

Medical electrical equipment — Dosimeters with ionization chambers as used in radiotherapy

The European Standard EN 60731:1997, with the incorporation of amendment A1:2002, has the status of a British Standard

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National foreword

This British Standard is the English language version of EN 60731:1997, including amendment A1:2002. It is identical with IEC 60731:1997, including amendment 1:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, previously designated to Technical Committee CH/83, Dosimeters (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;
- monitor related international and European developments and promulgate them in the UK.

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

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Summary of pages

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Medical electrical equipment — Dosimeters with ionization chambers as used in radiotherapy

(includes amendment A1:2002)

(IEC 60731:1997 + A1:2002)

Appareils électromédicaux —
Dosimètres à chambre d'ionisation utilisés en
radiothérapie
(inclut l'amendement A1:2002)
(CEI 60731:1997 + A1:2002)

Elektromedizinische Geräte —
Dosimeter mit Ionisationskammern zur
Verwendung in der Strahlentherapie
(enthält Änderung A1:2002)
(IEC 60731:1997 + A1:2002)

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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/170/FDIS, future edition 2 of IEC 60731, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60731 on 1997-10-01.

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Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex A and Annex ZA are normative and Annex B and Annex C are informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60731:1997 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62C/332/FDIS, future amendment 1 to IEC 60731:1997, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60731:1997 on 2002-09-01.

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- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2005-09-01

Endorsement notice

The text of amendment 1:2002 to the International Standard IEC 60731:1997 was approved by CENELEC as an amendment to the European Standard without any modification.

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Introduction

This International Standard is applicable to the performance of DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy.

The effectiveness of treatment of PATIENTS receiving radiotherapy depends on the accuracy of the dose of radiation received; an excessive dose can lead to excessive tissue damage, while an insufficient dose will not provide the therapeutic benefit sought. The equipment covered by this standard plays an essential part in achieving the required accuracy.

This standard is not concerned with the safety aspects of DOSIMETERS. The relevant IEC standards covering safety depend upon the way in which the DOSIMETER is used:

- if it is used in physical contact with a PATIENT the particular requirements for safety applying to DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy are contained in IEC 60601-2-9. These requirements supplement the general requirements for safety of MEDICAL ELECTRICAL EQUIPMENT given in IEC 60601-1 (1988), amendment 1 (1991) and amendment 2 (1995);
- if it is not used in physical contact with a PATIENT, then the safety requirements for DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy are contained in IEC 61010-1 (1990).

DOSIMETERS which comply with this standard should nevertheless be used in accordance with the relevant national or international dosimetry protocol (code of practice). In particular, measurements should be made to determine the ion collection efficiency and polarity effect of the CHAMBER under the exact conditions of use.

1 Scope and object

1.1 Scope

1.1.1 This International Standard specifies the performance requirements of RADIOTHERAPY DOSIMETERS, as defined in **3.1**, intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA (and their RATES) in photon or electron radiation fields as used in radiotherapy.

NOTE Throughout this standard:

- if no material is specified, the term “ABSORBED DOSE” or “DOSE” means “ABSORBED DOSE TO WATER (in water)” and the term “KERMA” means “AIR KERMA (in air)”;
- when the quantity “AIR KERMA (in air)” in units “Gy” is used, the quantity “EXPOSURE” in units “C/kg” is also allowable.

1.1.2 The dose-monitoring systems incorporated in radiotherapy treatment machines are not covered by this standard, neither are the re-entrant ion chambers used for brachytherapy source calibration.

1.1.3 This standard is applicable to the following types of DOSIMETER:

- a) FIELD-CLASS DOSIMETERS normally used for:
 - 1) the measurement of KERMA or DOSE in a radiation beam, either in air or in a PHANTOM;
 - 2) *in vivo* skin surface or intracavitary measurements of DOSE on PATIENTS;
- b) REFERENCE-CLASS DOSIMETERS normally used for the calibration of FIELD-CLASS DOSIMETERS.

NOTE REFERENCE-CLASS DOSIMETERS may be used as FIELD-CLASS DOSIMETERS.

1.2 Object

1.2.1 The object of this standard is:

- a) to establish requirements for a satisfactory level of performance for RADIOTHERAPY DOSIMETERS;
- b) to standardize methods for the determination of compliance with this level of performance.

1.2.2 Two levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSIMETERS;
- a higher level of performance applying to REFERENCE-CLASS DOSIMETERS.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and 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. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60051, *Direct acting indicating analogue electrical measuring instruments and their accessories*.

IEC 60417:1973, *Graphical symbols for use on equipment — Index, survey and compilation of the single sheets*.

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

IEC 60601-2-9:1987, *Medical electrical equipment — Part 2: Particular requirements for the safety of dosimeters used in radiotherapy with electrically-connected radiation detectors*.

IEC 60788:1984, *Medical radiology — Terminology*.

IEC 61000-4-1:1992, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 1: Overview of immunity tests — Basic EMC Publication*.

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge requirements — Basic EMC Publication*.

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 3: Radiated electromagnetic field requirements*.

IEC 61000-4-4:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 4: Electrical fast transient/burst requirements — Basic EMC Publication*.

IEC 61000-4-5:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 5: Surge immunity requirements*.

IEC 61000-4-6:1996, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 6: Conducted disturbances induced by radio frequency fields above 9 kHz*.

IEC 61000-4-11:1994, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 11: Voltage dips, short interruptions and voltage variation immunity tests*.

IEC 61010-1:1990, *Safety requirements for electrical equipment for measurement control, and laboratory use — Part 1: General requirements*.

IEC 61187:1993, *Electrical and electronic measuring equipment — Documentation*.

ISO 1993, *International Vocabulary of basic and general terms in metrology*.

ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*.

ICRU 33:1980, *Radiation Quantities and Units*.

3 Terminology and definitions

In this standard, the verbal form:

- “shall” implies that compliance with a requirement is mandatory for compliance with the standard;
- “should” implies that compliance with a requirement is strongly recommended but is not 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 standard are generally in agreement with those in IEC 60788 and ISO International vocabulary of basic and general terms in metrology, except that some definitions have been made more restricted. Any such special definitions shall be regarded as applying only to this standard.

Any terms not defined here in this clause have the meanings defined in the above publications or are assumed to be in general scientific usage.

The defined terms are printed in SMALL CAPITALS throughout this standard.

For the purpose of this International Standard the following definitions apply.

3.1

(RADIOTHERAPY) DOSIMETER

equipment which uses IONIZATION CHAMBERS for the measurement of AIR KERMA, ABSORBED DOSE, or the corresponding rates, in photon and electron radiation as used in radiation therapy

a RADIOTHERAPY DOSIMETER contains the following components:

- one or more CHAMBER ASSEMBLIES;
- a MEASURING ASSEMBLY (including possibly a separate display device);
- one or more STABILITY CHECK DEVICES (optional);
- one or more PHANTOMS or build-up caps (optional)

3.1.1

CHAMBER ASSEMBLY

the IONIZATION CHAMBER and all other parts to which the CHAMBER is permanently attached, except the MEASURING ASSEMBLY. It includes the electrical fitting and any permanently attached cable

3.1.1.1

(IONIZATION) CHAMBER

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

NOTE For this standard, the IONIZATION CHAMBER is considered to consist of the measuring volume, the collecting electrode, the guard electrode (if any), the outer electrode (which consists of the CHAMBER wall and possibly a conducting coating), those parts of the insulator adjacent to the measuring volume, the build-up cap and water-proof housing (if any).

there are several categories of IONIZATION CHAMBER:

- a) SHELL CHAMBER: An IONIZATION CHAMBER with a measuring volume of between $0,1 \text{ cm}^3$ and $1,0 \text{ cm}^3$ bounded by a rigid outer electrode mounted on a supporting stem. The measuring volume is usually symmetrical about the axis of the stem and the CHAMBER is intended to be used with the axis of symmetry perpendicular to the axis of the radiation beam. There are two types of SHELL CHAMBER:
 - 1) THIMBLE CHAMBER: The outer electrode takes the form of a rigid cylindrical wall closed at one end and mounted at the other on the supporting stem;
 - 2) SPHERICAL CHAMBER: The outer electrode takes the form of a rigid spherical wall mounted on the supporting stem;
- b) PARALLEL-PLATE CHAMBER: An IONIZATION CHAMBER with a measuring volume of between $0,01 \text{ cm}^3$ and $0,5 \text{ cm}^3$ bounded by parallel electrodes. The CHAMBER is intended to be used with the electrodes perpendicular to the axis of the radiation beam;
- c) VENTED CHAMBER: An IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere such that corrections to the RESPONSE for changes in air density need to be made;
- d) SEALED CHAMBER: An IONIZATION CHAMBER constructed in such a way as to restrict the pathway between the air inside the measuring volume and the atmosphere sufficiently to ensure that the RESPONSE of the CHAMBER is independent of changes in ambient conditions over a period of time stated by the MANUFACTURER;
- e) UNGUARDED IONIZATION CHAMBER: An IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor terminates in the cable and does not extend into the stem or body of the CHAMBER ASSEMBLY;
- f) PARTIALLY GUARDED IONIZATION CHAMBER: An IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor extends well into the stem or body of the CHAMBER ASSEMBLY but does not enter the air in the CHAMBER;
- g) GUARDED IONIZATION CHAMBER: An IONIZATION CHAMBER in which the guard conductor in the stem or body of the CHAMBER ASSEMBLY is continuous with a guard electrode that is in contact with the air inside the CHAMBER

3.1.2

MEASURING ASSEMBLY

a device to measure the charge (or current) from the IONIZATION CHAMBER and convert it into a form suitable for displaying the values of DOSE or KERMA (or their corresponding rates)

3.1.3

STABILITY CHECK DEVICE

a device which enables the stability of RESPONSE of the MEASURING ASSEMBLY and/or CHAMBER ASSEMBLY to be checked

NOTE The STABILITY CHECK DEVICE may be a purely electrical device, or a radiation source, or it may include both.

3.2

INDICATED VALUE

the 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

NOTE The INDICATED VALUE is equivalent to the “uncorrected observations” shown in Figure 1.

3.3

TRUE VALUE

the value of the physical quantity to be measured by an instrument

NOTE The TRUE VALUE is equivalent to the “value of measurand” shown in Figure 1.

3.4

CONVENTIONAL TRUE VALUE

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

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

NOTE 2 The possible bounds within which the CONVENTIONAL TRUE VALUE will lie are equivalent to the “values of measurand due to incomplete definition” shown in Figure 1.

3.4.1

STANDARD

an instrument which defines, represents physically, maintains or reproduces the unit of measurement of a quantity (or a multiple or submultiple of that unit) in order to transfer it to other instruments by comparison

3.4.1.1

NATIONAL STANDARD

a STANDARD recognized by an official national decision as the basis for fixing the value in that country of all other STANDARDS of the given quantity

3.4.1.2

WORKING STANDARD

a STANDARD which is traceable to the NATIONAL STANDARD

3.5**MEASURED VALUE**

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

NOTE The MEASURED VALUE is the “final result of measurement” shown in Figure 1.

3.5.1**ERROR OF MEASUREMENT**

the difference remaining between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

3.5.2**OVERALL UNCERTAINTY**

uncertainty associated with the MEASURED VALUE, i.e. it represents the bounds within which the ERROR OF MEASUREMENT is estimated to lie

NOTE For the purpose of this standard the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a confidence level of 95 % (see Annex A).

3.5.3**EXPANDED UNCERTAINTY**

defined in A.2.1

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

3.7**INFLUENCE QUANTITY**

any external quantity that may affect the performance of an instrument (see Table 3 for examples of INFLUENCE QUANTITIES)

3.8**INSTRUMENT PARAMETER**

any internal property of an instrument that may affect the performance of this instrument (see Table 3 for examples of INSTRUMENT PARAMETERS)

3.9**REFERENCE VALUE**

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

3.9.1**REFERENCE CONDITIONS**

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

3.10**STANDARD TEST VALUES**

a 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

3.10.1**STANDARD TEST CONDITIONS**

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

3.11

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

3.11.1

RELATIVE INTRINSIC ERROR

the ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

3.12

PERFORMANCE CHARACTERISTIC

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

3.12.1

RESPONSE

for a CHAMBER ASSEMBLY with an associated MEASURING ASSEMBLY it is the quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the IONIZATION CHAMBER

for a MEASURING ASSEMBLY on its own it is the quotient of the INDICATED VALUE divided by the input charge or current

for an IONIZATION CHAMBER on its own it is the quotient of the ionization charge or current divided by the CONVENTIONAL TRUE VALUE

3.12.1.1

SPECIFIED ENERGY RESPONSE

this is the RESPONSE of an IONIZATION CHAMBER calculated or measured for that type of CHAMBER as a function of radiation quality

3.12.2

RESOLUTION (of the display)

the 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

3.12.3

EQUILIBRATION 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 an INFLUENCE QUANTITY has been applied to the instrument

3.12.4

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

3.12.5

STABILIZATION TIME

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

3.12.6

(CHAMBER ASSEMBLY) LEAKAGE CURRENT

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

NOTE It is distinguished from ZERO DRIFT or ZERO SHIFT which arise in the MEASURING ASSEMBLY.

3.12.7**(MEASURING ASSEMBLY) ZERO DRIFT**

a continuous change in the near zero scale reading of the MEASURING ASSEMBLY in the “measure” condition with no signal present

3.12.8**(MEASURING ASSEMBLY) ZERO SHIFT**

a sudden change in the near zero scale reading of the MEASURING ASSEMBLY when the setting control is changed from the “zero” condition to the “measure” condition, with no signal present

3.12.9**NON-LINEARITY**

deviation from linearity, quantified as follows: on each range the half full scale reading M is taken as a reference; the input signal Q required to produce this REFERENCE SCALE READING is measured. At another scale reading m produced by an input signal q , the percentage deviation from linearity is given by:

$$100 \cdot [(m \cdot Q / M \cdot q) - 1]$$

NOTE 1 For a MEASURING ASSEMBLY set to the “DOSE” mode, the input signal is electric charge.

NOTE 2 For a MEASURING ASSEMBLY set to the “DOSE RATE” mode, the input signal is electric current.

3.13**VARIATION**

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

3.14**LIMITS OF VARIATION**

the 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 $+L$ %

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

the 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 not directly indicated by the instrument e.g. input current

NOTE Referred to as EFFECTIVE RANGE in this standard.

3.16**RATED RANGE (of USE)**

the 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

NOTE Referred to as RATED RANGE in this standard.

3.16.1**MINIMUM RATED RANGE**

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

3.17**REFERENCE POINT (of a CHAMBER)**

point of an IONIZATION CHAMBER, which during the calibration of the CHAMBER, is brought to coincidence with the point at which the CONVENTIONAL TRUE VALUE is specified

3.18

(MEDICAL ELECTRICAL) EQUIPMENT

electrical equipment, provided with not more than one connection to a particular SUPPLY MAINS and intended to diagnose, treat, or monitor the PATIENT under medical supervision and which makes physical or electrical contact with the PATIENT and/or transfers energy to or from the PATIENT and/or detects such energy transfer to or from the PATIENT (IEC 60601-1, **2.2.15**)

3.18.1

SUPPLY MAINS

permanently installed power source which may also be used to supply electrical apparatus that is outside the scope of this standard (IEC 60601-1, **2.12.10**)

3.18.2

PATIENT

living being (person or animal) undergoing medical investigation or dental treatment (IEC 60601-1, **2.12.4**)

3.18.3

ACCESSIBLE METAL PART

metal part of EQUIPMENT which can be touched without the use of a TOOL (IEC 60601-1, **2.1.2**)

3.18.4

TOOL

extra-corporeal object which may be used to secure or release fasteners or to make adjustments (IEC 60601-1, **2.12.12**)

3.19

CALIBRATION FACTOR

for a CHAMBER ASSEMBLY with an associated MEASURING ASSEMBLY it is the factor which converts the INDICATED VALUE, corrected to stated REFERENCE CONDITIONS, to the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the IONIZATION CHAMBER

for an IONIZATION CHAMBER calibrated on its own without a specified MEASURING ASSEMBLY, the CALIBRATION FACTOR converts the ionization charge or current, corrected to REFERENCE CONDITIONS, to the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the CHAMBER (this is the reciprocal of RESPONSE under REFERENCE CONDITIONS)

3.20

REFERENCE INDICATED VALUE

the INDICATED VALUE at which the CALIBRATION FACTOR of an instrument is determined

3.21

REFERENCE SCALE READING

the scale reading corresponding to the REFERENCE INDICATED VALUE

3.22

FIELD-CLASS DOSIMETER

DOSIMETER whose performance and stability are sufficient for it to be used to make ordinary routine measurements

3.23

REFERENCE-CLASS DOSIMETER

DOSIMETER whose performance and stability are sufficient for it to be used to calibrate other DOSIMETERS

3.24

TYPE TEST

test normally carried out on a single instrument of each design

NOTE The purpose of the TYPE TEST is to verify whether or not the design of the instrument renders it capable of meeting the requirements of the specification.

3.25

ROUTINE TEST

test carried out on all instruments of a production or delivery batch

3.26**ABSORBED DOSE TO WATER**

letter symbol $\bar{D}$. Following the definition in C.4 of ICRU 33, ABSORBED DOSE TO WATER is the quotient of $d\bar{\epsilon}$ by dm where $d\bar{\epsilon}$ is the mean energy imparted by IONIZING RADIATION to water of mass dm . The unit of ABSORBED DOSE TO WATER is Gy (where $1 \text{ Gy} = 1 \text{ J}\cdot\text{kg}^{-1}$)

3.26.1**ABSORBED DOSE RATE TO WATER**

letter symbol $\dot{\bar{D}}$. Following the definition in C.5 of ICRU 33 ABSORBED DOSE RATE TO WATER is the quotient of $d\bar{D}$ by dt , where $d\bar{D}$ is the increment of ABSORBED DOSE TO WATER in the time interval dt . The unit of ABSORBED DOSE RATE TO WATER is $\text{Gy}\cdot\text{s}^{-1}$ ($\text{Gy}\cdot\text{min}^{-1}$; $\text{Gy}\cdot\text{h}^{-1}$)

3.27**AIR KERMA**

letter symbol K . Following the definition in C.6 of ICRU 33 AIR KERMA is the quotient of dE_{tr} by dm where dE_{tr} is the sum of the initial kinetic energies of all the charged ionising particles liberated by uncharged ionising particles in air of mass dm . The unit of AIR KERMA is Gy (where $1 \text{ Gy} = 1 \text{ J}\cdot\text{kg}^{-1}$)

3.27.1**AIR KERMA RATE**

letter symbol $\dot{K}$. Following the definition in C.7 of ICRU 33 AIR KERMA RATE is the quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt . The unit of AIR KERMA RATE is $\text{Gy}\cdot\text{s}^{-1}$ ($\text{Gy}\cdot\text{min}^{-1}$; $\text{Gy}\cdot\text{h}^{-1}$)

3.28**EXPOSURE**

letter symbol X . Following the definition in C.8 of ICRU 33 EXPOSURE is the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in air of mass dm are completely stopped in air. The unit of EXPOSURE is $\text{C}\cdot\text{kg}^{-1}$

3.28.1**EXPOSURE RATE**

letter symbol $\dot{X}$. Following the definition in C.9 of ICRU 33 EXPOSURE RATE is the quotient of dX by dt , where dX is the increment of EXPOSURE in the time interval dt . The unit of EXPOSURE RATE is $\text{C}\cdot\text{kg}^{-1}\cdot\text{s}^{-1}$ ($\text{C}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$; $\text{C}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$)

3.29**ACCOMPANYING DOCUMENTS**

documents provided with an installation, equipment, ASSOCIATED EQUIPMENT or ACCESSORY and containing important information for the assembler, installer and USER, particularly regarding safety (IEC 60788, rm-82-01)

3.29.1**INSTRUCTIONS FOR USE**

those parts of the ACCOMPANYING DOCUMENTS giving the necessary information for safe and proper use and operation of the equipment (IEC 60788, rm-82-02)

3.29.2**USER**

when used in an IEC standard on electromedical equipment, organization or individual responsible for the use and maintenance of the equipment (IEC 60788, rm-85-01)

3.30**OPERATOR**

person utilizing an equipment individually with or without the aid of an assistant, who controls some or all functions of the equipment in his presence. (IEC 60788, rm-85-02)

3.31**MANUFACTURER**

listed in rm-85-03 of IEC 60788 as a "Term without definition"

4 General requirements

4.1 Performance requirements

For a complete DOSIMETER to comply with this standard, each of its components shall comply with the individual requirements in the appropriate clauses or subclauses in addition to the general requirements. The MANUFACTURER shall state whether a TYPE TEST or a ROUTINE TEST was used for a particular parameter.

For equipment which does not fulfil all the requirements of this standard, information shall be provided about those clauses with which it does not comply.

The performance requirements to be met

- for the CHAMBER ASSEMBLY are given in Clause 5;
- for the MEASURING ASSEMBLY are given in Clause 6;
- for the STABILITY CHECK DEVICE are given in Clause 7.

4.2 REFERENCE VALUES and STANDARD TEST VALUES

The MANUFACTURER shall state, either in the INSTRUCTIONS FOR USE, or on the test sheets, the REFERENCE VALUE of each of the INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS as listed in Table 1.

For those INFLUENCE QUANTITIES that can be controlled:

- a) the REFERENCE VALUE shall be the value customarily used during the radiation calibration of the equipment;
- b) the STANDARD TEST VALUE shall be the REFERENCE VALUE.

4.3 General test conditions and methods

4.3.1 STANDARD TEST CONDITIONS

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

- a) for the INFLUENCE QUANTITY under investigation;
- b) where local conditions of temperature and relative humidity are outside the STANDARD TEST CONDITIONS. In this case, the tester shall justify the validity of the test results.

4.3.2 Test of components

4.3.2.1 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.

4.3.2.2 Any tests may be carried out using the complete DOSIMETER, in particular this is the preferred method for investigating the effects of radio-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 a VARIATION lies in the CHAMBER ASSEMBLY 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.

4.3.2.3 When a CHAMBER ASSEMBLY and a MEASURING ASSEMBLY are tested separately, but supplied as a system, the two components shall be connected and the combined equipment shall have a measured overall RESPONSE within $\pm 0,5$ % of the overall RESPONSE calculated from the RESPONSES of the separate assemblies.

4.3.3 *RATED or EFFECTIVE RANGE of DOSE (or KERMA) RATES*

NOTE In the case of DOSE (or KERMA) measurements, the DOSE RATE (or KERMA RATE) can be regarded as an INFLUENCE QUANTITY. In this case, the term RATED RANGE of DOSE RATE (or KERMA RATE) is applicable.

In the case of DOSE RATE (or KERMA RATE) measurements, this quantity is an INDICATED VALUE. In this case, the term EFFECTIVE RANGE of DOSE RATE (or KERMA RATE) is used.

4.3.3.1 When a CHAMBER ASSEMBLY is tested separately, the RATED or EFFECTIVE RANGE of DOSE (or KERMA) RATES shall fulfil the appropriate requirements in Clause 5.

4.3.3.2 When a MEASURING ASSEMBLY is tested separately, the equivalent parameter is determined as the RATED or EFFECTIVE RANGE of input currents and this shall fulfil the appropriate requirements in Clause 6.

4.3.3.3 When however, by choice or necessity, the CHAMBER and MEASURING ASSEMBLIES are tested together, the RATED or EFFECTIVE RANGE of DOSE (or KERMA) RATES shall fulfil the relevant requirements in both Clause 5 and Clause 6.

4.3.4 *Uncertainty of measurement*

When measurements of VARIATION are made to verify that an equipment complies with specified LIMITS OF VARIATION, the OVERALL UNCERTAINTY of these measurements of VARIATION should be negligible compared with the specified LIMITS OF VARIATION.

If this is not possible, the OVERALL UNCERTAINTY of the measurement of VARIATION shall be taken into account in the evaluation of the equipment under test by adding the OVERALL UNCERTAINTY to the LIMITS OF VARIATION allowed.

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

NOTE For the purpose of this standard the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a confidence level of 95 % (see Annex A).

4.3.5 *Adjustments during test*

Compliance tests shall be performed with the instrument ready for use (including accessories if any), after the STABILIZATION TIME and after making preliminary adjustments as necessary. During tests, adjustments may be repeated at intervals as long as such an adjustment does not interfere with the effect to be verified. For example, the zero setting may be adjusted whenever necessary except during tests for measuring ZERO DRIFT and ZERO SHIFT.

4.3.6 *Test conditions particular to CHAMBER ASSEMBLIES*

When testing compliance with the performance requirements in Clause 5 (except for those in 5.1.1, 5.1.3 and 5.1.9) the polarizing voltage may be applied to the CHAMBER for 1 h before taking a measurement.

4.3.7 *Test conditions particular to MEASURING ASSEMBLIES*

4.3.7.1 Tests on the effect of electromagnetic fields and electrostatic discharges shall be made with the type of CHAMBER ASSEMBLY normally supplied connected to the input of the MEASURING ASSEMBLY.

4.3.7.2 Tests on ZERO DRIFT and ZERO SHIFT shall be made with the input of the MEASURING ASSEMBLY disconnected and shielded with a conducting grounded (earthed) screen, for example a metal dust cap.

4.3.7.3 Unless otherwise specified in the detailed instructions for testing, all other tests shall be made with a source of either electric charge or current connected to the input of the MEASURING ASSEMBLY as follows.

a) Measurements on DOSIMETERS shall be made with a charge source connected to the input. This circuit shall be able to inject variable accurately known discrete amounts of charge to the input either:

- 1) by charging or discharging a capacitor through a resistor (to limit the peak current to less than the maximum RATED input current; or
- 2) by applying a constant current for a known time (where this constant current is less than the maximum RATED input current).

The output of this charge source shall have been calibrated before use and be traceable to a national standard (either directly to a charge STANDARD or indirectly to voltage and capacitance STANDARDS or to voltage, resistance and time STANDARDS).

b) Measurements on DOSE RATE meters shall be made with a current source connected to the input. This circuit shall be able to inject variable accurately known constant currents to the input.

The output of this current source shall have been calibrated before use and be traceable to a national standard (either directly to a current STANDARD or indirectly to voltage and resistance STANDARDS).

NOTE 1 If tests are being made on a DOSIMETER/DOSE RATE meter with signal/guard input terminals which are at the polarizing voltage away from ground (earth) then the output circuit of the charge or current source will need to be "floating";

NOTE 2 The output circuit of the charge source needs to have a sufficiently high impedance so as not to cause a measurable increase in ZERO DRIFT or charge leakage;

NOTE 3 The output circuit of the current source should not influence the measured current. Some electrometers have FET protecting input resistors which may influence the current from non-IONIZATION CHAMBER type current sources.

4.3.8 Test conditions particular to STABILITY CHECK DEVICES

When testing compliance with the performance requirements in Clause 7, the reference MEASURING ASSEMBLY used shall be either that type intended to be checked by the STABILITY CHECK DEVICE or another instrument of equivalent or superior performance.

Additionally, in the case of an overall STABILITY CHECK DEVICE the reference CHAMBER ASSEMBLY used shall be one of a type intended to be checked by the STABILITY CHECK DEVICE.

4.3.9 Use of STABILITY CHECK DEVICES

Wherever a test method suggests the use of a STABILITY CHECK DEVICE but a suitable STABILITY CHECK DEVICE is not available, then it is permissible to use an external caesium-137 or cobalt-60 GAMMA RADIATION beam together with a reliable method for positioning the IONIZATION CHAMBER in a reproducible field.

4.4 Summary tables

Table 1 summarizes the REFERENCE and STANDARD TEST VALUES.

Table 2 summarizes the performance requirements (for FIELD-CLASS DOSIMETERS) under STANDARD TEST CONDITIONS.

Table 3 summarizes the RATED RANGES of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS and the specified LIMITS OF VARIATION for FIELD-CLASS DOSIMETERS of the PERFORMANCE CHARACTERISTICS affected.

The tables do not give the complete detail which is given in Clause 5 and Clause 6.

Table 1 — REFERENCE CONDITIONS and STANDARD TEST CONDITIONS**Table 1a) — CHAMBER ASSEMBLY**

INFLUENCE QUANTITY or INSTRUMENT PARAMETER	REFERENCE VALUES	STANDARD TEST VALUES
ALL IONIZATION CHAMBERS		
Field size	As at calibration	REFERENCE VALUE
CHAMBER orientation	As at calibration	REFERENCE VALUE
Source-CHAMBER distance	As at calibration	REFERENCE VALUE
Depth of CHAMBER in PHANTOM (g/cm ²)	As at calibration	REFERENCE VALUE
Source to PHANTOM distance	As at calibration	REFERENCE VALUE
Material of PHANTOM	As at calibration	Reference material
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
Ambient pressure	101,3 kPa	Atmospheric pressure
External fields	Zero	So small as not to affect the reading
STRAY RADIATION in X-ray room	Zero	As small as possible
DOSE RATE	As at calibration	EFFECTIVE RANGE
Polarizing voltage	Stated by the MANUFACTURER	REFERENCE VALUE ±10 %
STABILIZATION TIME	1 h after switch-on	>15 min after switch-on
SHELL CHAMBERS		
Radiation quality:		
— X-radiation in free air	1,8 mm Cu HVL	REFERENCE VALUE
— X- and γ-radiation in free air	⁶⁰ Co	REFERENCE VALUE
— X- and γ-radiation in PHANTOM	⁶⁰ Co	REFERENCE VALUE
— high-energy X- and γ-radiation	⁶⁰ Co	REFERENCE VALUE
— electrons	⁶⁰ Co or electrons as at calibration	REFERENCE VALUE
PARALLEL-PLATE CHAMBERS		
Radiation quality:		
— X-radiation	0,36 mm Al HVL, Tungsten anode	REFERENCE VALUE
— electrons	⁶⁰ Co or electrons as at calibration	REFERENCE VALUE

Table 1b) — MEASURING ASSEMBLY

INFLUENCE QUANTITY or INSTRUMENT PARAMETER	REFERENCE VALUES	STANDARD TEST VALUES
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
STRAY RADIATION at MEASURING ASSEMBLY	Zero	<7,5 μSv/h
Battery condition	New batteries	Within useful life
Mains voltage	Nominal	Nominal ±1 %
Mains frequency	Nominal	Nominal ±1 Hz
Scale reading	As at calibration	REFERENCE SCALE READING
Range	As at calibration	Reference range
Input current	Stated by the MANUFACTURER	REFERENCE VALUE
Operating position	Stated by the MANUFACTURER	Reference position
STABILIZATION TIME	1 h after switch-on	>15 min after switch-on

Table 2 — Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS**Table 2a) — CHAMBER ASSEMBLY**

PERFORMANCE CHARACTERISTICS	Limits	Subclause
LEAKAGE CURRENT	$\pm 0,5 \%$ ¹⁾	5.1.1
Long-term stability	$\pm 1,0 \%$ ²⁾	5.1.2.1
Accumulated DOSE stability	$\pm 1,0 \%$ ³⁾	5.1.2.2
¹⁾ Of ionization current produced by minimum RATED or EFFECTIVE DOSE RATE. ²⁾ Of response per year for cobalt-60 or caesium-137 GAMMA RADIATION. ³⁾ Of response per 10 ⁴ Gy for any radiation quality in the RATED RANGE.		

Table 2b) — MEASURING ASSEMBLY

PERFORMANCE CHARACTERISTICS	Limits	Subclause
RESOLUTION	$\pm 0,5 \%$ ¹⁾	6.1.2
Repeatability	$\pm 0,5 \%$ ²⁾	6.1.3
Long-term stability	$\pm 1,0 \%$ ³⁾	6.1.4
ZERO DRIFT — DOSIMETER	$\pm 1,0 \%$ ⁴⁾	6.2.1
ZERO DRIFT — DOSE RATE METER	$\pm 1,0 \%$ ⁵⁾	6.3.1
ZERO SHIFT — DOSIMETER	$\pm 1,0 \%$ ⁶⁾	6.2.2
ZERO SHIFT — DOSE RATE METER	$\pm 1,0 \%$ ⁵⁾	6.3.2
NON-LINEARITY — DOSIMETER	$\pm 0,5 \%$ ⁷⁾	6.2.3
NON-LINEARITY — DOSE RATE METER	$\pm 1,0 \%$ ⁷⁾	6.3.3
RESPONSE TIME	< 3 s	6.3.5
¹⁾ Of minimum EFFECTIVE scale reading. ²⁾ Relative standard deviation at minimum EFFECTIVE INDICATED VALUE. ³⁾ Of RESPONSE per year to input charge or current in the RATED or EFFECTIVE RANGE. ⁴⁾ Of rate of change of INDICATED VALUE produced by minimum RATED or EFFECTIVE input current. ⁵⁾ Of the INDICATED VALUE produced by minimum RATED or EFFECTIVE input current. ⁶⁾ Of minimum EFFECTIVE INDICATED VALUE. ⁷⁾ Of RESPONSE at 0,5 full scale reading on each range.		

Table 3 — LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS

Table 3a) — CHAMBER ASSEMBLY

INFLUENCE QUANTITY OR INSTRUMENT PARAMETER	MINIMUM RATED RANGE	LIMITS OF VARIATION	Note	Subclause
ALL IONIZATION CHAMBERS				
STABILIZATION TIME	15 min to 2 h	±0,5 %	1)	5.1.3
Post-irradiation leakage	5 s after irradiation ¹¹⁾	±1,0 %	2)	5.1.4
Minimum DOSE RATE	As specified by MANUFACTURER	±0,5 %	3)	5.1.5.1
Maximum DOSE RATE	As specified by MANUFACTURER	−1,0 %	1)	5.1.5.2
MAXIMUM ABSORBED DOSE per pulse	As stated by MANUFACTURER	−1,0 %	1)	5.1.6
STRAY RADIATION effect	Specified conditions	±1,0 %	1)	5.1.7
Guard/collector insulation	±1 V ¹¹⁾	$\geq 1 \times 10^{11} \Omega$	—	5.1.8
Cable microphony	Specified conditions	±0,1 pA	—	5.1.9
Polarity of polarizing voltage	Maximum permitted positive and negative values	1,0 %	4)	5.1.10
SHELL CHAMBERS				
Radiation quality:				
— X-radiation in free air	2 mm Al to 3 mm Cu HVL (70 kV to 250 kV or 30 keV to 140 keV)	±2,0 %	5) 6)	5.2.1.1
— X- and γ -radiation in free air	1,8 mm Cu HVL to ^{60}Co (200 kV or 100 keV to 1,33 MeV)	±4,0 %	7) 6)	5.2.1.2
— X- and γ -radiation in <u>PHANTOM</u>	0,42 mm Cu HVL to ^{60}Co (140 kV or 60 keV to 1,33 MeV)	±4,0 %, or ±2,0 %	7) 6) 8) 6)	5.2.1.3
— high-energy X- and γ -radiation in <u>PHANTOM</u>	^{60}Co to 25 MV	±2,0 %	8)	5.2.1.4
— electrons in PHANTOM	9 MeV to 25 MeV	±2,0 %	8)	5.2.1.5
Field size — Stem scatter	As specified by MANUFACTURER	±1,0 %	1)	5.2.2.1
Field size — Stem leakage	As specified by MANUFACTURER	±0,5 %	1)	5.2.2.2
Orientation — Rotation	0° to 360°	±0,5 %	1)	5.2.3.1
Orientation — Tilt	±5°	±1,0 %	1)	5.2.3.2
PARALLEL-PLATE CHAMBERS				
Radiation quality:				
— X-radiation	0,05 mm Al to 2 mm Al HVL (12kV to 70kV or 8 keV to 30 keV)	±2,0 %	5) 6)	5.3.1.1
— electrons	5 MeV to 25 MeV	±1,0 %	9)	5.3.1.2
Field size	As specified by MANUFACTURER	±2,0 %	1)	5.3.2
Orientation — Tilt	±5°	±1,0 %	1)	5.3.3
VENTED CHAMBERS				
Atmospheric pressure change	±5 % to ±10 % ¹¹⁾	<10 s	10)	5.4.1
Temperature	+15 °C to +35 °C	±1,0 %	1)	5.4.2
Humidity:	—	—	—	—
— LEAKAGE CURRENT	20 % to 80 % RH (<20 g·m ^{−3})	±1,0 %	3)	5.4.3.1
— RESPONSE	20 % to 80 % RH (<20 g·m ^{−3})	±0,5 %	1)	5.4.3.2
SEALED CHAMBERS				
Atmospheric pressure change	±10 % ¹¹⁾	±1,0 %	1)	5.5.1
Temperature	+10 °C to +40 °C	±1,0 %	1)	5.5.2

1) Percentage change of RESPONSE within the RATED RANGE for the respective quantity.

2) LEAKAGE CURRENT as percentage of ionization current during previous 10 min irradiation.

3) LEAKAGE CURRENT as percentage of ionization current produced by minimum RATED or EFFECTIVE DOSE RATE.

4) Percentage change of RESPONSE caused by reversal of polarity under specified irradiation conditions, measured after stabilization of RESPONSE at each polarity.

5) Percentage change of RESPONSE for AIR KERMA over the RATED RANGE of radiation quality.

6) The MINIMUM RATED RANGE of tube voltage is expressed in kV. The MINIMUM RATED RANGE of mean energy is expressed in keV or MeV. In each case, the mean energy value given is that of a mono-energetic photon of the same HVL rather than the mean energy derived from the spectrum.

7) Percentage difference between the AIR KERMA RESPONSE at the REFERENCE radiation quality and the AIR KERMA RESPONSE at other specified radiation qualities within the RATED RANGE.

8) Percentage change of RESPONSE from a SPECIFIED ENERGY RESPONSE for ABSORBED DOSE TO WATER over the RATED RANGE of radiation quality.

9) Percentage of change of perturbation factor from unity.

10) Time required for the change in ionization current to reach 90 % of its final value.

11) This is a test parameter not a true RATED RANGE.

Table 3b) — MEASURING ASSEMBLY

INFLUENCE QUANTITY OR INSTRUMENT PARAMETER	MINIMUM RATED RANGE	LIMITS OF VARIATION	Note	Subclause
All MEASURING ASSEMBLIES				
STABILIZATION TIME	15 min to 6 h	±0,5 %	1)	6.1.5
DOSIMETERS				
Range changing	All ranges	±0,5 %	1)	6.2.4
Dead time	As specified by MANUFACTURER	±0,5 %	1)	6.2.5
Temperature: — RESPONSE	+15 °C to +35 °C	±1,0 %	1)	6.2.6
— ZERO DRIFT	+15 °C to +35 °C	±1,0 %	2)	6.2.6
Humidity: Charge leakage	20 % to 80 % RH (<20 g·m ⁻³)	±1,0 %	2)	6.2.7
STRAY RADIATION effect	0 to 0,2 mSv/h	±1,0 %	2)	6.2.8
Charge leakage	all ranges at 90 % of full scale	±0,5 %	2)	6.2.9
DOSE RATE dependence	As specified by MANUFACTURER	±0,5 %	1)	6.2.10
DOSE RATE meters				
Range changing	All ranges	±1,0 %	1)	6.3.4
Temperature: — RESPONSE	+15 °C to +35 °C	±1,0 %	1)	6.3.6
— ZERO DRIFT	+15 °C to +35 °C	±1,0 %	3)	6.3.6
— ZERO SHIFT	+15 °C to +35 °C	±1,0 %	3)	6.3.6
Humidity: — RESPONSE	20 % to 80 % RH (<20 g·m ⁻³)	±1,0 %	1)	6.3.7
— ZERO DRIFT	20 % to 80 % RH (<20 g·m ⁻³)	±1,0 %	3)	6.3.7
— ZERO SHIFT	20 % to 80 % RH (<20 g·m ⁻³)	±1,0 %	3)	6.3.7
STRAY RADIATION effect	0 to 0,2 mSv/h	±1,0 %	3)	6.3.8
Battery operated MEASURING ASSEMBLIES				
Battery condition	Useful life	±0,5 %	1)	6.4.1
Mains operated MEASURING ASSEMBLIES				
Mains voltage (static)	-12 % to +10 % of nominal	±0,5 %	1)	6.5.1
Mains voltage (VARIATION)	-12 % to +10 % of nominal in 10 s or less	±0,5 %	4)	6.5.2
¹⁾ Percentage of change of response within the EFFECTIVE RANGE of the measured quantity. ²⁾ Percentage of rate of change of INDICATED VALUE produced by minimum EFFECTIVE input current or DOSE RATE. ³⁾ Percentage of change of INDICATED VALUE produced by minimum EFFECTIVE input current or DOSE RATE. ⁴⁾ Percentage of minimum EFFECTIVE INDICATED VALUE.				

Table 3c) — CHAMBER and MEASURING ASSEMBLIES combined

INFLUENCE QUANTITY OR INSTRUMENT PARAMETER	MINIMUM RATED RANGE	LIMITS OF VARIATION	Note	Subclause
All CHAMBER AND MEASURING ASSEMBLIES				
Electrostatic discharge	As in IEC 61000-4-2	±1,0 %	1)	6.1.6.1
Radiated electromagnetic fields	As in IEC 61000-4-3	±1,0 %	1)	6.1.6.2
Conducted disturbances induced by fast transients/burst	As in IEC 61000-4-4	±1,0 %	1)	6.1.6.3
Conducted disturbances induced by surges	As in IEC 61000-4-5	±1,0 %	1)	6.1.6.4
Conducted disturbances induced by radio-frequencies	As in IEC 61000-4-6	±1,0 %	1)	6.1.6.3
Voltage dips/short interruptions	As in IEC 61000-4-11	±1,0 %	1)	6.1.6.5
¹⁾ Percentage of minimum effective scale reading.				

4.5 Classification of equipment according to LIMITS OF VARIATION

4.5.1 FIELD-CLASS DOSIMETER

A RADIOTHERAPY DOSIMETER shall be classified as FIELD-CLASS if the performance requirements listed in Table 1, Table 2 and Table 3 are met.

4.5.2 REFERENCE-CLASS DOSIMETER

A RADIOTHERAPY DOSIMETER may be classified as REFERENCE-CLASS if in addition to the performance requirements listed in Table 1, Table 2 and Table 3 being met, the more stringent requirements of not more than half the limits listed apply for all the following PERFORMANCE CHARACTERISTICS.

- CHAMBER ASSEMBLY:
 - long-term stability (see 5.1.2.1);
 - post-irradiation leakage (see 5.1.4).
- MEASURING ASSEMBLY:
 - long-term stability (see 6.1.4);
 - RESOLUTION (see 6.1.2);
 - repeatability (see 6.1.3);
 - ZERO DRIFT (see 6.2.1 and 6.3.1);
 - ZERO SHIFT (see 6.2.2 and 6.3.2).

NOTE Where two performance levels are specified for the effects of INFLUENCE QUANTITIES (or INSTRUMENT PARAMETERS), in phrases such as “LIMITS OF VARIATION shall be $\pm x$ % ($\pm y$ %)”, the first figure, $\pm x$ %, refers to a FIELD-CLASS DOSIMETER and the second figure in parentheses, ($\pm y$ %), refers to a REFERENCE-CLASS DOSIMETER.

A REFERENCE-CLASS CHAMBER shall not be a SEALED CHAMBER.

5 CHAMBER ASSEMBLY performance requirements

The general performance requirements that apply to the air-filled IONIZATION CHAMBERS normally used for radiotherapy dosimetry are given in 5.1.

The particular performance requirements for:

- THIMBLE or SPHERICAL CHAMBERS are given in 5.2;
- PARALLEL-PLATE CHAMBERS are given in 5.3;
- VENTED CHAMBERS are given in 5.4;
- SEALED CHAMBERS are given in 5.5.

NOTE This standard does not cover those other types of CHAMBERS (e.g. extrapolation, free-air, condenser) which are only very rarely used for radiotherapy dosimetry. For these types of CHAMBERS, it is recommended that the MANUFACTURER should state the RATED RANGE of radiation quality and DOSE RATE, the RATED RANGES of INFLUENCE QUANTITIES, and the LIMITS OF VARIATION of RESPONSE, leakage current or induced current within these ranges.

5.1 General performance requirements for (RADIOTHERAPY) IONIZATION CHAMBERS

5.1.1 CHAMBER ASSEMBLY LEAKAGE CURRENT *without irradiation*

The CHAMBER ASSEMBLY LEAKAGE CURRENT without irradiation, but with the maximum RATED polarizing voltage applied to the CHAMBER ASSEMBLY, shall not exceed $\pm 0,5$ % of the ionization current produced by the minimum EFFECTIVE DOSE RATE.

NOTE If a range of polarizing voltages is stated to be suitable for use with the chamber, the CHAMBER ASSEMBLY LEAKAGE CURRENT may be stated for various lower polarizing potentials.

Compliance with this performance requirement shall be checked by carrying out the test described in a) to c).

- a) Apply the maximum rated polarizing voltage to the CHAMBER ASSEMBLY and measure the CHAMBER ASSEMBLY LEAKAGE CURRENT (without irradiation) 15 min (or less), 1 h and 6 h later.*
- b) Irradiate the IONIZATION CHAMBER under REFERENCE CONDITIONS and determine the linear relationship between ionization current and DOSE RATE.*
- c) Use this relationship to express the CHAMBER ASSEMBLY LEAKAGE CURRENT as a percentage of the ionization current produced by the minimum EFFECTIVE DOSE RATE.*

5.1.2 Stability

5.1.2.1 Long-term stability

The LIMITS OF VARIATION of RESPONSE of an IONIZATION CHAMBER when irradiated in a reproducible field of cobalt-60 or caesium-137 GAMMA RADIATION shall be not greater than

- $\pm 1,0$ % over one year, for a FIELD-CLASS CHAMBER ASSEMBLY;
- $\pm 0,5$ % over one year, for a REFERENCE-CLASS CHAMBER ASSEMBLY.

NOTE 1 Over a number of years the RESPONSE of an IONIZATION CHAMBER can change owing to dimensional changes and to changes in the nature of the surfaces surrounding the measuring volume; the latter effect may also cause the energy dependence of the IONIZATION CHAMBER to change with time.

Compliance with this performance requirement shall be checked by retaining a representative CHAMBER, stored under STANDARD TEST CONDITIONS, and investigating its long-term stability, by making measurements at intervals of not more than one month under REFERENCE CONDITIONS, over a period of not less than:

- six months in the case of a FIELD-CLASS CHAMBER; or*
- one year in the case of a REFERENCE-CLASS CHAMBER.*

NOTE 2 If during this test period a trend in RESPONSE is indicated for any radiation quality in the RATED RANGE of greater than $\pm 1,0$ % per year, the MANUFACTURER should inform the users of the desirability of recalibration. The MANUFACTURER should also take steps to re-design the CHAMBER with the objective of obtaining the required long-term stability.

5.1.2.2 Accumulated DOSE stability

After the CHAMBER ASSEMBLY has been homogeneously irradiated with a DOSE of 10^4 Gy at a DOSE RATE of not greater than 0,1 Gy/s using the maximum RATED field size at any radiation quality within the RATED RANGE:

- the LIMITS OF VARIATION of RESPONSE of the IONIZATION CHAMBER due to the effect of this accumulated DOSE shall be not greater than $\pm 1,0$ %;
- the CHAMBER ASSEMBLY shall still meet the performance requirements for post-irradiation leakage (see 5.1.4), LEAKAGE CURRENT without irradiation (see 5.1.1) and STRAY RADIATION effect (see 5.1.7).

Compliance with this performance requirement shall be checked by:

- measuring the RESPONSE of the IONIZATION CHAMBER in a reproducible radiation field, at both the minimum and maximum RATED radiation qualities, before and after delivering the specified accumulated DOSE to the CHAMBER ASSEMBLY;*
- repeating the tests for post-irradiation leakage, LEAKAGE CURRENT without irradiation and STRAY RADIATION effect after delivering the specified accumulated DOSE to the CHAMBER ASSEMBLY.*

5.1.3 STABILIZATION TIME

During a period of between 15 min and 2 h after applying the polarizing voltage the LIMITS OF VARIATION of RESPONSE shall be not greater than $\pm 0,5\%$ of the RESPONSE measured 1 h after applying the polarizing voltage, for the case where the IONIZATION CHAMBER is continuously irradiated from the moment the polarizing voltage is applied.

Compliance with this performance requirement shall be checked by carrying out the test described in a) and b).

- a) Apply the polarizing voltage and irradiate the ionization chamber by placing it in a cobalt-60 or caesium-137 gamma-radiation beam, set to the reference field size at the reference dose rate.*
- b) Whilst keeping the ionization chamber continuously irradiated, measure the response approximately 15 min, 1 h and 2 h later.*

5.1.4 Post-irradiation leakage

Within 5 s after the end of a 10 min irradiation, the transient LEAKAGE CURRENT shall have decreased to $\pm 1,0\%$ ($\pm 0,5\%$) of the ionization current produced in the measuring volume during the irradiation.

NOTE This effect arises in that part of the stem insulator or cable irradiated in the radiation beam, and is a current that is produced by the radiation, continues after the radiation has ceased and commonly decreases exponentially with time.

Compliance with this performance requirement shall be checked by carrying out the test described in a) to f).

- a) Select a measuring assembly with an output signal proportional to the current measured. Connect this output to a suitable recording device (e.g. a chart recorder). The combined system shall be able to measure and record current from the chamber with a time constant of 0,5 s or less.*
- b) Position the ionization chamber in a cobalt-60 gamma radiation beam set to the maximum rated field size. The chamber reference point should be at the centre of the field and at a distance from the source at which the dose rate is the reference value.*
- c) Irradiate the ionization chamber and record the ionization current produced.*
- d) After 10 min, stop the irradiation and record the leakage current for a period of 10 s.*
- e) Read the value of the transient leakage current recorded 5 s after the irradiation ceased and calculate its magnitude as a percentage of the mean current recorded during the irradiation.*
- f) Repeat steps b) to e) inclusive, but for a dose rate near the minimum of the rated range.*

5.1.5 RATED or EFFECTIVE RANGE of DOSE RATE (continuous radiation)

5.1.5.1 Minimum RATED or EFFECTIVE DOSE RATE

The minimum RATED or EFFECTIVE DOSE RATE is the lowest DOSE RATE at which the performance requirement on the CHAMBER ASSEMBLY LEAKAGE CURRENT is met (see 5.1.1).

5.1.5.2 Maximum RATED or EFFECTIVE DOSE RATE

The maximum RATED or EFFECTIVE DOSE RATE is the highest DOSE RATE at which the performance requirement on the CHAMBER ion collection efficiency is met.

NOTE At high DOSE RATES, the RESPONSE may vary due to the following effects:

- a) ion recombination within the measuring volume which causes the ion collection efficiency to be less than 100 %;
- b) the behaviour of leakage currents across that part of the insulator that is irradiated in the radiation beam. For the purpose of this requirement, it may be assumed that if the CHAMBER ASSEMBLY complies with the requirements of stem leakage in 5.2.2.2 and for post-irradiation leakage in 5.1.4, the influence of leakage current across the insulator on DOSE RATE dependence will be insignificant.

The ion collection efficiency shall be not less than 99,0 % when the IONIZATION CHAMBER is irradiated at the maximum RATED or EFFECTIVE continuous DOSE RATE with the recommended polarizing voltage applied to the CHAMBER ASSEMBLY. This requirement shall be met for both polarities of polarizing voltage.

If a range of polarizing voltages is stated to be suitable for use with the CHAMBER, the ion collection efficiency at the maximum RATED or EFFECTIVE DOSE RATE shall be stated for various polarizing voltages.

Compliance with this performance requirement shall be checked by carrying out the test described in a) to g), separately for each polarity of polarizing voltage.

a) Ensure that the chamber assembly has been tested for stem leakage (see 5.2.2.2) and post-irradiation leakage (see 5.1.4) and use the results of these tests where necessary to isolate the value of the ion collection efficiency.

b) Whilst keeping the continuous DOSE RATE $\dot{D}_c$ constant at a convenient high value, measure the ionization current at five or more different polarizing voltages between 20 % and 100 % of the recommended polarizing voltage.

c) Plot or calculate by regression analysis $1/I_{V,c}$ against $1/V^2$ where $I_{V,c}$ is the ionization current at polarizing voltage V , when the CHAMBER is irradiated at continuous dose rate $\dot{D}_c$.

d) If a straight line results, perform the calculations described in paragraph e) to f), otherwise proceed with paragraph g).

e) Read the value of the saturation ionization current, $I_{0,c}$, in amperes, from the graph, or the regression analysis, as the value on the $1/I_{V,c}$ -axis when the line is extrapolated to $(1/V^2) = 0$.

f) For the recommended polarizing voltage V_R calculate the maximum rated or effective dose rate, $\dot{D}_{m,c}$ in Gy/min, (in continuous radiation) for which the percentage ionization collection efficiency is 99 %

$$\dot{D}_{m,c} = \frac{0,01 \cdot \dot{D}_c \cdot I_{R,c}}{I_{0,c} - I_{R,c}}$$

where $I_{R,c}$ is the ionization current at recommended polarization voltage V_R , when the CHAMBER is irradiated at continuous DOSE RATE $\dot{D}_{m,c}$.

g) If a straight line does not result, calculate in Gy/min from the numerical value:

$$\dot{D}_{m,c} = \frac{V_R^2}{4d^4}$$

where d is the distance in millimetres of the electrodes of a PARALLEL PLATE CHAMBER and V_R is in volts. For cylindrical CHAMBERS d is to be replaced by:

$$d_{cyl} = (a-b) \left[\frac{(a/b)+1}{(a/b)-1} \cdot \frac{\ln(a/b)}{2} \right]^{1/2}$$

and for SPHERICAL CHAMBERS by

$$d_{sph} = (a-b) \left[\frac{1}{3} \left(\frac{a}{b} + 1 + \frac{b}{a} \right) \right]^{1/2}$$

where a represents the radius of the outer electrode and b the radius of the inner one in millimetres.

5.1.6 Maximum RATED DOSE per pulse (pulsed radiation)

The maximum RATED DOSE per pulse is the largest DOSE per pulse for which the performance requirement on the CHAMBER ion collection efficiency is met.

The ion collection efficiency shall be not less than 99,0 % when the IONIZATION CHAMBER is irradiated at the maximum RATED DOSE per pulse (swept beam excluded) with the recommended polarizing voltage applied to the CHAMBER ASSEMBLY. This requirement shall be met for both polarities of polarizing voltage.

If a range of polarizing voltages is stated to be suitable for use with the CHAMBER, the ion collection efficiency at the maximum RATED DOSE per pulse shall be stated for various polarizing voltages.