BRITISH STANDARD

BS EN
60580:2000
IEC 60580:2000

Dose area product meters

The European Standard EN 60580:2000 has the status of a British Standard

ICS 11.040.50; 17.240

National foreword

This British Standard is the official English language version of EN 60580:2000. It is identical with IEC 60580:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/83, Dosemeters (medical), which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

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EUROPEAN STANDARD **EN 60580**

NORME EUROPÉENNE

EUROPÄISCHE NORM May 2000

ICS 11.040.50

Supersedes HD 379 S1:1979

English version

Medical electrical equipment
Dose area product meters
(IEC 60580:2000)

Appareils électromédicaux
Radiamètres de produit exposition-surface
(CEI 60580:2000)

Medizinische elektrische Geräte
Dosisflächenprodukt-Messgeräte
(IEC 60580:2000)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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

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Foreword

The text of document 62C/272/FDIS, future edition 1 of IEC 60580, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60580 on 2000-02-01.

This European Standard supersedes HD 379 S1:1979.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2000-11-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2003-02-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60580:2000 was approved by CENELEC as a European Standard without any modification.

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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 fulfil the special requirements laid down in this International Standard.

MEDICAL ELECTRICAL EQUIPMENT – DOSE AREA PRODUCT METERS

1 Scope and object

This International Standard 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.

The object of this International Standard 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.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60417 (all parts), *Graphical symbols for use on equipment*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

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 safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

IEC 60788:1984, *Medical radiology – Terminology*

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* [1)]

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

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*

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 Terminology 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*; 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:

3.1
ACCOMPANYING DOCUMENTS
documents 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 (Letter symbol *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

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

Unit: J kg^{-1}

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

3.3
AIR KERMA RATE (Letter symbol $\dot{K}$)
quotient of dK by dt, where dK is the increment of AIR KERMA in the time interval dt, thus

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

Unit: J kg^{-1} s^{-1}

If the special name gray is used, the unit of AIR KERMA rate is gray per second (Gy s^{-1}) (ICRU 60)

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.

3.6
CORRECTION FACTOR
dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS (IEC 60731)

3.7
DOSE AREA PRODUCT (Letter symbol $K \cdot A$)
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. The unit of DOSE AREA PRODUCT is Gym^2.

3.8
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

A DOSE AREA PRODUCT METER contains the following components:

– IONIZATION CHAMBER
– MEASURING ASSEMBLY
– STABILITY CHECK DEVICE

3.9

DOSE AREA PRODUCT RATE (Letter symbol $\dot{K} \cdot A$)

quotient of an increment of DOSE AREA PRODUCT by the corresponding increment of time. The unit of DOSE AREA PRODUCT RATE is Gym^2/s

3.10

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

The concept of EFFECTIVE RANGE may, 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)

NOTE The EFFECTIVE RANGE of INDICATED VALUES is referred to as EFFECTIVE RANGE in this standard.

3.11

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)

3.12

FILTRATION

modification of characteristics of ionizing radiation on passing through matter

NOTE 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.

3.13

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

3.14

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 (IEC 60731)

3.15

INFLUENCE QUANTITY

any external quantity that may affect the performance of an instrument (e.g. ambient temperature, RADIATION QUALITY etc.) (IEC 60731)

3.16

INSTRUMENT PARAMETER

any internal property of an instrument that may affect the performance of this instrument (IEC 60731)

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)

3.18
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.

3.19
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

3.21
LIMITS OF VARIATION
maximum VARIATION of a PERFORMANCE CHARACTERISTIC, y, permitted by this standard. 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 $+L$ % (IEC 60731)

3.22
MANUFACTURER
organization or individual who produces an equipment

3.23
MEASURED VALUE
value of a physical quantity derived by applying all relevant corrections to an INDICATED VALUE

3.24
MEASURING ASSEMBLY
device to convert the output from the IONIZATION CHAMBER into a form suitable for the display of the value(s) of DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE

3.25
MEDICAL RADIOLOGICAL EXAMINATION
medical examination using effects of ionizing radiation

3.26
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 standard (IEC 60731)

3.27
PATIENT
living being (person or animal) undergoing medical investigation or treatment (IEC 60601-1)

3.28
PERFORMANCE CHARACTERISTIC
one of the quantities used to define the performance of an instrument (e.g. RESPONSE, LEAKAGE CURRENT) (IEC 60731)

3.29
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

3.30
RADIATION QUALITY
for a specific type of RADIATION, the description of any characteristic that depends on its energy spectrum

NOTE For the purposes of this International Standard, 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 within which the IONIZATION CHAMBER 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. Its limits are the maximum and MINIMUM RATED VALUES (IEC 60731)

NOTE The EFFECTIVE RANGE of use is referred to as RATED RANGE in this standard.

3.33
REFERENCE CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES (IEC 60731)

3.34
REFERENCE VALUE
particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purpose of reference, 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 (IEC 60731)

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 by the CONVENTIONAL TRUE VALUE (IEC 60731)

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 (IEC 60731)

3.38
RESOLUTION OF THE DISPLAY
smallest change of scale reading to which a numerical value can be assigned without further interpolation:

– for an analogue display, the RESOLUTION is the smallest fraction of a scale interval that can be determined by an observer under specified conditions;

– for a digital display, the RESOLUTION is the smallest significant increment of the reading (IEC 60731)

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 and/or MEASURING ASSEMBLY to be checked

NOTE The STABILITY CHECK DEVICE may 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 has been applied to the IONIZATION CHAMBER (IEC 60731 modified)

3.41
STANDARD TEST CONDITIONS
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES (IEC 60731)

3.42
STANDARD TEST VALUES
value(s), 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 (IEC 60731)

3.43
TRUE VALUE
value of the physical quantity to be measured by an instrument (IEC 60731)

3.44
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

3.45
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

3.46
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) (IEC 60731)

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 and MEASURING ASSEMBLY. For a DOSE AREA PRODUCT METER designed to operate with one or more IONIZATION CHAMBERS, each combination of the MEASURING ASSEMBLY and IONIZATION CHAMBER 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 Table 1.

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 2.

4.5 General test conditions

4.5.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 2 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

4.5.2.1 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 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.

4.5.2.2 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 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 or in the MEASURING ASSEMBLY (e.g. 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 should be allowed to attain thermal equilibrium with the environment and it should have the polarizing voltage 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 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 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 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 3 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.

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 International Standard, the COMBINED STANDARD UNCERTAINTY may 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).

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. 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 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

4.8.3.1 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.

4.8.3.2 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

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

4.8.5.2 The SENSITIVE VOLUME of the IONIZATION CHAMBER 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 is proportional to the area of the USEFUL FIELD, all other conditions being constant.

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

The presence of the IONIZATION CHAMBER shall not displace the edge of the indicated area in the plane of the exit surface of the IONIZATION CHAMBER by more than 2 mm.

4.8.5.4 The QUALITY EQUIVALENT FILTRATION of the IONIZATION CHAMBER 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.

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.

4.9 STABILITY CHECK DEVICE

4.9.1 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.

4.9.2 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 6.

4.10 Adjustment

4.10.1 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 and the PATIENT; e.g. the backboard of a fluoroscopic stand or the table top of an equipment with under-table X-RAY TUBE.

4.10.2 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 comply with IEC 60601-1 if they are placed in the patient environment, otherwise they must comply with IEC 60950.

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.

5.2 Warning function

If the instrument features a warning function such as graphical or audible level settings, the warning function should have the same RELATIVE INTRINSIC ERROR as the device. The warning function must 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 ±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 ±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 ±10 %. It is allowed that the warning function is activated/deactivated with a delay of up to 3 s.

5.3 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 5.

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 %.

5.4 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.

5.5 STABILIZATION TIME

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

5.6 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, or by injecting an equivalent electrical signal, then resetting the DOSE AREA PRODUCT METER once and noting the residual reading.

5.7 Drift of INDICATED VALUES

5.7.1 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 hour.

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 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.

5.7.2 On all DOSE AREA PRODUCT ranges, when the DOSE AREA PRODUCT METER is left in the "measure" condition 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, by exposing the relevant IONIZATION CHAMBER 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. If the IONIZATION CHAMBER 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.

5.7.3 The 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 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.

5.7.4 On all DOSE AREA PRODUCT RATE ranges, the 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 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 to provide for an appropriate test current.

5.8 Long term stability

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

Compliance with this performance requirement shall be checked by retaining a representative MEASURING ASSEMBLY and IONIZATION CHAMBER, 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 separately.

5.9 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.

5.10 Spatial uniformity of RESPONSE

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

Compliance with this performance requirement shall be checked by displacing the IONIZATION CHAMBER 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

The LIMITS OF VARIATION $\pm L$ due to the effects of INFLUENCE QUANTITIES are summarised in Table 6. 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 column 4 of Table 6.

6.1 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 6.

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, 70, 100, 150 kV X-RAY TUBE VOLTAGE, with a TOTAL FILTRATION of 2,5 mm aluminium.*

6.2 DOSE AREA PRODUCT RATE dependence of DOSE AREA PRODUCT measurements

6.2.1 MEASURING ASSEMBLY

For DOSE AREA PRODUCT measurements the equation :

$$\frac{R_{max} - R_{min}}{R_{max} + R_{min}} \leq 0{,}05$$

shall be fulfilled over the whole RATED RANGE of DOSE AREA PRODUCT RATE. R_{max} is the maximum RESPONSE over the RATED RANGE of DOSE AREA PRODUCT RATE and R_{min} is the minimum RESPONSE.

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.

6.2.2 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)]

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

In this formula, $\dot{K}_{max}$ 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 be less than or equal to 1,11.

6.3 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 6.

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.

6.4 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 6.

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.

6.5 Operating voltage

6.5.1 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 6, 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 a.c. power supply adjusted to the upper and lower boundaries of the RATED RANGE of operating voltage stated by the MANUFACTURER and compared with a reference set of readings at nominal operating voltage.

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1) Boag 1966 (see Bibliography)

6.6 Air pressure

The LIMITS OF VARIATION of RESPONSE shall not be greater than those given in Table 6 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.

6.7 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 6 for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity (absolute humidity not to exceed 20 g/m^3). 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. At least four measurements shall be performed, one under each of the following climatic conditions:

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

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.

6.8 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 6.10 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 2.

Compliance with this requirement shall be checked as described in 6.10.

6.9 Electromagnetic compatibility

6.9.1 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 6 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.

6.9.2 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 6.

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 and MEASURING ASSEMBLY that are normally exposed in the radiation beam), when the instrument is set to the "measure" condition on its most sensitive range (if the ranges are selectable). The electrostatic discharge shall be equivalent to that from a capacitor of 150 pF charged to a voltage of 6 kV and discharged through a resistor of 330 Ω (severity level 3 for contact discharge as described in IEC 61000-4-2). When instruments with insulated surfaces are tested, the air discharge method with a voltage of 8 kV (severity level 3) shall be used.

6.9.3 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 6.

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, 90, 100, 110, 120, 130, 140, 150, 160, 180, 200, 220, 240, 260, 290, 320, 350, 380, 420, 460, 510, 560, 620, 680, 750, 820, 900 and 1 000 MHz with a field strength of 10 V/m may be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in Table 6 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 6.8.3 and 6.8.4 do not apply, tests at 27 MHz shall also be performed.

6.9.4 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 6.

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.

6.9.5 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 6. The test is not to be performed on the connection lines between the IONIZATION CHAMBER 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.

6.9.6 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 6.

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

6.10 COMBINED STANDARD UNCERTAINTY

The DOSE AREA PRODUCT METER shall be designed in a way that a COMBINED STANDARD UNCERTAINTY of ±25 % (k = 2) is not exceeded.

The formalism given in IEC 60731 shall be used to determine the COMBINED STANDARD UNCERTAINTY. An example is given in Table 7.

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 standard;

– 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

The IONIZATION CHAMBER 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 complies with this standard;

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

– QUALITY EQUIVALENT FILTRATION of the IONIZATION CHAMBER;

– RATED RANGE of RADIATION QUALITIES.

Compliance shall be checked by inspection.

8 ACCOMPANYING DOCUMENTS

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

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

8.3 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 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;

– 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 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; 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 and the PATIENT.

Compliance shall be checked by inspection.

8.4 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.

Table 1 – Minimum EFFECTIVE RANGES

1a – DOSE AREA PRODUCT

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1{,}0 – 1{,}0 \cdot 10^{5})$ µGym^2
Long time fluoro	$(1{,}0 \cdot 10^{1} – 1{,}0 \cdot 10^{6})$ µGym^2
Paediatric procedures	$(1{,}0 \cdot 10^{-1} – 1{,}0 \cdot 10^{4})$ µGym^2

1b – DOSE AREA PRODUCT RATE

Application	Minimum EFFECTIVE RANGE
Standard procedures	$(1{,}0 \cdot 10^{-1} – 1{,}0 \cdot 10^{3})$ µGym^2/s
Paediatric procedures	$(1{,}0 \cdot 10^{-1} – 1{,}0 \cdot 10^{3})$ µGym^2/s [a]
[a] $(1{,}0 \cdot 10^{-2} – 1{,}0 \cdot 10^{3})$ µGym^2/s recommended	

Table 2 – 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.

Table 3 – Number of readings required to detect true differences Δ (95 % confidence level) between two sets of instrument readings

	Number of readings required, *n*							
	COEFFICIENT OF VARIATION, *v*							
Δ	< 0,5 %	0,5 %	1 %	2 %	3 %	4 %	5 %	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.

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 µGym² $K{\cdot}A \geq$ 10,0 µGym²	I = ± (10 % + 1 digit) I = ± 10 %
DOSE AREA PRODUCT RATE, $\dot{K}{\cdot}A$	$\dot{K}{\cdot}A$ < 1,0 µGym²/s $\dot{K}{\cdot}A \geq$ 1,0 µGym²/s	I = ± (10 % + 1 digit) I = ± 10 %

Table 5 – 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 µGym² $K{\cdot}A \geq$ 10,0 µGym²	5 % 2 %
DOSE AREA PRODUCT RATE, $\dot{K}{\cdot}A$	$\dot{K}{\cdot}A$ < 1,0 µGym²/s $\dot{K}{\cdot}A \geq$ 1,0 µGym²/s	5 % 2 %

Table 6 – 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)	$(1{,}0 \cdot 10^{-1} – 1{,}5 \cdot 10^{4})$ µGym²/s Paediatric procedures: $(1{,}0 \cdot 10^{-2} – 1{,}5 \cdot 10^{4})$ µGym²/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 Relative humidity	+15 – +40 °C ≤ 80 % (maximum 20 g/m³)	+20 °C 50 %	±3 %	6.7
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.

Table 7 – Example for assessment of the COMBINED STANDARD UNCERTAINTY

INFLUENCE QUANTITY or PEFORMANCE CHARACTERISTIC	Clause	± *L* in %	Relative uncertainty in %
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	5.1		10,0
COMBINED STANDARD UNCERTAINTY, k=2 [g]			24,9

[a] uniform probability distribution, symmetric limits ±*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

Bibliography

BOAG, *Ionization Chambers*, in Radiation Dosimetry, Vol. 2, 1-72, Attix, Roesch, New York, London; Academic Press, 1966

INDEX OF DEFINED TERMS

(1) defined in IEC 60788 (2) defined in IEC 60731 (3) defined in ISO: *Guide to the expression of uncertainty in measurement* (1993)

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
IEC 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A13	1990 1994 1996
		NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995.		
IEC 60601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 60601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993 1997
IEC 60731	1997	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	EN 60731	1997
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 60950 (mod) + corr. February	1999 2000	Safety of information technology equipment	EN 60950	2000
IEC 61000-4-2	1995	Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995
IEC 61000-4-3 (mod)	1995	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-4	1995	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995

Publication	Year	Title	EN/HD	Year
IEC 61000-4-5	1995	Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-11	1994	Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	1994
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995
ICRU 60	1998	International Commission on Radiation Units and Measurements, Fundamental Quantities and Units for Ionizing Radiation, Report 60	-	-
ISO	1993	International Vocabulary of basic and general terms in metrology	-	-
ISO Guide	1993	Guide to the expression of uncertainty in measurement	-	-

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