RESOLUTION of reading

Within the whole EFFECTIVE RANGE OF INDICATED VALUES the RESOLUTION of the reading shall be less than or equal to 10 %.

Compliance with this performance requirement shall be checked by inspection.

5.6 STABILIZATION TIME

The STABILIZATION TIME as stated by the MANUFACTURER shall not exceed 15 min.

5.7 Reset on DOSE AREA PRODUCT ranges

On all DOSE AREA PRODUCT ranges, after resetting the DOSE AREA PRODUCT METER once, the reading shall not be greater than the RESOLUTION of the reading.

Compliance with this performance requirement shall be checked on each DOSE AREA PRODUCT range by obtaining a near full scale reading, either by exposing a suitable ~~IONIZATION CHAMBER~~ RADIATION DETECTOR, or by injecting an equivalent electrical signal, then resetting the DOSE AREA PRODUCT METER once and noting the residual reading.

5.8 Drift of INDICATED VALUES

During absence of RADIATION, and after resetting the DOSE AREA PRODUCT METER, the INDICATED VALUE shall be less than 10 % of the minimum EFFECTIVE DOSE AREA PRODUCT for at least 1 h.

Compliance with this performance requirement shall be checked by noting the reading in the most sensitive range 15 min, 30 min, 45 min and 1 h after the DOSE AREA PRODUCT METER has been reset, and with no resetting or compensation adjustment during the test. If the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

On all DOSE AREA PRODUCT ranges, when the DOSE AREA PRODUCT METER is left in the ~~"measure" condition~~ measurement mode after being exposed to the minimum EFFECTIVE DOSE AREA PRODUCT the INDICATED VALUE shall not change by more than 10 % per hour.

Compliance with this performance requirement shall be checked for each allowable combination of DOSE AREA PRODUCT range and ~~IONIZATION CHAMBER~~ RADIATION DETECTOR, by exposing the relevant ~~IONIZATION CHAMBER~~ RADIATION DETECTOR until the display reads just above the stated minimum EFFECTIVE DOSE AREA PRODUCT, then stopping the exposure and noting the rate of change of scale reading whilst keeping the DOSE AREA PRODUCT METER in the ~~"measure" condition~~ measurement mode. If the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the

REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

The RADIATION DETECTOR LEAKAGE CURRENT of a DOSE AREA PRODUCT METER shall not exceed 10 % of the current produced by the MINIMUM RATED DOSE AREA PRODUCT RATE.

Compliance with this performance requirement shall be checked by exposing the DOSE AREA PRODUCT METER with the MINIMUM RATED DOSE AREA PRODUCT RATE until the display reads just above the minimum EFFECTIVE DOSE AREA PRODUCT. The INDICATED VALUE shall be within ± 10 % of the CONVENTIONAL TRUE VALUE. If the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

On all DOSE AREA PRODUCT RATE ranges, the RADIATION DETECTOR LEAKAGE CURRENT of a DOSE AREA PRODUCT METER shall not exceed 10 % of the current produced by the minimum EFFECTIVE DOSE AREA PRODUCT RATE of the range in use, after any compensation adjustment has been made.

Compliance with this performance requirement shall be checked by exposing the DOSE AREA PRODUCT METER with the minimum EFFECTIVE DOSE AREA PRODUCT RATE. If the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test. A current source may be used parallel to the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR to provide for an appropriate test current.

5.9 Long term stability

For all RADIATION QUALITIES within the RATED RANGE, the LIMITS OF VARIATION of RESPONSE when the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR is irradiated in a reproducible field shall not be greater than ~~± 5 % per year~~

- $\pm 2,0$ % over 1 year, for a REFERENCE-CLASS DOSE AREA PRODUCT METER,
- $\pm 5,0$ % over 1 year, for a FIELD-CLASS DOSE AREA PRODUCT METER.

Compliance with this performance requirement shall be checked by retaining a representative MEASURING ASSEMBLY and ~~IONIZATION CHAMBER~~ RADIATION DETECTOR, stored under STANDARD TEST CONDITIONS, and investigating their 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 ASSEMBLY and ~~IONIZATION CHAMBER~~ RADIATION DETECTOR separately.

5.10 RESPONSE TIME

An INDICATED VALUE of 90 % of the final INDICATED VALUE shall be reached within a time not greater than 3 s after the end of the irradiation.

Compliance with this performance requirement shall be checked exposing the DOSE AREA PRODUCT METER with a DOSE AREA PRODUCT just above the minimum EFFECTIVE INDICATED VALUE and just below the maximum EFFECTIVE INDICATED VALUE for a period of 1 ms. On DOSE AREA PRODUCT RATE ranges, the corresponding DOSE AREA PRODUCT RATES shall be applied suddenly, and kept constant for at least 10 s.

5.11 Spatial uniformity of RESPONSE

Over the RATED FIELD SIZE the spatial uniformity of RESPONSE shall not vary by more than $\pm 5\%$.

Compliance with this performance requirement shall be checked by displacing the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR in a small test field until the RATED FIELD SIZE is covered. The test field shall be a square or circular field with an area of approximately ~~10 %~~ of the MINIMUM RATED FIELD SIZE.

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 summarised in Table 5. For any change of an INFLUENCE QUANTITY within its RATED RANGE the change of the DOSE AREA PRODUCT METER'S RESPONSE shall not be greater than the values in Table 5, Column 4 or 5 dependent on the classification of the DOSE AREA PRODUCT METER.

6.2 Energy dependence of RESPONSE

Over the RATED RANGE, 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 instrument's RESPONSE with RADIATION QUALITY shall be measured under the same irradiation conditions as for CALIBRATION. The X-RAY TUBE VOLTAGE listed below shall be used as a minimum. Additional X-RAY TUBE VOLTAGE shall be used to cover the entire RATED RANGE:

- 50 kV, 70 kV, 100 kV, 150 kV X-RAY TUBE VOLTAGE, ~~with a TOTAL FILTRATION of 2,5 mm aluminium~~ RQR 3, RQR 5, RQR 8, RQR 10 x IEC 61267.

6.3 DOSE AREA PRODUCT RATE dependence of DOSE AREA PRODUCT measurements

6.3.1 MEASURING ASSEMBLY

For DOSE AREA PRODUCT measurements the Equation (2) shall be fulfilled over the whole RATED RANGE of DOSE AREA PRODUCT RATE.

$$\frac{R_{\max} - R_{\min}}{R_{\max} + R_{\min}} \leq a \quad (2)$$

where

R_{\max} is the maximum RESPONSE over the RATED RANGE of DOSE AREA PRODUCT RATE and

R_{\min} is the minimum RESPONSE,

$a = 0,03$ for REFERENCE CLASS INSTRUMENTS, and

$a = 0,05$ for FIELD CLASS INSTRUMENTS.

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

6.3.2 IONIZATION CHAMBER – Recombination losses

For the maximum RATED AIR KERMA RATE, the ion collection efficiency of the IONIZATION CHAMBER shall be at least 90 % when the normal polarizing voltage is applied.

NOTE No CORRECTION FACTOR for recombination losses has to be applied, as long as the IONIZATION CHAMBER is used within its RATED RANGE of AIR KERMA RATE.

Compliance with this performance requirement shall be checked by computing the CORRECTION FACTOR for the maximum RATED AIR KERMA RATE [1]²:

$$k_s = 1 + 2,4 \dot{K}_{\max} d^4 / U^2$$

where

\dot{K}_{\max} is the maximum RATED AIR KERMA RATE as stated by the MANUFACTURER, given in Gy/s;

d is the electrode distance of the plane-parallel IONIZATION CHAMBER, given in mm;

U is the nominal polarizing voltage of the IONIZATION CHAMBER, given in V.

To comply with the performance requirement, k_s ~~must~~ shall be less than or equal to ~~1,11~~ 1,10.

6.4 IRRADIATION TIME

Over the RATED RANGE, the LIMITS OF VARIATION of RESPONSE with changes in IRRADIATION TIME shall not be greater than those given in Table 5.

Compliance with this performance requirement shall be checked by varying the IRRADIATION TIME for a given DOSE AREA PRODUCT from 1 ms to 30 s, the ratios between the IRRADIATION TIMES being not greater than 10:1. It is allowed to make an equivalent electrical test on the MEASURING ASSEMBLY.

6.5 Field size

Over the RATED RANGE, the LIMITS OF VARIATION of RESPONSE with changes in field size shall not be greater than those given in Table 5.

Compliance with this performance requirement shall be checked by measuring the VARIATION in RESPONSE with the field size for three square or circular field sizes. These shall be the maximum and the minimum RATED FIELD SIZES, as well as a field size defined by the average of the areas of the former field sizes. Any convenient AIR KERMA RATE may be used.

6.6 Operating voltage

The LIMIT OF VARIATION of RESPONSE due to VARIATION of the operating voltage between +10 % and –10 % of the nominal voltage shall not be greater than the limit stated in Table 5, over the RATED RANGE of mains voltage as stated by the MANUFACTURER.

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

6.7 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. It is permissible for the MEASURED VALUE to be

² Figures in square brackets refer to the bibliography.

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. All readings shall be corrected for air density before this comparison is made.

6.8 Temperature and humidity

The LIMITS OF VARIATION of the DOSE AREA PRODUCT METER'S RESPONSE shall not be greater than the values 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/m³). 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 DOSE AREA PRODUCT METER shall be exposed to varying levels of temperature and air humidity. The measurements may be carried out separately for the MEASURING ASSEMBLY and for the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR. At least four measurements shall be performed, one under each of the climatic conditions described in Table 7.

Table 7 – Climatic conditions

Temperature °C	Relative humidity %	Absolute humidity g/m ³
20	50	8,5
15	80	11,5
26,5	80	20,0
35	50	20,0

All readings shall be corrected for air density before this comparison is made. The DOSE AREA PRODUCT METER 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 Air density fluctuation in the IONIZATION CHAMBER

It is allowed that a DOSE AREA PRODUCT METER does not automatically correct for air density fluctuation in the IONIZATION CHAMBER. The DOSE AREA PRODUCT METER shall be designed in a way that the COMBINED STANDARD UNCERTAINTY stated in 6.11 is not exceeded, including effects of air density fluctuations within the RATED RANGE of temperature and air pressure. The REFERENCE VALUE for the air temperature in the IONIZATION CHAMBER may differ from the value given in Table 3.

Compliance with this requirement shall be checked as described in 6.11.

6.10 Electromagnetic compatibility

6.10.1 General

DOSE AREA PRODUCT METERS shall comply with IEC 60601-1-2. Requirements specific to DOSE AREA PRODUCT METERS are outlined in the following subclauses. Clinical utility is maintained if the LIMITS OF VARIATION given in Table 5 are not exceeded.

In order to reduce the number of test points, the compliance tests described in the following subclauses may be used instead of the corresponding tests described in IEC 60601-1-2.

NOTE 1 "Complete equipment" means the MEASURING ASSEMBLY connected to an IONIZATION CHAMBER of a type customarily supplied with the MEASURING ASSEMBLY.

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

6.10.2 Electrostatic discharge

The maximum spurious indications 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 ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and MEASURING ASSEMBLY that are normally exposed in the RADIATION beam), when the instrument is set to the ~~"measure" condition~~ measurement mode 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.

6.10.3 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 DOSE AREA PRODUCT METER set to the most sensitive range (if the ranges are selectable), while measurements are performed both with and without the presence of the high-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 MHz, 90 MHz, 100 MHz, 110 MHz, 120 MHz, 130 MHz, 140 MHz, 150 MHz, 160 MHz, 180 MHz, 200 MHz, 220 MHz, 240 MHz, 260 MHz, 290 MHz, 320 MHz, 350 MHz, 380 MHz, 420 MHz, 460 MHz, 510 MHz, 560 MHz, 620 MHz, 680 MHz, 750 MHz, 820 MHz, 900 MHz and 1 000 MHz with a field strength of 10 V/m may be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in Table 5 is observed at one of these given frequencies, additional tests in the range of ± 5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the DOSE AREA PRODUCT METER in all three orientations as described in IEC 61000-4-3. For battery-operated instruments, for which the requirements of 6.10.3 and 6.10.4 do not apply, tests at 27 MHz shall also be performed.

6.10.4 Conducted disturbances induced by bursts and high frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to conducted disturbances induced by bursts and high 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 high-frequency fields (IEC 61000-4-6). The severity level shall, in both cases, be level 3 as described in these documents.

6.10.5 Surges

The maximum spurious indications (both transient and permanent) of the display or data output due to surges shall be less than the limits in Table 5. The test is not to be performed on the connection lines between the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and the MEASURING ASSEMBLY.

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 disturbances induced by surges (IEC 61000-4-5). The severity level shall be level 3 as described in this document.

6.10.6 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.

6.11 COMBINED STANDARD UNCERTAINTY

The DOSE AREA PRODUCT METER shall be designed in a way that a COMBINED STANDARD UNCERTAINTY of

- $\pm 15\%$ ($k = 2$) for a REFERENCE-CLASS DOSE AREA PRODUCT METER, and
- $\pm 25\%$ ($k = 2$) for a FIELD-CLASS DOSE AREA PRODUCT METER

is not exceeded. The uncertainty of the CALIBRATION coefficient shall be included.

The formalism given in ~~IEC 60731~~ GUM shall be used to determine the COMBINED STANDARD UNCERTAINTY. Examples are given in ~~Table 7~~ Tables 8 and 9.

Table 7 — Example for assessment of the COMBINED STANDARD UNCERTAINTY

INFLUENCE QUANTITY OF PERFORMANCE CHARACTERISTIC	Clause	$\pm L$ %	Relative uncertainty %
RADIATION QUALITY ^a	6.1	8	4,6
DOSE AREA PRODUCT RATE ^a	6.2.1	5	2,9
AIR KERMA RATE ^b	6.2.2	10	2,9
IRRADIATION TIME ^a	6.3	5	2,9
Field size ^a	6.4	5	2,9
Operating voltage ^a	6.5	2	1,2
Air pressure ^a	6.6	2	1,2
Temperature and relative humidity ^a	6.7	3	1,7
Electromagnetic compatibility ^a	6.9	5	2,9
Drift of INDICATED VALUES ^a	5.7	10	5,8
Uncorrected air density fluctuation in IONIZATION CHAMBER, air pressure ^{a,c}	6.8	4,8	2,8
Uncorrected air density fluctuation in IONIZATION CHAMBER, air temperature ^{a,d}	6.8	7,6	4,4
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k=1$ ^e			11,4
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k=2$ ^f			22,8
RELATIVE INTRINSIC ERROR, $k=2$	5.4		10,0
COMBINED STANDARD UNCERTAINTY, $k=2$ ^g			24,9

^a uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$

^b uniform probability distribution, limits ranging from 0 to L , i.e. relative uncertainty = $L/\sqrt{12}$

^c RATED RANGE of air pressure (96,7 — 106) kPa, REFERENCE VALUE 101,3 kPa

^d RATED RANGE of air temperature (15 — 60) °C, REFERENCE VALUE 37 °C

^e root-mean-square of relative uncertainties

^f root-mean-square of relative uncertainties, multiplied by 2

^g root-mean-square of COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS ($k=2$) and RELATIVE INTRINSIC ERROR

**Table 8 – Example for assessment of the COMBINED STANDARD UNCERTAINTY –
FIELD-CLASS DOSE AREA PRODUCT METER**

INFLUENCE QUANTITY OR PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
RADIATION QUALITY ^a	6.2	8	4,6
DOSE AREA PRODUCT RATE ^a	6.3.1	5	2,9
AIR KERMA RATE ^b	6.3.2	10	2,9
IRRADIATION TIME ^a	6.4	5	2,9
Field size ^a	6.5	5	2,9
Operating voltage ^a	6.6	2	1,2
Air pressure ^a	6.7	2	1,2
Temperature and relative humidity ^a	6.8	3	1,7
Electromagnetic compatibility ^a	6.10	5	2,9
Drift of INDICATED VALUES ^a	5.8	10	5,8
Uncorrected air density fluctuation, air pressure ^{a c}	6.9	4,6	2,7
Uncorrected air density fluctuation, air temperature ^{a d}	6.9	7,3	4,2
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 1$ ^e			11,3
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 2$ ^f			23
CALIBRATION		5	2,9
COMBINED STANDARD UNCERTAINTY, $k = 2$			23

^a uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$

^b uniform probability distribution, limits ranging from 0 to L , i.e. relative uncertainty = $L/\sqrt{12}$

^c assumed range of air pressure (96,7 to 106) kPa, REFERENCE VALUE 101,3 kPa

^d assumed range of air temperature (15 to 60) °C, REFERENCE VALUE 37 °C

^e root-mean-square of relative uncertainties

^f root-mean-square of relative uncertainties, multiplied by 2

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**Table 9 – Example for assessment of the COMBINED STANDARD UNCERTAINTY –
REFERENCE-CLASS DOSE AREA PRODUCT METER**

INFLUENCE QUANTITY OR PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
RADIATION QUALITY ^a	6.2	8	4,6
DOSE AREA PRODUCT RATE ^a	6.3.1	3	1,7
AIR KERMA RATE ^b	6.3.2	5	1,4
IRRADIATION TIME ^a	6.4	3	1,7
Field size ^a	6.5	2	1,2
Operating voltage ^a	6.6	1	0,6
Air pressure ^a	6.7	1	0,6
Temperature and relative humidity ^a	6.8	2	1,2
Electromagnetic compatibility ^a	6.10	1	0,6
Drift of INDICATED VALUES ^a	5.8	2	1,2
Uncorrected air density fluctuation, air pressure ^{a c}	6.9	4,6	2,7
Uncorrected air density fluctuation, air temperature ^{a d}	6.9	5,1	2,9
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 1$ ^e			7,1
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 2$ ^f			14
CALIBRATION		5	2,9
COMBINED STANDARD UNCERTAINTY, $k = 2$			15

^a uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$
^b uniform probability distribution, limits ranging from 0 to L , i.e. relative uncertainty = $L/\sqrt{12}$
^c assumed range of air pressure (96,7 to 106) kPa, REFERENCE VALUE 101,3 kPa
^d assumed range of air temperature (15 to 45) °C, REFERENCE VALUE 20 °C
^e root-mean-square of relative uncertainties
^f root-mean-square of relative uncertainties, multiplied by 2

7 Marking

7.1 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 document;
- type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognised;
- 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.

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

Compliance shall be checked by inspection.

7.2 ~~IONIZATION CHAMBER~~ RADIATION DETECTOR

The ~~IONIZATION CHAMBER~~ RADIATION 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 ~~IONIZATION CHAMBER~~ RADIATION DETECTOR complies with this document;
- type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognised;
- QUALITY EQUIVALENT FILTRATION of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR;
- RATED RANGE of RADIATION QUALITIES.

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 DOSE AREA PRODUCT METER, including its type number and MANUFACTURER. In addition the ACCOMPANYING DOCUMENTS shall contain the following information applicable to each type of ~~IONIZATION CHAMBER~~ RADIATION DETECTOR supplied:

- intended use of the DOSE AREA PRODUCT METER, e.g. standard procedures, paediatric procedures;
- RATED RANGE of use for RADIATION QUALITY;
- data giving typical dependence of RESPONSE on RADIATION QUALITY;
- reference direction of incident RADIATION;
- maximum RATED DOSE AREA PRODUCT;
- a warning that, on DOSE AREA PRODUCT ranges, maximum RATED DOSE AREA PRODUCT RATE should not be exceeded;
- 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;
- RATED RANGE of use for field size;
- RATED RANGE of use for AIR KERMA RATE at the position of the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR;
- for IONIZATION CHAMBER
 - nominal polarizing voltage of the IONIZATION CHAMBER;
 - electrode distance of the IONIZATION CHAMBER;
 - table, diagram or formula for air density correction (if required);
- table or formula for VARIATION of check indication or check time, as a result of decreased activity of radioactive source (if necessary);

- the procedure by which the INDICATED VALUE of the instrument can be checked by means of the STABILITY CHECK DEVICE and, where necessary, the procedure for adjustment of the sensitivity of the instrument to a specified scale reading;
- a recommendation that the stability check should be carried out at intervals not longer than one month;
- the procedure used to determine the drift of INDICATED VALUES, and the maximum permissible value of the drift of INDICATED VALUES when determined in this manner;
- the procedure by which an overall check of the CALIBRATION of the instrument can be made;
- a recommendation that the overall check should be made at intervals not longer than every two years and in any case following a repair which might have affected the CALIBRATION;
- the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR under test should be calibrated either with or without an absorber, and the user should be referred in the ACCOMPANYING DOCUMENTS to any correction that might be necessary to allow for local conditions;
- when a DOSE AREA PRODUCT METER is calibrated and it is not known whether an absorber will be used, the MANUFACTURER should carry out calibrations, both with and without an absorber of 0,5 mm aluminium, as a type test on a number of ~~IONIZATION CHAMBERS~~ RADIATION DETECTOR; results of a typical CALIBRATION should be given in the ACCOMPANYING DOCUMENTS;
- the procedure of adjustment of the INDICATED VALUE to the presence or absence of absorbers between the ~~IONIZATION CHAMBER~~ RADIATION DETECTOR and the PATIENT.

Compliance shall be checked by inspection.

The MANUFACTURER shall state the REFERENCE VALUES and STANDARD TEST VALUES in the ACCOMPANYING DOCUMENTS or in the test sheets.

Compliance shall be checked by inspection.

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Dose area product meters

Appareils électromédicaux – Radiamètres de produit exposition-surface

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –
DOSE AREA PRODUCT METERS**

FOREWORD

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International Standard IEC 60850 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published 2000, and constitutes a technical revision.

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

- a) a second class of devices is introduced with tighter uncertainty tolerances;
- b) this document has been expanded to include detectors other than ionization chambers;
- c) radiation qualities have been updated to the new definitions according to IEC 61267;
- d) a requirement on the linearity of the dose area product rate measurement was added;
- e) changed chamber light transmission requirement from 70 % to 60 %.

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

FDIS	Report on voting
62C/744/FDIS	62C/751/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: small roman type;
- *test specifications: italic type*;
- TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 3 OR LISTED IN THE INDEX: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

Diagnostic radiology is the largest contributor to man-made ionizing radiation to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS or procedures has therefore become a central issue in recent years. The purpose of routine measurement of DOSE AREA PRODUCT is to help in achieving an overall reduction in the radiation received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS. Provided adequate records are kept, it is possible to determine PATIENT doses, to compare different examination techniques, to establish a technique giving minimum RADIATION to a PATIENT, and to ensure a maintenance of that technique; in this respect, such measurements have a place of particular importance in training establishments. Examination of records may also indicate a deterioration in the efficiency of the image-production system.

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MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

1 Scope

This document specifies the performance and testing of DOSE AREA PRODUCT METERS intended to measure DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE to which the PATIENT is exposed during MEDICAL RADIOLOGICAL EXAMINATIONS.

This document is applicable to the following types of DOSE AREA PRODUCT METERS:

- a) FIELD-CLASS DOSE AREA PRODUCT METERS normally used for the measurement of DOSE AREA PRODUCTS during MEDICAL RADIOLOGICAL EXAMINATIONS;
- b) REFERENCE-CLASS DOSE AREA PRODUCT METERS normally used for the CALIBRATION of FIELD-CLASS DOSIMETERS.

NOTE REFERENCE-CLASS DOSE AREA PRODUCT METERS can be used as FIELD-CLASS DOSE AREA PRODUCT METERS.

The object of this document is

- 1) to establish requirements for a satisfactory level of performance for DOSE AREA PRODUCT METERS, and
- 2) to standardize the methods for the determination of compliance with this level of performance.

Two levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSE AREA PRODUCT METERS;
- a higher level of performance applying to REFERENCE-CLASS DOSE AREA PRODUCT METERS.

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

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

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

IEC 62368-1, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

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 61000-4-5, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge 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, *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 60601-1:2005, IEC TR 60788:2004 and the following apply.

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

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

NOTE 1 An index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch.

3.1

ACCOMPANYING DOCUMENT

document provided with an installation, equipment, associated equipment or accessory, containing important information for the assembler, installer and user, particularly regarding safety

3.2

AIR KERMA

K

quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Note 1 to entry: Unit: $J\ kg^{-1}$.

Note 2 to entry: The special name for the unit of AIR KERMA is gray (Gy) (ICRU 85A).

3.3**AIR KERMA RATE** \dot{K}

quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt , thus

$$\dot{K} = \frac{dK}{dt}$$

Note 1 to entry: Unit: $\text{J kg}^{-1} \text{s}^{-1}$.

Note 2 to entry: The special name for the unit of AIR KERMA rate is gray per second (Gy s^{-1}) (ICRU 85A).

3.4**COEFFICIENT OF VARIATION**

standard deviation of a set of readings expressed as a percentage of the mean value of these readings

3.5**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]

3.6**DOSE AREA PRODUCT** $K \cdot A$

product of the area of the USEFUL BEAM and the AIR KERMA over the cross-section of the USEFUL BEAM, both quantities being measured at the same distance from the FOCAL SPOT

Note 1 to entry: The unit of DOSE AREA PRODUCT is Gym^2 .

3.7**DOSE AREA PRODUCT METER**

equipment for the measurement of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE in the beam of an X-ray machine used for diagnostic MEDICAL RADIOLOGICAL EXAMINATIONS

Note 1 to entry: A DOSE AREA PRODUCT METER contains the following components:

- RADIATION DETECTOR;
- MEASURING ASSEMBLY;
- STABILITY CHECK DEVICE.

3.8**DOSE AREA PRODUCT RATE** $\dot{K} \cdot A$

quotient of an increment of DOSE AREA PRODUCT by the corresponding increment of time

Note 1 to entry: The unit of DOSE AREA PRODUCT RATE is Gym^2/s .

3.9**EFFECTIVE RANGE (of INDICATED VALUES)**

range of INDICATED VALUES for which an instrument complies with a stated performance; the maximum (minimum) EFFECTIVE INDICATED VALUE is the highest (lowest) in this range

Note 1 to entry: The concept of EFFECTIVE RANGE can, for example, also be applied to scale readings and to related quantities that are not directly indicated by the instrument, e.g. input current. Its limits are the maximum and MINIMUM RATED VALUES.

Note 2 to entry: The EFFECTIVE RANGE of INDICATED VALUES is referred to as EFFECTIVE RANGE in this document.

3.10**FIELD-CLASS DOSE AREA PRODUCT METER**

DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to make routine measurements

Note 1 to entry: DOSE AREA PRODUCT METERS built in or permanently connected to the diagnostic X-ray unit are normally field-class instruments, but can also be reference-class instruments.

3.11**FILTRATION**

modification of characteristics of ionizing RADIATION on passing through matter

Note 1 to entry: FILTRATION includes:

- modification of the energy spectrum of ionizing RADIATION by preferential absorption of components;
- modification of the spatial distribution of RADIATION intensity over the cross section of a RADIATION beam, by differential ATTENUATION.

3.12**HALF-VALUE LAYER**

thickness of a specified material which under NARROW BEAM CONDITIONS attenuates photon RADIATION according to its energy spectrum to an extent such that the AIR KERMA RATE is reduced to one half of the value that is measured without the material

3.13**INDICATED VALUE**

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

[SOURCE: IEC 60731:2011, 3.2]

3.14**INFLUENCE QUANTITY**

any external quantity that may affect the performance of an instrument (e.g. ambient temperature, RADIATION QUALITY etc.)

[SOURCE: IEC 60731:2011, 3.7, modified – addition of the parenthesis]

3.15**INSTRUMENT PARAMETER**

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

[SOURCE: IEC 60731:2011, 3.8]

3.16**IONIZATION CHAMBER**

detector consisting of a chamber filled with a suitable medium, usually gaseous, in which an electric field, insufficient to induce charge multiplication, is provided for the collection at the electrodes of charges associated with ions and the electrons produced in the SENSITIVE VOLUME of the detector by ionizing RADIATION

3.17**IRRADIATION TIME**

duration of irradiation determined according to specific methods, usually the time during which the rate of a RADIATION quantity exceeds a specified level

3.18**LIMITS OF VARIATION**

maximum VARIATION of a PERFORMANCE CHARACTERISTIC, y , permitted by this document

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

[SOURCE: IEC 60731:2011, 3.13, modified – addition of " y , permitted by this document".]

3.19

LINEARITY

maximum VARIATION of the RESPONSE of an instrument within the EFFECTIVE RANGE of measurement quantity, permitted by this document

3.20

MANUFACTURER

organization or individual who produces an equipment

3.21

MEASURED VALUE

value of a physical quantity derived by applying all relevant corrections to an INDICATED VALUE

3.22

MEASURING ASSEMBLY

device to convert the output from the RADIATION DETECTOR into a form suitable for the display of the value(s) of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE

3.23

MEDICAL RADIOLOGICAL EXAMINATION

medical examination using ionizing RADIATION

3.24

MINIMUM RATED RANGE

least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this document

[SOURCE: IEC 60731:2011, 3.15.1, modified – addition of "in order to comply with this document".]

3.25

PATIENT

living being (person or animal) undergoing medical investigation or treatment

[SOURCE: IEC 60601-1:2005, 3.76, modified – replacement of "a medical, surgical or dental procedure" by "medical investigation or treatment"]

3.26

PERFORMANCE CHARACTERISTIC

one of the quantities used to define the performance of an instrument (e.g. RESPONSE, RADIATION DETECTOR LEAKAGE CURRENT)

[SOURCE: IEC 60731:2011, 3.11, modified – modification of the example]

3.27

QUALITY EQUIVALENT FILTRATION

quantitative indication of the FILTRATION effected by one or several layer(s) of reference material(s) which, if substituted in a beam of specified RADIATION QUALITY under NARROW BEAM CONDITION for the material or an object under consideration, give(s) the same RADIATION QUALITY as for the material under consideration

3.28**RADIATION DETECTOR**

equipment, generally sub-assembly, or substance which, in the presence of RADIATION, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of the incident RADIATION

3.29**RADIATION DETECTOR LEAKAGE CURRENT**

any current in the signal path arising in the RADIATION DETECTOR system which is not produced by ionizing RADIATION in the measuring volume

3.30**RADIATION QUALITY**

for a specific type of RADIATION, the description of any characteristic that depends on its energy spectrum

Note 1 to entry: For the purposes of this document, a practical approximation of RADIATION QUALITY is expressed as the quotient of the first HALF-VALUE LAYER and the second HALF-VALUE LAYER.

3.31**RATED FIELD SIZE**

size of the USEFUL BEAM at the RADIATION DETECTOR within which the RADIATION DETECTOR performs to its specification

3.32**RATED RANGE (of use)**

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.

Note 2 to entry: The EFFECTIVE RANGE of use is referred to as RATED RANGE in this document.

[SOURCE: IEC 60731:2011, 3.15, modified – Addition of the Note 2 to entry.]

3.33**REFERENCE CONDITIONS**

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

[SOURCE: IEC 60731:2011, 3.9.1]

3.34**REFERENCE-CLASS DOSE AREA PRODUCT METER**

DOSE AREA PRODUCT METER whose performance and stability are sufficient for it to be used to calibrate other DOSE AREA PRODUCT METERS or for higher-precision field use requirements

3.35**REFERENCE VALUE**

particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purpose 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]

3.36**RESPONSE**

quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

[SOURCE: IEC 60731:2011, 3.11.1, modified – "ionization charge or current" was replaced by "indicated value".]

3.37

RESPONSE TIME

the time taken for a scale 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, modified – "scale" was added to the definition.]

3.38

RESOLUTION OF THE DISPLAY

smallest change of scale reading to which a numerical value can be assigned without further interpolation

Note 1 to entry: For an analogue display, the RESOLUTION is the smallest fraction of a scale interval that can be determined by an observer under specified conditions.

Note 2 to entry: For a digital display, the RESOLUTION is the smallest significant increment of the reading.

[SOURCE: IEC 60731:2011, 3.11.2, modified – Addition of new notes to entry.]

3.39

STABILITY CHECK DEVICE

device, either separate or integral part of the DOSE AREA PRODUCT METER, which enables the stability of the RESPONSE of the RADIATION DETECTOR and/or MEASURING ASSEMBLY to be checked

Note 1 to entry: The STABILITY CHECK DEVICE can be a purely electrical device.

3.40

STABILIZATION TIME

time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value, after the DOSE AREA PRODUCT METER has been switched on and after the polarizing voltage, if needed, has been applied to the RADIATION DETECTOR

3.41

STANDARD TEST CONDITIONS

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

[SOURCE: IEC 60731:2011, 3.10.1]

3.42

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]

3.43

USEFUL BEAM

all X-rays which emerge through a cone defined by the focus point and the specified aperture of its PROTECTIVE SHIELDING or of its BEAM-LIMITING DEVICE

3.44

USEFUL FIELD

cross section of the USEFUL BEAM, perpendicular to its specified direction at a specified distance from the FOCAL SPOT or at a specified plane of measurement

3.45

VARIATION

relative difference, $\Delta y/y$, between the values of a PERFORMANCE CHARACTERISTIC, y , when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) successively assumes 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]

4 General requirements

4.1 Performance requirements

In Clauses 5 and 6 the performance requirements are stated for a complete DOSE AREA PRODUCT METER including both the RADIATION DETECTOR and MEASURING ASSEMBLY. For a DOSE AREA PRODUCT METER designed to operate with one or more RADIATION DETECTORS, each combination of the MEASURING ASSEMBLY and RADIATION DETECTOR shall comply with the requirements in 4.6, and in Clauses 5 and 6 relevant to this combination.

4.2 Minimum EFFECTIVE RANGES of DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE

The minimum EFFECTIVE RANGES of DOSE AREA PRODUCT and DOSE AREA PRODUCT RATE are listed in Tables 1 and 2.

Table 1 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1,0 - 1,0 \times 10^5) \mu\text{Gym}^2$
Long time fluoro	$(1,0 \times 10^1 - 1,0 \times 10^6) \mu\text{Gym}^2$
Paediatric procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^4) \mu\text{Gym}^2$

Table 2 – Minimum EFFECTIVE RANGES – DOSE AREA PRODUCT RATE

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$
Paediatric procedures	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}^a$
^a $(1,0 \times 10^{-2} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$ recommended	

4.3 Plane of measurement

The instrument shall be designed so as to indicate the DOSE AREA PRODUCT and/or the DOSE AREA PRODUCT RATE in the USEFUL BEAM for the plane in which the RADIATION is incident on the PATIENT, excluding, as far as practicable, the contribution of back-scattering to the MEASURED VALUE.

4.4 REFERENCE VALUES and STANDARD TEST CONDITIONS

These values are as given in Table 3.

Table 3 – REFERENCE VALUES and STANDARD TEST CONDITIONS

INFLUENCE QUANTITY	REFERENCE VALUES	STANDARD TEST CONDITIONS
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
Air pressure	101,3 kPa	Atmospheric pressure
DOSE AREA PRODUCT RATE ^a	As at CALIBRATION	REFERENCE VALUE ±10 %
RADIATION QUALITY	100 kV (RQR 8, IEC 61267)	REFERENCE VALUE
IRRADIATION TIME	As at CALIBRATION	REFERENCE VALUE ±10 %
Field size	As at CALIBRATION	REFERENCE VALUE
Electromagnetic fields	Zero	Insignificant ^b
^a DOSE AREA PRODUCT RATE is only an INFLUENCE QUANTITY for DOSE AREA PRODUCT MEASUREMENTS. ^b Insignificant means that the field is sufficiently small not to have any determinable effect on the RESPONSE of the DOSE AREA PRODUCT METER, e.g. as exists in a normal laboratory environment without special shielding.		

4.5 General test conditions

4.5.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 3 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.

4.5.2 Test of components

The preferred procedure for verifying that the performance requirements are met is to test the components separately, in which case:

- tests on the RADIATION DETECTOR shall be performed using a "high-precision" MEASURING ASSEMBLY;
- tests on the MEASURING ASSEMBLY shall be carried out using a "high-precision" current or charge source, as required, connected to the input.

In this context, "high precision" means that the PERFORMANCE CHARACTERISTICS of the test equipment shall be such that they perturb the value of the particular PERFORMANCE CHARACTERISTIC being measured by less than one-quarter of the LIMITS OF VARIATION.

Any tests may be carried out using the complete DOSE AREA PRODUCT METER; in particular, this is the preferred method for investigating the effects of high-frequency electromagnetic fields and electrostatic discharges on a cable-connected RADIATION DETECTOR supplied with a MEASURING ASSEMBLY as a system. Some tests performed with the whole system cannot give information as to whether the origin of the VARIATION lies in the RADIATION DETECTOR or in the MEASURING ASSEMBLY (e.g. RADIATION DETECTOR LEAKAGE CURRENT and ZERO DRIFT). If a complete system is tested and the relevant INFLUENCE QUANTITY affects both parts, the quadratic sum of the separate LIMITS OF VARIATION may be taken as an overall LIMIT OF VARIATION.

4.5.3 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, the RADIATION DETECTOR should be allowed to attain thermal equilibrium with the environment and it should have the polarizing voltage, if needed, applied for a period of time equal to or greater than the specified STABILIZATION TIME.

4.5.4 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 RADIATION DETECTOR LEAKAGE CURRENT.

4.5.5 Uniformity of RADIATION field

The uniformity over the part of the USEFUL FIELD used for the compliance test shall be checked, for example, by scanning the RADIATION field with a small RADIATION DETECTOR compared with the size of the USEFUL FIELD. Appropriate corrections shall be made to ensure an uncertainty of the test results of not more than one-fifth of the LIMITS OF VARIATION under test.

NOTE The field uniformity of any X-RAY TUBE is subject to deterioration in use; regular checks are made.

4.6 Statistical fluctuations

At low DOSE AREA PRODUCT and DOSE AREA PRODUCT 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 4 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 , and the COEFFICIENT OF VARIATION, v , of the sets of readings (assumed to be equal for each set) is listed.

Table 4 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings

Δ	Number of readings required, n							
	COEFFICIENT OF VARIATION, v							
	< 0,5 %	0,5 %	1 %	2 %	3 %	4 %	5 %	10 %
1 %	*	6	25	100	250	400	600	2 500
2 %	*	*	6	25	55	100	150	550
3 %	*	*	*	12	25	45	70	250
4 %	*	*	*	6	15	25	40	150
5 %	*	*	*	*	9	16	25	100
10 %	*	*	*	*	*	*	7	25

NOTE 1 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 are at least five times the 63 % RESPONSE TIME of the instrument, in order to ensure that the readings are statistically independent.

NOTE 2 For measurements marked * at least five repeated readings are taken.

4.7 Uncertainty of measurement

When measurements of VARIATION are made to verify that an equipment complies with specified LIMITS OF VARIATION, the COMBINED STANDARD 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 COMBINED STANDARD UNCERTAINTY of the measurement is less than one half of the LIMITS OF VARIATION, the COMBINED STANDARD 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 COMBINED STANDARD UNCERTAINTY to the LIMITS OF VARIATION allowed.

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

NOTE For the purposes of this document, the COMBINED STANDARD UNCERTAINTY can be taken as the relative EXPANDED UNCERTAINTY expanded with a coverage factor of two.

4.8 Constructional requirements as related to performance

4.8.1 Display

4.8.1.1 Units

The SI unit of DOSE AREA PRODUCT is Gym^2 . The SI unit of DOSE AREA PRODUCT RATE is Gym^2/s . The indicated unit shall be that of the measuring quantity: DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE (i.e. Gym^2 or Gym^2/s , SI prefixes are allowed).

NOTE Units such as mGycm^2 or mGycm^2/s comply with SI rules.

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

4.8.1.2 Digital displays

DOSE AREA PRODUCT METERS shall have a digital display, which may be also realized by means of a digital interface. 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 concerning display shall be checked by inspection.

4.8.2 Indication of polarizing voltage failure

DOSE AREA PRODUCT METERS shall be provided with a means of indicating if the polarizing voltage, if needed, does not meet the MANUFACTURER's requirement for satisfactory operation.

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

4.8.3 Over-ranging

On all DOSE AREA PRODUCT RATE ranges, the DOSE AREA PRODUCT METER shall clearly indicate over-range when the full scale reading is exceeded.

Compliance shall be checked by increasing the DOSE AREA PRODUCT RATE slowly but continuously until the display shows over-range. An equivalent electrical test can be made on the MEASURING ASSEMBLY. When testing for compliance with the requirement on over-ranging it is not necessary to use REFERENCE CONDITIONS.

On all DOSE AREA PRODUCT ranges, the DOSE AREA PRODUCT METER shall clearly indicate over-range when the full scale reading is exceeded.

Compliance shall be checked on each DOSE AREA PRODUCT range by exposing the relevant DOSE AREA PRODUCT METER until the display reads just below the stated full scale. The irradiation should then be continued in DOSE AREA PRODUCT steps approximately equal to the RESOLUTION of the display for the range in use, until the display shows over-range. An equivalent electrical test can be made on the MEASURING ASSEMBLY. When testing for compliance with the requirement on over-ranging it is not necessary to use REFERENCE CONDITIONS.

4.8.4 Indication of reset or other inactive condition

During any period of time when the DOSE AREA PRODUCT METER is inactive, e.g. following the reset procedure, this state shall be indicated.

Compliance with this constructional requirement shall be checked by inspection.

4.8.5 RADIATION DETECTOR

The RADIATION DETECTOR shall be capable of being situated between the BEAM-LIMITING DEVICE and the PATIENT (see 4.3).

The SENSITIVE VOLUME of the RADIATION DETECTOR shall be capable of being positioned so that for VARIATIONS in the area of a uniform USEFUL FIELD the output current of the RADIATION DETECTOR is proportional to the area of the USEFUL FIELD, all other conditions being constant.

If the RADIATION DETECTOR is specified for use with a light beam diaphragm, the transparency of the RADIATION DETECTOR to visible light shall be such as to transmit at least 60 % of the luminous flux.

The presence of the RADIATION DETECTOR shall not displace any edge of the indicated area in the plane of the exit surface of the RADIATION DETECTOR by more than 2 mm due to refraction or similar effects.

The QUALITY EQUIVALENT FILTRATION of the RADIATION DETECTOR shall not exceed 0,5 mm aluminium of a purity of not less than 99 %.

The QUALITY EQUIVALENT FILTRATION shall be marked in thickness of aluminium on the outside of the RADIATION DETECTOR.

The QUALITY EQUIVALENT FILTRATION shall be measured using the RADIATION QUALITY RQR 5.

4.9 STABILITY CHECK DEVICE

The MEASURING ASSEMBLY shall contain a STABILITY CHECK DEVICE which can be brought into operation by a change-over switch and by means of which the user may check the electrical stability of the MEASURING ASSEMBLY in a simple manner.

The VARIATION in the output signal from the STABILITY CHECK DEVICE shall be less than ± 2 %. On a digital display the mean value of the readings created by the STABILITY CHECK DEVICE shall be at least 50.

Compliance with this requirement shall be checked over the MINIMUM RATED RANGE of the INFLUENCE QUANTITIES: operating voltage, air pressure, temperature, relative humidity and electromagnetic compatibility, as listed in Table 5.

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

INFLUENCE QUANTITY	MINIMUM RATED RANGE	REFERENCE CONDITIONS	LIMITS OF VARIATION <i>L</i>		SUB- CLAUSE
			REFERENCE- CLASS	FIELD- CLASS	
RADIATION QUALITY	50 kV to 150 kV RQR 3 to RQR 10 x IEC 61267	100 kV RQR 8 x IEC 61267	±8 %	±8 %	6.2
DOSE AREA PRODUCT RATE (in the case of DOSE AREA PRODUCT measurements)	($1,0 \times 10^{-1}$ to $1,5 \times 10^4$) $\mu\text{Gym}^2/\text{s}$ Paediatric procedures: ($1,0 \times 10^{-2}$ to $1,5 \times 10^4$) $\mu\text{Gym}^2/\text{s}$	As at CALIBRATION	±3 %	±5 %	6.3.1
AIR KERMA RATE	As stated by the MANUFACTURER	As at CALIBRATION	±5 %	±10 %	6.3.2
IRRADIATION TIME	1 ms to 1 h	As at CALIBRATION	±3 %	±5 %	6.4
Field size	As stated by the MANUFACTURER	As at CALIBRATION	±2 %	±5 %	6.5
Operating voltage	–10 % to +10 %	Nominal voltage ^a	±1 %	±2 %	6.6
Air pressure	80,0 kPa to 106,0 kPa	101,3 kPa	±1 %	±2 %	6.7
Temperature	+15 °C to +40 °C	+20 °C	±2 %	±3 %	6.8
Relative humidity	≤ 80 % (maximum 20 g/m ³)	50 %			
Electromagnetic compatibility	See 6.10	Without any disturbance	±1 % ^b	±5 % ^b	6.10
Drift of indicated values			±2 %	±10 %	5.8
Long term stability			±2 %	±5	5.9
Air density fluctuation, pressure ^c		As at CALIBRATION	±5 % ^b	±5 % ^b	6.9
Air density fluctuation, temperature ^c		As at CALIBRATION	±7,5 %	±7,5 % ^b	6.9

^a The nominal voltage need not be a single value but may be expressed as a range.

^b Of minimum EFFECTIVE DOSE AREA PRODUCT or minimum EFFECTIVE DOSE AREA PRODUCT RATE, respectively.

^c Devices may be calibrated at installation against local conditions.

4.10 Adjustment

A means of adjustment shall be provided so that the DOSE AREA PRODUCT for the plane in which the RADIATION is incident on the PATIENT can be indicated with the accuracy required by Clauses 5 and 6 in cases where absorbing materials are permanently present between the RADIATION DETECTOR and the PATIENT; e.g. the backboard of a fluoroscopic stand or the table top of an equipment with under-table X-RAY TUBE.

This adjustment shall be capable of being locked to prevent inadvertent or incompetent alteration and shall be described sufficiently in the ACCOMPANYING DOCUMENTS for a necessary adjustment to be correctly made.

4.11 Electrical safety

DOSE AREA PRODUCT METERS shall comply with IEC 60601-1. Connected peripheral devices (computers, printers) shall comply with IEC 60601-1 if they are placed in the PATIENT ENVIRONMENT, otherwise they shall comply with IEC 62368-1.

5 Limits of PERFORMANCE CHARACTERISTICS under STANDARD TEST CONDITIONS

5.1 Classification of DOSE AREA PRODUCT METERS according to LIMITS OF VARIATION

5.1.1 REFERENCE-CLASS DOSE AREA PRODUCT METERS

A DOSE AREA PRODUCT METER may be classified as REFERENCE-CLASS if the performance requirements listed in Table 5 Column 4 are met.

5.1.2 FIELD-CLASS DOSE AREA PRODUCT METERS

A DOSE AREA PRODUCT METER shall be classified as FIELD-CLASS if the performance requirements listed in Table 5 Column 5 are met.

5.2 LINEARITY

For DOSE AREA PRODUCT RATE measurements, the Equation (1) shall be fulfilled over the whole RATED RANGE of DOSE AREA PRODUCT RATE.

$$\frac{R_{\max} - R_{\min}}{R_{\max} + R_{\min}} \leq a \quad (1)$$

where

R_{\max} is the maximum RESPONSE over the RATED RANGE of DOSE AREA PRODUCT RATE, and

R_{\min} is the minimum RESPONSE,

$a = 0,03$ for REFERENCE CLASS DOSE AREA PRODUCT METERS, and

$a = 0,05$ for FIELD CLASS DOSE AREA PRODUCT METERS.

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

5.3 Warning function

If the instrument features a warning function such as graphical or audible level settings, the warning function shall be activated when a DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE is reached that corresponds to the set level within $\pm 10\%$. The warning function shall be activated within 3 s after the level setting is reached.

Compliance with this requirement shall be checked by setting levels at one or more points in each decade over the EFFECTIVE RANGE of DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE and at the limits of the EFFECTIVE RANGE. On DOSE AREA PRODUCT ranges a constant input signal shall be applied. The warning function shall be activated when a DOSE AREA PRODUCT is reached that corresponds to the set level within $\pm 10\%$. On DOSE AREA PRODUCT RATE ranges an increasing input signal shall be applied. The warning function shall be activated when a DOSE AREA PRODUCT RATE is reached that corresponds to the set level within $\pm 10\%$. Then the input signal shall be decreased; the warning function shall be inactivated when a DOSE AREA PRODUCT RATE is reached that corresponds to the set level within $\pm 10\%$. It is allowed that the warning function is activated/deactivated with a delay of up to 3 s.

5.4 Repeatability

When a measurement is repeated with the same DOSE AREA PRODUCT METER under unaltered conditions, the COEFFICIENT OF VARIATION of the measurement shall not exceed the maximum value given in Table 6.

Compliance with this performance requirement shall be checked by measuring the COEFFICIENT OF VARIATION for a DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE which corresponds approximately to a reading with a RESOLUTION of at least 0,25 %.

Table 6 – Maximum values for the COEFFICIENT OF VARIATION, V_{\max}

Quantity	Range of measurement	Maximum COEFFICIENT OF VARIATION V_{\max}
DOSE AREA PRODUCT, $K \cdot A$	$K \cdot A < 10,0 \mu\text{Gym}^2$	5 %
	$K \cdot A \geq 10,0 \mu\text{Gym}^2$	2 %
DOSE AREA PRODUCT RATE, $\dot{K} \cdot A$	$\dot{K} \cdot A < 1,0 \mu\text{Gym}^2/\text{s}$	5 %
	$\dot{K} \cdot A \geq 1,0 \mu\text{Gym}^2/\text{s}$	2 %

5.5 RESOLUTION of reading

Within the whole EFFECTIVE RANGE OF INDICATED VALUES the RESOLUTION of the reading shall be less than or equal to 10 %.

Compliance with this performance requirement shall be checked by inspection.

5.6 STABILIZATION TIME

The STABILIZATION TIME as stated by the MANUFACTURER shall not exceed 15 min.

5.7 Reset on DOSE AREA PRODUCT ranges

On all DOSE AREA PRODUCT ranges, after resetting the DOSE AREA PRODUCT METER once, the reading shall not be greater than the RESOLUTION of the reading.

Compliance with this performance requirement shall be checked on each DOSE AREA PRODUCT 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 DOSE AREA PRODUCT METER once and noting the residual reading.

5.8 Drift of INDICATED VALUES

During absence of RADIATION, and after resetting the DOSE AREA PRODUCT METER, the INDICATED VALUE shall be less than 10 % of the minimum EFFECTIVE DOSE AREA PRODUCT for at least 1 h.

Compliance with this performance requirement shall be checked by noting the reading in the most sensitive range 15 min, 30 min, 45 min and 1 h after the DOSE AREA PRODUCT METER has been reset, and with no resetting or compensation adjustment during the test. If the RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

On all DOSE AREA PRODUCT ranges, when the DOSE AREA PRODUCT METER is left in the measurement mode after being exposed to the minimum EFFECTIVE DOSE AREA PRODUCT the INDICATED VALUE shall not change by more than 10 % per hour.

Compliance with this performance requirement shall be checked for each allowable combination of DOSE AREA PRODUCT range and RADIATION DETECTOR, by exposing the relevant RADIATION DETECTOR until the display reads just above the stated minimum EFFECTIVE DOSE AREA PRODUCT, then stopping the exposure and noting the rate of change of scale reading whilst keeping the DOSE AREA PRODUCT METER in the measurement mode. If the RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

The RADIATION DETECTOR LEAKAGE CURRENT of a DOSE AREA PRODUCT METER shall not exceed 10 % of the current produced by the MINIMUM RATED DOSE AREA PRODUCT RATE.

Compliance with this performance requirement shall be checked by exposing the DOSE AREA PRODUCT METER with the MINIMUM RATED DOSE AREA PRODUCT RATE until the display reads just above the minimum EFFECTIVE DOSE AREA PRODUCT. The INDICATED VALUE shall be within ± 10 % of the CONVENTIONAL TRUE VALUE. If the RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test.

On all DOSE AREA PRODUCT RATE ranges, the RADIATION DETECTOR LEAKAGE CURRENT of a DOSE AREA PRODUCT METER shall not exceed 10 % of the current produced by the minimum EFFECTIVE DOSE AREA PRODUCT RATE of the range in use after any compensation adjustment has been made.

Compliance with this performance requirement shall be checked by exposing the DOSE AREA PRODUCT METER with the minimum EFFECTIVE DOSE AREA PRODUCT RATE. If the RADIATION DETECTOR is connected to the MEASURING ASSEMBLY by means of a cable, the maximum cable length as stated by the MANUFACTURER shall be used for this test. This test shall be performed at the REFERENCE VALUES for temperature and relative humidity, as well as at the maximum RATED temperature and humidity, and with no compensation adjustment during the test. A current source may be used parallel to the RADIATION DETECTOR to provide for an appropriate test current.

5.9 Long term stability

For all RADIATION QUALITIES within the RATED RANGE, the LIMITS OF VARIATION of RESPONSE when the RADIATION DETECTOR is irradiated in a reproducible field shall not be greater than

- $\pm 2,0$ % over 1 year, for a REFERENCE-CLASS DOSE AREA PRODUCT METER,
- $\pm 5,0$ % over 1 year, for a FIELD-CLASS DOSE AREA PRODUCT METER.

Compliance with this performance requirement shall be checked by retaining a representative MEASURING ASSEMBLY and RADIATION DETECTOR, stored under STANDARD TEST CONDITIONS, and investigating their 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 ASSEMBLY and RADIATION DETECTOR separately.

5.10 RESPONSE TIME

An INDICATED VALUE of 90 % of the final INDICATED VALUE shall be reached within a time not greater than 3 s after the end of the irradiation.

Compliance with this performance requirement shall be checked exposing the DOSE AREA PRODUCT METER with a DOSE AREA PRODUCT just above the minimum EFFECTIVE INDICATED VALUE and just below the maximum EFFECTIVE INDICATED VALUE for a period of 1 ms. On DOSE AREA PRODUCT RATE ranges, the corresponding DOSE AREA PRODUCT RATES shall be applied suddenly, and kept constant for at least 10 s.

5.11 Spatial uniformity of RESPONSE

Over the RATED FIELD SIZE the spatial uniformity of RESPONSE shall not vary by more than $\pm 5\%$.

Compliance with this performance requirement shall be checked by displacing the RADIATION DETECTOR in a small test field until the RATED FIELD SIZE is covered. The test field shall be a square or circular field with an area of approximately the MINIMUM RATED FIELD SIZE.

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 summarised in Table 5. For any change of an INFLUENCE QUANTITY within its RATED RANGE the change of the DOSE AREA PRODUCT METER'S RESPONSE shall not be greater than the values in Table 5, Column 4 or 5 dependent on the classification of the DOSE AREA PRODUCT METER.

6.2 Energy dependence of RESPONSE

Over the RATED RANGE, 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 instrument's RESPONSE with RADIATION QUALITY shall be measured under the same irradiation conditions as for CALIBRATION. The X-RAY TUBE VOLTAGE listed below shall be used as a minimum. Additional X-RAY TUBE VOLTAGE shall be used to cover the entire RATED RANGE:

- 50 kV, 70 kV, 100 kV, 150 kV X-RAY TUBE VOLTAGE, RQR 3, RQR 5, RQR 8, RQR 10 x IEC 61267.

6.3 DOSE AREA PRODUCT RATE dependence of DOSE AREA PRODUCT measurements

6.3.1 MEASURING ASSEMBLY

For DOSE AREA PRODUCT measurements the Equation (2) shall be fulfilled over the whole RATED RANGE of DOSE AREA PRODUCT RATE.

$$\frac{R_{\max} - R_{\min}}{R_{\max} + R_{\min}} \leq a \quad (2)$$

where

R_{\max} is the maximum RESPONSE over the RATED RANGE of DOSE AREA PRODUCT RATE and

R_{\min} is the minimum RESPONSE,

$a = 0,03$ for REFERENCE CLASS INSTRUMENTS, and

$a = 0,05$ for FIELD CLASS INSTRUMENTS.

Compliance with this performance requirement shall be checked by measuring the DOSE AREA PRODUCT RESPONSE resulting from the minimum to the maximum RATED DOSE AREA PRODUCT RATE, with measurements made at DOSE AREA PRODUCT RATES in steps not greater than one order of magnitude. The DOSE AREA PRODUCT applied shall be kept approximately constant, by

varying the exposure time. It is allowed to make an equivalent electrical test on the MEASURING ASSEMBLY.

6.3.2 IONIZATION CHAMBER – Recombination losses

For the maximum RATED AIR KERMA RATE, the ion collection efficiency of the IONIZATION CHAMBER shall be at least 90 % when the normal polarizing voltage is applied.

NOTE No CORRECTION FACTOR for recombination losses has to be applied, as long as the IONIZATION CHAMBER is used within its RATED RANGE OF AIR KERMA RATE.

Compliance with this performance requirement shall be checked by computing the CORRECTION FACTOR for the maximum RATED AIR KERMA RATE [1]¹:

$$k_s = 1 + 2,4 \dot{K}_{\max} d^4 / U^2$$

where

\dot{K}_{\max} is the maximum RATED AIR KERMA RATE as stated by the MANUFACTURER, given in Gy/s;

d is the electrode distance of the plane-parallel IONIZATION CHAMBER, given in mm;

U is the nominal polarizing voltage of the IONIZATION CHAMBER, given in V.

To comply with the performance requirement, k_s shall be less than or equal to 1,10.

6.4 IRRADIATION TIME

Over the RATED RANGE, the LIMITS OF VARIATION OF RESPONSE with changes in IRRADIATION TIME shall not be greater than those given in Table 5.

Compliance with this performance requirement shall be checked by varying the IRRADIATION TIME for a given DOSE AREA PRODUCT from 1 ms to 30 s, the ratios between the IRRADIATION TIMES being not greater than 10:1. It is allowed to make an equivalent electrical test on the MEASURING ASSEMBLY.

6.5 Field size

Over the RATED RANGE, the LIMITS OF VARIATION OF RESPONSE with changes in field size shall not be greater than those given in Table 5.

Compliance with this performance requirement shall be checked by measuring the VARIATION in RESPONSE with the field size for three square or circular field sizes. These shall be the maximum and the minimum RATED FIELD SIZES, as well as a field size defined by the average of the areas of the former field sizes. Any convenient AIR KERMA RATE may be used.

6.6 Operating voltage

The LIMIT OF VARIATION OF RESPONSE due to VARIATION of the operating voltage between +10 % and –10 % of the nominal voltage shall not be greater than the limit stated in Table 5, over the RATED RANGE of mains voltage as stated by the MANUFACTURER.

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

¹ Figures in square brackets refer to the bibliography.

6.7 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. 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. All readings shall be corrected for air density before this comparison is made.

6.8 Temperature and humidity

The LIMITS OF VARIATION of the DOSE AREA PRODUCT METER'S RESPONSE shall not be greater than the values 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/m³). 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 DOSE AREA PRODUCT METER shall be exposed to varying levels of temperature and air humidity. The measurements may be carried out separately for the MEASURING ASSEMBLY and for the RADIATION DETECTOR. At least four measurements shall be performed, one under each of the climatic conditions described in Table 7.

Table 7 – Climatic conditions

Temperature °C	Relative humidity %	Absolute humidity g/m ³
20	50	8,5
15	80	11,5
26,5	80	20,0
35	50	20,0

All readings shall be corrected for air density before this comparison is made. The DOSE AREA PRODUCT METER 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 Air density fluctuation in the IONIZATION CHAMBER

It is allowed that a DOSE AREA PRODUCT METER does not automatically correct for air density fluctuation in the IONIZATION CHAMBER. The DOSE AREA PRODUCT METER shall be designed in a way that the COMBINED STANDARD UNCERTAINTY stated in 6.11 is not exceeded, including effects of air density fluctuations within the RATED RANGE of temperature and air pressure. The REFERENCE VALUE for the air temperature in the IONIZATION CHAMBER may differ from the value given in Table 3.

Compliance with this requirement shall be checked as described in 6.11.

6.10 Electromagnetic compatibility

6.10.1 General

DOSE AREA PRODUCT METERS shall comply with IEC 60601-1-2. Requirements specific to DOSE AREA PRODUCT METERS are outlined in the following subclauses. Clinical utility is maintained if the LIMITS OF VARIATION given in Table 5 are not exceeded.

In order to reduce the number of test points, the compliance tests described in the following subclauses may be used instead of the corresponding tests described in IEC 60601-1-2.

NOTE 1 "Complete equipment" means the MEASURING ASSEMBLY connected to an IONIZATION CHAMBER of a type customarily supplied with the MEASURING ASSEMBLY.

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

6.10.2 Electrostatic discharge

The maximum spurious indications 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 RADIATION DETECTOR and MEASURING ASSEMBLY that are normally exposed in the RADIATION beam), when the instrument is set to the measurement mode 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.

6.10.3 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 DOSE AREA PRODUCT METER set to the most sensitive range (if the ranges are selectable), while measurements are performed both with and without the presence of the high-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 MHz, 90 MHz, 100 MHz, 110 MHz, 120 MHz, 130 MHz, 140 MHz, 150 MHz, 160 MHz, 180 MHz, 200 MHz, 220 MHz, 240 MHz, 260 MHz, 290 MHz, 320 MHz, 350 MHz, 380 MHz, 420 MHz, 460 MHz, 510 MHz, 560 MHz, 620 MHz, 680 MHz, 750 MHz, 820 MHz, 900 MHz and 1 000 MHz with a field strength of 10 V/m may be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in Table 5 is observed at one of these given frequencies, additional tests in the range of ± 5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the DOSE AREA PRODUCT METER in all three orientations as described in IEC 61000-4-3. For battery-operated instruments, for which the requirements of 6.10.3 and 6.10.4 do not apply, tests at 27 MHz shall also be performed.

6.10.4 Conducted disturbances induced by bursts and high frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to conducted disturbances induced by bursts and high 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 high-frequency fields (IEC 61000-4-6). The severity level shall, in both cases, be level 3 as described in these documents.

6.10.5 Surges

The maximum spurious indications (both transient and permanent) of the display or data output due to surges shall be less than the limits in Table 5. The test is not to be performed on the connection lines between the RADIATION DETECTOR and the MEASURING ASSEMBLY.

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 disturbances induced by surges (IEC 61000-4-5). The severity level shall be level 3 as described in this document.

6.10.6 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.

6.11 COMBINED STANDARD UNCERTAINTY

The DOSE AREA PRODUCT METER shall be designed in a way that a COMBINED STANDARD UNCERTAINTY of

- $\pm 15\%$ ($k = 2$) for a REFERENCE-CLASS DOSE AREA PRODUCT METER, and
- $\pm 25\%$ ($k = 2$) for a FIELD-CLASS DOSE AREA PRODUCT METER

is not exceeded. The uncertainty of the CALIBRATION coefficient shall be included.

The formalism given in GUM shall be used to determine the COMBINED STANDARD UNCERTAINTY. Examples are given in Tables 8 and 9.

**Table 8 – Example for assessment of the COMBINED STANDARD UNCERTAINTY –
FIELD-CLASS DOSE AREA PRODUCT METER**

INFLUENCE QUANTITY OR PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
RADIATION QUALITY ^a	6.2	8	4,6
DOSE AREA PRODUCT RATE ^a	6.3.1	5	2,9
AIR KERMA RATE ^b	6.3.2	10	2,9
IRRADIATION TIME ^a	6.4	5	2,9
Field size ^a	6.5	5	2,9
Operating voltage ^a	6.6	2	1,2
Air pressure ^a	6.7	2	1,2
Temperature and relative humidity ^a	6.8	3	1,7
Electromagnetic compatibility ^a	6.10	5	2,9
Drift of INDICATED VALUES ^a	5.8	10	5,8
Uncorrected air density fluctuation, air pressure ^{a c}	6.9	4,6	2,7
Uncorrected air density fluctuation, air temperature ^{a d}	6.9	7,3	4,2
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 1$ ^e			11,3
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 2$ ^f			23
CALIBRATION		5	2,9
COMBINED STANDARD UNCERTAINTY, $k = 2$			23
^a uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$ ^b uniform probability distribution, limits ranging from 0 to L , i.e. relative uncertainty = $L/\sqrt{12}$ ^c assumed range of air pressure (96,7 to 106) kPa, REFERENCE VALUE 101,3 kPa ^d assumed range of air temperature (15 to 60) °C, REFERENCE VALUE 37 °C ^e root-mean-square of relative uncertainties ^f root-mean-square of relative uncertainties, multiplied by 2			

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**Table 9 – Example for assessment of the COMBINED STANDARD UNCERTAINTY –
REFERENCE-CLASS DOSE AREA PRODUCT METER**

INFLUENCE QUANTITY OR PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
RADIATION QUALITY ^a	6.2	8	4,6
DOSE AREA PRODUCT RATE ^a	6.3.1	3	1,7
AIR KERMA RATE ^b	6.3.2	5	1,4
IRRADIATION TIME ^a	6.4	3	1,7
Field size ^a	6.5	2	1,2
Operating voltage ^a	6.6	1	0,6
Air pressure ^a	6.7	1	0,6
Temperature and relative humidity ^a	6.8	2	1,2
Electromagnetic compatibility ^a	6.10	1	0,6
Drift of INDICATED VALUES ^a	5.8	2	1,2
Uncorrected air density fluctuation, air pressure ^{a c}	6.9	4,6	2,7
Uncorrected air density fluctuation, air temperature ^{a d}	6.9	5,1	2,9
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 1$ ^e			7,1
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, $k = 2$ ^f			14
CALIBRATION		5	2,9
COMBINED STANDARD UNCERTAINTY, $k = 2$			15

^a uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$

^b uniform probability distribution, limits ranging from 0 to L , i.e. relative uncertainty = $L/\sqrt{12}$

^c assumed range of air pressure (96,7 to 106) kPa, REFERENCE VALUE 101,3 kPa

^d assumed range of air temperature (15 to 45) °C, REFERENCE VALUE 20 °C

^e root-mean-square of relative uncertainties

^f root-mean-square of relative uncertainties, multiplied by 2

7 Marking

7.1 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 document;
- type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognised;
- 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.

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

Compliance shall be checked by inspection.

7.2 RADIATION DETECTOR

The RADIATION 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 RADIATION DETECTOR complies with this document;
- type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognised;
- QUALITY EQUIVALENT FILTRATION of the RADIATION DETECTOR;
- RATED RANGE of RADIATION QUALITIES.

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 DOSE AREA PRODUCT METER, including its type number and MANUFACTURER. In addition the ACCOMPANYING DOCUMENTS shall contain the following information applicable to each type of RADIATION DETECTOR supplied:

- intended use of the DOSE AREA PRODUCT METER, e.g. standard procedures, paediatric procedures;
- RATED RANGE of use for RADIATION QUALITY;
- data giving typical dependence of RESPONSE on RADIATION QUALITY;
- reference direction of incident RADIATION;
- maximum RATED DOSE AREA PRODUCT;
- a warning that, on DOSE AREA PRODUCT ranges, maximum RATED DOSE AREA PRODUCT RATE should not be exceeded;
- 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;
- RATED RANGE of use for field size;
- RATED RANGE of use for AIR KERMA RATE at the position of the RADIATION DETECTOR;
- for IONIZATION CHAMBER
 - nominal polarizing voltage of the IONIZATION CHAMBER;
 - electrode distance of the IONIZATION CHAMBER;
 - table, diagram or formula for air density correction (if required);
- table or formula for VARIATION of check indication or check time, as a result of decreased activity of radioactive source (if necessary);
- the procedure by which the INDICATED VALUE of the instrument can be checked by means of the STABILITY CHECK DEVICE and, where necessary, the procedure for adjustment of the sensitivity of the instrument to a specified scale reading;
- a recommendation that the stability check should be carried out at intervals not longer than one month;

- the procedure used to determine the drift of INDICATED VALUES, and the maximum permissible value of the drift of INDICATED VALUES when determined in this manner;
- the procedure by which an overall check of the CALIBRATION of the instrument can be made;
- a recommendation that the overall check should be made at intervals not longer than every two years and in any case following a repair which might have affected the CALIBRATION;
- the RADIATION DETECTOR under test should be calibrated either with or without an absorber, and the user should be referred in the ACCOMPANYING DOCUMENTS to any correction that might be necessary to allow for local conditions;
- when a DOSE AREA PRODUCT METER is calibrated and it is not known whether an absorber will be used, the MANUFACTURER should carry out calibrations, both with and without an absorber of 0,5 mm aluminium, as a type test on a number of RADIATION DETECTOR; results of a typical CALIBRATION should be given in the ACCOMPANYING DOCUMENTS;
- the procedure of adjustment of the INDICATED VALUE to the presence or absence of absorbers between the RADIATION DETECTOR and the PATIENT.

Compliance shall be checked by inspection.

The MANUFACTURER shall state the REFERENCE VALUES and STANDARD TEST VALUES in the ACCOMPANYING DOCUMENTS or in the test sheets.

Compliance shall be checked by inspection.

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RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE**

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La Norme internationale IEC 60850 a été établie par le sous-comité 62C: Appareils de radiothérapie, de médecine nucléaire et de dosimétrie du rayonnement, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2000, et constitue une révision technique.

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

- a) une deuxième classe de dispositifs a été introduite, avec des tolérances d'incertitude plus strictes;
- b) la présente norme a été étendue pour inclure les détecteurs autres que les chambres d'ionisation;

- c) les qualités de rayonnement ont été mises à jour en fonction des nouvelles définitions de l'IEC 61267;
- d) une exigence relative à la linéarité du mesurage du débit de produit exposition-surface a été ajoutée;
- e) l'exigence relative à la transmission lumineuse de la chambre a été modifiée, passant de 70 % à 60 %.

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

FDIS	Report on voting
62C/744/FDIS	62C/751/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de la présente Norme internationale.

Ce document a été rédigé selon les directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères d'imprimerie suivants sont utilisés:

- exigences dont la conformité peut être vérifiée par un essai et définitions: caractères romains;
- explications, conseils, énoncés de portée générale, exceptions et références: petits caractères romains;
- *modalités d'essai: caractères italiques;*
- TERMES EMPLOYÉS DANS CETTE NORME ET QUI SONT DÉFINIS À L'ARTICLE 3 OU RÉPERTORIÉS DANS L'INDEX: PETITES MAJUSCULES.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "<http://webstore.iec.ch>" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Le radiodiagnostic est la plus importante source de rayonnements ionisants produits par l'homme à laquelle le public est exposé. Par conséquent, la réduction de l'exposition reçue par les PATIENTS soumis à des procédures ou EXAMENS RADIOLOGIQUES MEDICAUX est devenue un problème central au cours de ces dernières années. L'objectif du mesurage de routine du PRODUIT EXPOSITION-SURFACE est de contribuer à une réduction globale des rayonnements reçus par les PATIENTS qui sont soumis à des EXAMENS RADIOLOGIQUES MEDICAUX. Il est possible de déterminer les doses reçues par le PATIENT, de comparer les différentes techniques d'examen, d'établir une technique exposant le PATIENT à un minimum de rayonnements, et d'assurer le suivi de cette technique, à condition de tenir des dossiers appropriés; à ce sujet, de tels mesurages occupent une place particulièrement importante dans les établissements de formation. L'examen des dossiers peut aussi indiquer une baisse de l'efficacité du système de production d'image.

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APPAREILS ÉLECTROMÉDICAUX – RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE

1 Domaine d'application

Le présent document spécifie la performance et l'essai des RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE destinés au mesurage du PRODUIT EXPOSITION-SURFACE et/ou du DÉBIT DE PRODUIT EXPOSITION-SURFACE auquel le PATIENT est exposé au cours des EXAMENS RADIOLOGIQUES MÉDICAUX.

Le présent document est applicable aux types suivants de RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE:

- a) les RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE normalement utilisés pour le mesurage des PRODUITS EXPOSITION-SURFACE au cours des EXAMENS RADIOLOGIQUES MÉDICAUX;
- b) les RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE RÉFÉRENCE normalement utilisés pour l'ÉTALONNAGE des DOSIMÈTRES DE CLASSE DE ROUTINE.

NOTE Les RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE RÉFÉRENCE peuvent être utilisés en tant que RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE.

L'objet du présent document est

- 1) d'établir les exigences pour assurer un niveau de performance satisfaisant des RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE, et
- 2) de normaliser les méthodes pour déterminer la conformité à ce niveau de performance.

Deux niveaux de performance sont spécifiés:

- un niveau inférieur de performance applicable aux RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE;
- un niveau supérieur de performance applicable aux RADIAMÈTRES DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE RÉFÉRENCE.

2 Références normatives

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

IEC 60417, *Symboles graphiques utilisables sur le matériel* (disponible à l'adresse <http://www.graphical-symbols.info/equipment>)

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

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

IEC 62368-1, *Équipements des technologies de l'audio/vidéo, de l'information et de la communication – Partie 1: Exigences de sécurité*

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

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

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

IEC 61000-4-5, *Compatibilité électromagnétique (CEM) – Partie 4-5: Techniques d'essai et de mesure – Essai d'immunité aux ondes de choc*

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

IEC 61000-4-11, *Compatibilité électromagnétique (CEM) – Partie 4-11: Techniques d'essai et de mesure – Essais d'immunité aux creux de tension, coupures brèves et variations de tension*

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

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

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005, l'IEC TR 60788:2004 ainsi que les suivants, s'appliquent.

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

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

NOTE 1 Un index des termes définis figure à la fin de ce document.

NOTE 2 Un Glossaire IEC peut être consulté sur le site std.iec.ch.

3.1

DOCUMENT D'ACCOMPAGNEMENT

document fourni avec une installation, un équipement, un équipement ou accessoire associé, contenant des informations importantes pour l'assembleur, l'installateur et l'utilisateur, concernant particulièrement la sécurité

3.2

KERMA DANS L'AIR

K

quotient de dE_{tr} par dm , où dE_{tr} est la somme des énergies cinétiques initiales de toutes les particules chargées dans une masse d'air dm , donc

$$K = \frac{dE_{tr}}{dm}$$

Note 1 à l'article: Unité: $J\ kg^{-1}$.

Note 2 à l'article: Le nom spécial de l'unité de KERMA DANS L'AIR est le gray (Gy) (ICRU 85A).

3.3

DEBIT DE KERMA DANS L'AIR

\dot{K}

quotient de dK par dt , où dK représente l'incrément de KERMA DANS L'AIR dans l'intervalle de temps dt , donc

$$\dot{K} = \frac{dK}{dt}$$

Note 1 à l'article: Unité: $J\ kg^{-1}\ s^{-1}$.

Note 2 à l'article: Le nom spécial pour l'unité de débit de KERMA DANS L'AIR est le gray par seconde ($Gy\ s^{-1}$) (ICRU 85A).

3.4

COEFFICIENT DE VARIATION

écart type d'un ensemble de lectures, exprimée sous la forme d'un pourcentage de la valeur moyenne de ces lectures

3.5

FACTEUR DE CORRECTION

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

[SOURCE: IEC 60731:2011, 3.6]

3.6

PRODUIT EXPOSITION-SURFACE

$K \cdot A$

produit de la surface du FAISCEAU UTILE par le KERMA DANS L'AIR sur la section efficace du FAISCEAU UTILE, les deux grandeurs étant mesurées à la même distance du FOYER

Note 1 à l'article: L'unité de mesure du PRODUIT EXPOSITION-SURFACE est le Gym^2 .

3.7

RADIOMETRE DE PRODUIT EXPOSITION-SURFACE

appareil destiné à mesurer le PRODUIT EXPOSITION-SURFACE ou le DEBIT DE PRODUIT EXPOSITION-SURFACE dans le faisceau d'un appareil à RAYONNEMENT X utilisé pour des EXAMENS RADIOLOGIQUES MEDICAUX diagnostiques

Note 1 à l'article: Un radiamètre de PRODUIT EXPOSITION-SURFACE contient les éléments suivants:

- DETECTEUR DE RAYONNEMENT;
- ENSEMBLE DE MESURAGE;
- CONTRÔLEUR DE CONSTANCE.

3.8

DEBIT DE PRODUIT EXPOSITION-SURFACE

$\dot{K} \cdot A$

quotient d'un incrément de PRODUIT EXPOSITION-SURFACE par l'incrément de temps correspondant

Note 1 à l'article: L'unité du débit de PRODUIT EXPOSITION-SURFACE est le Gym^2/s .

3.9

DOMAINE UTILE (des VALEURS INDIQUEES)

domaine des VALEURS INDIQUEES à l'intérieur duquel un instrument se conforme à une performance indiquée; la VALEUR INDIQUEE EFFECTIVE maximale (minimale) est la plus élevée (basse) indiquée dans ce domaine

Note 1 à l'article: Le concept de DOMAINE UTILE peut aussi s'appliquer à des valeurs lues et à des grandeurs associées qui ne sont pas indiquées directement par l'appareil, par exemple le courant d'entrée. Ses limites sont les VALEURS ASSIGNEES MINIMALE et maximale.

Note 2 à l'article: Dans le présent document, le DOMAINE UTILE des VALEURS INDIQUEES est désigné par le terme DOMAINE UTILE.

3.10

RADIOMETRE DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE ROUTINE

RADIOMETRE DE PRODUIT EXPOSITION-SURFACE dont les performances et la constance sont suffisantes pour lui permettre d'effectuer les mesurages de routine

Note 1 à l'article: Les RADIOMETRES DE PRODUIT EXPOSITION-SURFACE intégrés ou raccordés de façon permanente à l'unité radiogène de diagnostic sont généralement des instruments de classe de routine, mais ils peuvent également être des instruments de classe de référence.

3.11

FILTRATION

modification des caractéristiques de rayonnements ionisants par suite de leur passage au travers d'une matière

Note 1 à l'article: La FILTRATION comprend:

- la modification du spectre d'énergie des rayonnements ionisants par absorption préférentielle des composants;
- la modification de la distribution spatiale de l'intensité du RAYONNEMENT sur la section efficace d'un faisceau de RAYONNEMENT par ATTENUATION différentielle.

3.12

COUCHE DE DEMI-TRANSMISSION

épaisseur d'un matériau spécifié lequel, dans des CONDITIONS DE FAISCEAU ETROIT, atténue les rayonnements de photon selon leur spectre d'énergie en réduisant le DEBIT DE KERMA DANS L'AIR de la moitié de la valeur mesurée sans lui

3.13

VALEUR INDIQUEE

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

[SOURCE: IEC 60731:2011, 3.2]

3.14

GRANDEUR D'INFLUENCE

grandeur externe susceptible d'affecter les performances d'un instrument (par exemple, la température ambiante, la QUALITE DE RAYONNEMENT, etc.)

[SOURCE: IEC 60731:2011, 3.7, modifié – ajout de la parenthèse]

3.15

PARAMETRE D'INSTRUMENT

propriété interne d'un instrument qui est susceptible d'affecter ses performances

[SOURCE: IEC 60731:2011, 3.8]

3.16**CHAMBRE D'IONISATION**

détecteur constitué d'une chambre remplie d'un médium approprié, généralement gazeux, dans laquelle un champ électrique, insuffisant pour provoquer une multiplication de charge, sert à collecter sur les électrodes les charges associées aux ions et aux électrons produits par le RAYONNEMENT ionisant dans le VOLUME UTILE du détecteur

3.17**TEMPS D'IRRADIATION**

durée d'irradiation déterminée selon des méthodes spécifiques, habituellement temps pendant lequel le débit d'une grandeur de RAYONNEMENT dépasse un niveau spécifié

3.18**LIMITES DE VARIATION**

VARIATION maximale admise d'une CARACTERISTIQUE DE PERFORMANCE, y , autorisées par le présent document

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

[SOURCE: IEC 60731:2011, 3.13, modifié – ajout de " y , autorisées par le présent document".]

3.19**LINEARITE**

VARIATION maximale de la REPOSE d'un instrument dans le DOMAINE UTILE des grandeurs de mesure, autorisée par le présent document

3.20**CONSTRUCTEUR**

organisation ou individu produisant un équipement

3.21**VALEUR MESUREE**

valeur d'une grandeur physique dérivée en appliquant toutes les corrections pertinentes à une VALEUR INDIQUEE

3.22**ENSEMBLE DE MESURAGE**

dispositif destiné à convertir le signal de sortie d'un DETECTEUR DE RAYONNEMENT sous une forme convenant à l'affichage de la ou des valeurs du PRODUIT EXPOSITION-SURFACE ou du DEBIT DE PRODUIT EXPOSITION-SURFACE

3.23**EXAMEN MEDICAL RADIOLOGIQUE**

examen médical utilisant les rayonnements ionisants

3.24**DOMAINE ASSIGNE MINIMAL**

plus petit domaine d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT dans lequel cet instrument doit fonctionner à l'intérieur des LIMITES DE VARIATION spécifiées en restant conforme au présent document

[SOURCE: IEC 60731:2011, 3.15.1, modifié – ajout de "en restant conforme au présent document".]

3.25**PATIENT**

être vivant (personne ou animal) soumis à un examen ou à un traitement médical

[SOURCE: IEC 60601-1:2005, 3.76, modifié – remplacement de "une procédure de nature médicale, chirurgicale ou dentaire" par "un examen ou à un traitement médical"]

3.26

CARACTERISTIQUE DE PERFORMANCE

une des grandeurs servant à définir la performance d'un instrument (par exemple, la REPONSE, le COURANT DE FUITE du DETECTEUR DE RAYONNEMENT

[SOURCE: IEC 60731:2011, 3.11, modifié – modification de l'exemple]

3.27

FILTRATION DE QUALITE EQUIVALENTE

indication quantitative de la FILTRATION effectuée par une ou plusieurs couches de matériaux de référence qui, substitués au matériau ou à un objet à l'étude dans un faisceau de QUALITE DE RAYONNEMENT spécifiée et en CONDITION DE FAISCEAU ETROIT, donnent la même QUALITE DE RAYONNEMENT

3.28

DETECTEUR DE RAYONNEMENT

appareil, partie d'appareil ou substance qui, en présence d'un RAYONNEMENT, fournit, directement ou indirectement, un signal ou une autre indication utilisable pour mesurer une ou plusieurs grandeurs liées au RAYONNEMENT incident

3.29

COURANT DE FUITE DU DETECTEUR DE RAYONNEMENT

tout courant, sur le trajet du signal, qui naît dans le système du détecteur de RAYONNEMENT et qui n'est pas dû au RAYONNEMENT ionisant dans le volume de mesure

3.30

QUALITE DU RAYONNEMENT

pour un type de RAYONNEMENT spécifique, la description de toute caractéristique dépendant de son spectre d'énergie

Note 1 à l'article: Aux fins du présent document, une approximation pratique de la QUALITE DU RAYONNEMENT est exprimée par le quotient de la division de la première COUCHE DE DEMI-TRANSMISSION par la deuxième COUCHE DE DEMI-TRANSMISSION.

3.31

TAILLE DE CHAMP NORMALE

taille du FAISCEAU UTILE au DETECTEUR DE RAYONNEMENT à l'intérieur duquel le DETECTEUR DE RAYONNEMENT fonctionne selon ses spécifications

3.32

DOMAINE ASSIGNE (d'utilisation)

domaine des valeurs d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT à l'intérieur duquel cet instrument fonctionnera à l'intérieur des LIMITES DE VARIATION

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

Note 2 à l'article: Dans le présent document, la PLAGE EFFECTIVE d'utilisation est appelée DOMAINE ASSIGNE.

[SOURCE: IEC 60731:2011, 3.15, modifié – Ajout de la Note 2 à l'article.]

3.33

CONDITIONS DE REFERENCE

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

[SOURCE: IEC 60731:2011, 3.9.1]

3.34**RADIOMETRE DE PRODUIT EXPOSITION-SURFACE DE CLASSE DE REFERENCE**

RADIOMETRE DE PRODUIT EXPOSITION-SURFACE dont les performances et la constance sont suffisantes pour lui permettre d'effectuer l'ÉTALONNAGE d'autres RADIOMETRES DE PRODUIT EXPOSITION-SURFACE ou de répondre à des exigences d'utilisation pour des champs de précision plus élevée

3.35**VALEUR DE REFERENCE**

valeur particulière d'une GRANDEUR D'INFLUENCE (ou d'un PARAMETRE D'INSTRUMENT) choisie pour servir de référence

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

[SOURCE: IEC 60731:2011, 3.9]

3.36**REPONSE**

quotient de la VALEUR INDIQUEE par la VALEUR CONVENTIONNELLEMENT VRAIE

[SOURCE: IEC 60731:2011, 3.11.1, modifié – remplacement de "de la charge ou du courant d'ionisation" par "de la valeur indiquée".]

3.37**TEMPS DE REPONSE**

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

[SOURCE: IEC 60731:2011, 3.11.4, modifié – Cette modification ne s'applique qu'à l'anglais.]

3.38**POUVOIR DE RESOLUTION DE L'AFFICHAGE**

plus petite variation de valeur lue qui peut être chiffrée numériquement sans interpolation

Note 1 à l'article: Avec un affichage analogique, le POUVOIR DE RESOLUTION est la plus petite fraction d'un intervalle d'échelle pouvant être déterminée par un observateur dans des conditions spécifiées.

Note 2 à l'article: Avec un affichage numérique, le POUVOIR DE RESOLUTION est le plus petit accroissement de la lecture.

[SOURCE: IEC 60731:2011, 3.11.2, modifié – Ajout de nouvelles notes à l'article.]

3.39**CONTROLEUR DE CONSTANCE**

dispositif, qui peut être séparé ou faire partie intégrante du RADIOMETRE DE PRODUIT EXPOSITION-SURFACE, permettant de vérifier la stabilité de la REPONSE du DETECTEUR DE RAYONNEMENT et/ou de l'ENSEMBLE DE MESURAGE

Note 1 à l'article: Le CONTROLEUR DE CONSTANCE peut être un dispositif purement électrique.

3.40**TEMPS DE STABILISATION**

temps nécessaire pour qu'une CARACTERISTIQUE DE PERFORMANCE donnée entre et se maintienne à l'intérieur d'un écart spécifié autour de sa valeur finale d'équilibre, après la mise sous tension du RADIOMETRE DE PRODUIT EXPOSITION-SURFACE et après que la tension de polarisation a été appliquée, si nécessaire, au DETECTEUR DE RAYONNEMENT

3.41**CONDITIONS D'ESSAI NORMALISEES**

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

[SOURCE: IEC 60731:2011, 3.10.1]

3.42**VALEURS D'ESSAI NORMALISEES**

valeur, ensemble de valeurs ou gamme de valeurs d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'INSTRUMENT qui sont admises pour effectuer des ÉTALONNAGES ou des essais d'une autre GRANDEUR D'INFLUENCE ou d'un autre PARAMETRE D'INSTRUMENT

[SOURCE: IEC 60731:2011, 3.10]

3.43**FAISCEAU UTILE**

ensemble de tous les rayons X passant dans un cône défini par le point de focalisation et l'ouverture spécifiée de son BLINDAGE DE PROTECTION ou de son DISPOSITIF DE LIMITATION DE FAISCEAU

3.44**CHAMP UTILE**

section droite du FAISCEAU UTILE, perpendiculaire à la direction spécifiée de celui-ci et à une distance spécifiée du FOYER ou à un plan de mesure spécifique

3.45**VARIATION**

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

[SOURCE: IEC 60731:2011, 3.12]

4 Exigences générales**4.1 Exigences de performance**

Les exigences de performance sont énoncées aux Articles 5 et 6 pour un RADIOMETRE DE PRODUIT EXPOSITION-SURFACE complet comprenant à la fois le DETECTEUR DE RAYONNEMENT et L'ENSEMBLE DE MESURAGE. Pour un RADIOMETRE DE PRODUIT EXPOSITION-SURFACE conçu pour fonctionner avec un ou plusieurs DETECTEURS DE RAYONNEMENT, chaque combinaison D'ENSEMBLE DE MESURAGE et de DETECTEUR DE RAYONNEMENT doit être conforme aux exigences de 4.6 et des Articles 5 et 6 qui se rapportent à cette combinaison.

4.2 DOMAINES UTILES minimaux de PRODUIT EXPOSITION-SURFACE et de DEBIT DE PRODUIT EXPOSITION-SURFACE

Les DOMAINES UTILES minimaux de PRODUIT EXPOSITION-SURFACE et de DEBIT DE PRODUIT EXPOSITION-SURFACE sont répertoriés dans les Tableaux 1 et 2.

Tableau 1 – DOMAINES UTILES minimaux – PRODUIT EXPOSITION-SURFACE

Application	DOMAINE UTILE minimal
Procédures normales	$(1,0 - 1,0 \times 10^5) \mu\text{Gym}^2$
Radioscopie longue durée	$(1,0 \times 10^1 - 1,0 \times 10^6) \mu\text{Gym}^2$
Procédures pédiatriques	$(1,0 \times 10^{-1} - 1,0 \times 10^4) \mu\text{Gym}^2$

Tableau 2 – DOMAINES UTILES minimaux – DEBIT DE PRODUIT EXPOSITION-SURFACE

Application	DOMAINE UTILE minimal
Procédures normales	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$
Procédures pédiatriques	$(1,0 \times 10^{-1} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}^a$
^a $(1,0 \times 10^{-2} - 1,0 \times 10^3) \mu\text{Gym}^2/\text{s}$ recommandée	

4.3 Plan de mesure

L'instrument doit être conçu de manière à indiquer le PRODUIT EXPOSITION-SURFACE et/ou le DEBIT DE PRODUIT EXPOSITION-SURFACE dans le FAISCEAU UTILE pour le plan dans lequel le RAYONNEMENT est incident au PATIENT, en excluant, autant que possible, la contribution des réflexions à la VALEUR MESUREE.

4.4 VALEURS DE REFERENCE et CONDITIONS D'ESSAI NORMALISEES

Ces valeurs sont indiquées dans le Tableau 3.

Tableau 3 – VALEURS DE REFERENCE et CONDITIONS D'ESSAI NORMALISEES

GRANDEUR D'INFLUENCE	VALEURS DE RÉFÉRENCE	CONDITIONS D'ESSAI NORMALISÉES
Température	+20 °C	+15 °C à +25 °C
Humidité relative	50 %	30 % à 75 %
Pression d'air	101,3 kPa	Pression atmosphérique
DEBIT DE PRODUIT EXPOSITION-SURFACE ^a	Comme à l'ÉTALONNAGE	VALEUR DE REFERENCE ±10 %
QUALITE DE RAYONNEMENT	100 kV (RQR 8, IEC 61267)	VALEUR DE REFERENCE
TEMPS D'IRRADIATION	Comme à l'ÉTALONNAGE	VALEUR DE REFERENCE ±10 %
Taille de champ	Comme à l'ÉTALONNAGE	VALEUR DE REFERENCE
Champs électromagnétiques	Zéro	Non significatif ^b
^a Le DEBIT DE PRODUIT EXPOSITION-SURFACE n'est considéré comme une GRANDEUR D'INFLUENCE que pour les MESURAGES DE PRODUIT EXPOSITION-SURFACE.		
^b Non significatif signifie ici que le champ est assez petit pour n'avoir aucun effet détectable sur la REPONSE du RADIOMETRE DE PRODUIT EXPOSITION-SURFACE, par exemple tel qu'il est rencontré dans un environnement de laboratoire normal sans blindage spécial.		

4.5 Conditions générales d'essai

4.5.1 CONDITIONS D'ESSAI NORMALISÉES

Les CONDITIONS D'ESSAI NORMALISEES répertoriées dans le Tableau 3 doivent être respectées pendant les procédures d'essai, sauf

- a) celles concernant la GRANDEUR D'INFLUENCE soumise à investigation;