BS EN 62467-1:2015

BSI Standards Publication

Medical electrical equipment — Dosimetric instruments as used in brachytherapy

Part 1: Instruments based on well-type ionization chambers

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National foreword

This British Standard is the UK implementation of EN 62467-1:2015. It is identical to IEC 62467-1:2009.

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

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

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English Version

Medical electrical equipment - Dosimetric instruments as used in brachytherapy - Part 1: Instruments based on well-type ionization chambers (IEC 62467-1:2009)

Appareils électromédicaux - Instruments de dosimétrie utilisés en curiethérapie - Partie 1: Instruments conçus pour les chambres d'ionisation à puits (IEC 62467-1:2009)

Medizinische elektrische Geräte - Dosimetriegeräte zur Anwendung in der Brachytherapie - Teil 1: Messgeräte mit Schachtionisationskammern (IEC 62467-1:2009)

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European Committee for Electrotechnical Standardization
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European foreword

The text of document 62C/460/FDIS, future edition 1 of IEC 62467-1, 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 approved by CENELEC as EN 62467-1:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 62467-1:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-3:2008	NOTE	Harmonized as EN 60601-1-3:2008 (not modified).
IEC 61010-1	NOTE	Harmonized as EN 61010-1.
IEC 61676:2002	NOTE	Harmonized as EN 61676:2002 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60050-393	2003	International Electrotechnical Vocabulary - Part 393: Nuclear instrumentation - Physical phenomena and basic concepts	-	-
IEC 60417	-	Graphical symbols for use on equipment	-	-
IEC 60580	2000	Medical electrical equipment - Dose area product meters	EN 60580	2000
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
-	-		+ A12	2014
IEC 60731	1997	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	-	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61187	-	Electrical and electronic measuring equipment - Documentation	EN 61187	-
IEC 61674	1997	Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging	EN 61674	1997
ISO/IEC Guide 99	2007	International vocabulary of metrology - Basic and general concepts and associated terms (VIM)	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETRIC INSTRUMENTS AS USED IN BRACHYTHERAPY –

Part 1: Instruments based on well-type ionization chambers

FOREWORD

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International Standard IEC 62467-1 has been prepared by subcommittee 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62, Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/460/FDIS	62C/468/RVD

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

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

A list of all parts of the IEC 62467 series, published under the general title *Medical electrical equipment – Dosimetric instruments as used in brachytherapy,* can be found on the IEC website.

In this standard the following print types are used: Requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, general statements and exceptions: in small roman type;

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 OR IN THE PUBLICATIONS INDICATED IN THE INDEX OF DEFINED TERMS: IN SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

The wide range of WELL-TYPE IONIZATION CHAMBER instruments currently being used for BRACHYTHERAPY sources indicates the need for a standard for uniformity in measurement and test techniques for WELL-TYPE IONIZATION CHAMBER instruments. Measurements of the output of BRACHYTHERAPY sources have distinct requirements that differ from the assay of sources used in diagnostic nuclear medicine. This translates into the requirements for the measurement devices. Many times similar instrumentation is used for both applications; however, there are tighter requirements for those instruments used for BRACHYTHERAPY sources. Such devices are composite systems consisting of an IONIZATION CHAMBER, either integrally coupled or connected to appropriate electronic circuitry that converts the ionization current to a readout, which can be converted to a quantity appropriate to the source being measured. The ionization current produced can be either read directly or as accumulated charge (current integrated over time) and then converted manually to the appropriate quantity, AIR KERMA STRENGTH (REFERENCE AIR KERMA RATE) or ABSORBED DOSE TO WATER. The principles of operation of the IONIZATION CHAMBER are well known and are not repeated here. In addition, the readout device many times also has application to therapy uses and is well known. Although this standard is written using the quantity AIR KERMA STRENGTH, the principles are the same for other quantities such as REFERENCE AIR KERMA RATE.

In principle the quantity measured is the dose volume integral from which under specified conditions the dose quantities AIR KERMA STRENGTH, REFERENCE AIR KERMA RATE, or ABSORBED DOSE TO WATER at a depth can be deduced. The signal produced by the chamber is the electrical current or charge, which is to be measured with an electrometer meeting criteria according to IEC 60731. The current or charge is converted to the dosimetric quantity of interest by means of a source type specific CALIBRATION FACTOR.

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETRIC INSTRUMENTS AS USED IN BRACHYTHERAPY –

Part 1: Instruments based on well-type ionization chambers

1 Scope and object

This part of IEC 62467 specifies the performance and some related constructional requirements of WELL-TYPE IONIZATION CHAMBERS and associated measurement apparatus, as defined in Clause 3, intended for the determination of a quantity, such as AIR KERMA STRENGTH or REFERENCE AIR KERMA RATE in photon radiation fields or ABSORBED DOSE TO WATER at a depth, in photon and beta radiation fields used in BRACHYTHERAPY, after appropriate calibration for a given type of source.

This International Standard covers the techniques for the quantification of the quantity appropriate for the BRACHYTHERAPY source under consideration. This quantity may be AIR KERMA STRENGTH or REFERENCE AIR KERMA RATE at 1 m, or ABSORBED DOSE TO WATER at a depth (e.g. 2 mm or 5 mm). Measurement of these quantities may be accomplished by a variety of WELL-TYPE IONIZATION CHAMBERS or systems currently available for this purpose. This standard applies to products intended for low dose rate, high dose rate, intravascular, both photon and beta, BRACHYTHERAPY measurements. It does not apply to instruments for nuclear medicine applications. The application of the standard is limited to instruments that incorporate WELL-TYPE IONIZATION CHAMBERS as detectors.

The intended use is the measurement of the output of radioactive, encapsulated sources for intracavitary (insertion into body cavities) or interstitial (insertion into body tissue) applications.

The object of this standard is

a) to establish requirements for a satisfactory level of performance for WELL-TYPE CHAMBER SYSTEMS, and
b) to standardize the methods for the determination of compliance with this level of performance.

This standard is not concerned with the safety aspects of WELL-TYPE CHAMBER SYSTEMS. The WELL-TYPE CHAMBER SYSTEMS covered by this standard are not intended for use in patient environment. The electrical safety of WELL-TYPE CHAMBER SYSTEMS is covered in IEC 61010-1. The operation of the electrometer measuring system is covered in IEC 60731.

2 Normative references

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

IEC 60050-393:2003, *International Electrotechnical Vocabulary – Part 393: Nuclear instrumentation – Physical phenomena and basic concepts*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60580:2003, *Medical electrical equipment – Dose area product meters*

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

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

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

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

IEC 61674:1997, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

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

3 Terms and definitions

For the purposes of this document the following definitions apply.

The definitions given in this standard are generally in agreement with those in IEC/TR 60788 and ISO/IEC Guide 99 (IVM). Any term not defined in this clause or in the relevant publications cited in the Index of defined terms has the meaning defined in IEC/TR 60788 and ISO/IEC Guide 99 or is assumed to be in general scientific usage.

3.1
absorbed dose to water
D
quotient of $\mathrm{d}\bar{\varepsilon}$ by $\mathrm{d}m$ where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by IONIZING RADIATION to water of mass $\mathrm{d}m$

NOTE 1 The unit of ABSORBED DOSE TO WATER is Gy (where 1 Gy = 1 $J \cdot kg^{-1}$).

NOTE 2 This definition is derived from the definition in C.4 of ICRU 33 (see Bibliography).

[IEC 60731:1997, definition 3.26]

3.2
air kerma strength
product of AIR KERMA RATE in free space (in vacuo) due to photons greater than a low energy cut off and the square of the distance of the calibration point from the source centre along the perpendicular bisector

NOTE 1 Energy cut-off is generally 5 keV.

NOTE 2 The unit is Gy m^2/s.

NOTE 3 In practice the unit μGy m^2/h is used frequently.

3.3
chamber assembly leakage current
leakage current
any current in the signal path arising in the CHAMBER ASSEMBLY which is not produced by ionization in the measuring volume

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

3.4
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 60731:1997, definition 3.6]

3.5
effective range
effective range of indicated values
range of INDICATED VALUES for which an instrument complies with a stated performance

NOTE 1 The maximum (minimum) EFFECTIVE INDICATED VALUE is the highest (lowest) in this range.

NOTE 2 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.

[IEC 60731:1997, definition 3.15]

3.6
equilibration time
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

[IEC 60731:1997, definition 3.12.3]

3.7
error of measurement
difference remaining between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

[IEC 60731:1997, definition 3.5.1]

3.8
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 60731:1997, definition 3.2]

3.9
influence quantity
any external quantity that may affect the performance of an instrument

[IEC 60731:1997, definition 3.7]

NOTE E.g. ambient temperature, radiation quality etc.

3.10
instrument parameter
any internal property of an instrument that may affect the performance of this instrument

[IEC 60731:1997, definition 3.8]

3.11
measured value
best estimate of the TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS and the CALIBRATION FACTOR

[IEC 60731:1997, definition 3.5]

3.12
measuring assembly
<WELL-TYPE IONIZATION CHAMBERS> device to measure the charge (or current) from the WELL-TYPE IONIZATION CHAMBER and possibly convert it into a form suitable for the quantity to be measured

3.13
overall uncertainty
uncertainty associated with the MEASURED VALUE

NOTE 1 I.e. representing the bounds within which the ERROR OF MEASUREMENT is estimated to lie.

[IEC 60731:1997, definition 3.5.2, modified]

NOTE 2 See also Clause 5.

3.14
reference air kerma rate
AIR KERMA RATE in free space (in vacuo) due to photons greater than a low energy cut off at the distance of 1 m

NOTE 1 Energy cut-off is generally 5 keV.

NOTE 2 The unit is Gy/s.

NOTE 3 In practice the unit μGy/h is used frequently.

NOTE 4 The AIR KERMA STRENGTH is numerically identical to the REFERENCE AIR KERMA RATE.

3.15
reference conditions
conditions under which all influence quantities and INSTRUMENT PARAMETERS have their REFERENCE VALUES

[IEC 60731:1997, definition 3.9.1]

3.16
reference point of a well-type chamber
point of maximum signal for a specified point source along the measuring length of a WELL-TYPE IONIZATION CHAMBER

NOTE The term reference point is often referred to as "sweet spot".

3.17
reference value
particular value of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER chosen for the purpose of reference

[IEC 60731:1997, definition 3.9, modified]

NOTE 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.

3.18
response
<WELL-TYPE IONIZATION CHAMBER> quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE of the REFERENCE AIR KERMA RATE (in 1 m distance from the source)

3.19
sealed well-type ionization chamber
a WELL-TYPE IONIZATION CHAMBER constructed in such a way as to restrict the pathway between the air inside the measuring volume and the atmosphere to insure that the RESPONSE of the chamber is independent of changes in ambient conditions over a period of time stated by the MANUFACTURER

3.20
stabilization time
time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value after the MEASURING ASSEMBLY has been switched on and the polarizing voltage has been applied to the IONIZATION CHAMBER

[IEC 60731:1997, definition 3.12.5]

3.21
standard test conditions
conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

[IEC 60731:1997, definition 3.10.1]

3.22
standard test value
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

[IEC 60731:1997, definition 3.10]

3.23
stray radiation
for IONIZING RADIATION, all radiation except that of the specified RADIATION BEAM under consideration, but including its RESIDUAL RADIATION

[IEC 60601-1-3:2008, 3.75]

3.24
true value
value of the physical quantity to be measured by an instrument

[IEC 60731:1997, definition 3.3]

3.25
usable length
length along the axis of a WELL-TYPE IONIZATION CHAMBER between the two points at which the signal for a specified point source has fallen to a specified portion of the signal at the REFERENCE POINT OF A WELL-TYPE CHAMBER

NOTE The term USABLE LENGTH is often referred to as "sweet length".

3.26
vented well-type ionization chamber
a WELL-TYPE 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

3.27
well-type chamber system
combined WELL-TYPE IONIZATION CHAMBER and MEASURING ASSEMBLY to obtain the reading which can be converted to the quantity to be measured

3.28
well-type ionization chamber
detector in which the BRACHYTHERAPY source is inserted into the IONIZATION CHAMBER

NOTE The solid angle over which a WELL-TYPE IONIZATION CHAMBER is sensitive to radiation should be of the order of 4 π, where the exact value of the solid angle is not relevant.

4 General requirements

4.1 PERFORMANCE REQUIREMENTS

Each of the components of a WELL-TYPE CHAMBER SYSTEM shall comply with the individual requirements in the appropriate clauses or subclauses in addition to the general requirements. The instruments shall be installed and operated in accordance with the MANUFACTURER's instructions.

In Clauses 5 and 6, the performance requirements are stated for a complete WELL-TYPE CHAMBER SYSTEM including both the WELL-TYPE IONIZATION CHAMBER and MEASURING ASSEMBLY. For a MEASURING ASSEMBLY designed to operate with one or more WELL-TYPE IONIZATION CHAMBERS, each combination of the WELL-TYPE CHAMBER SYSTEM shall comply with the requirements in 4.4, and in Clauses 5 and 6 relevant to this combination.

During the immunity tests for electromagnetic compatibility (see IEC 60731) BASIC SAFETY and ESSENTIAL PERFORMANCE shall be guaranteed.

ESSENTIAL PERFORMANCE is guaranteed if the limits listed in Table 2 are not exceeded during the immunity tests. ESSENTIAL PERFORMANCE is also ensured if during the immunity tests the reading of the MEASURING ASSEMBLY, or the data output, are clearly characterized as invalid, e.g. by means of a warning message or in case of a latch-up.

NOTE Examples for warning messages for invalid readings are high voltage error or overload messages.

4.2 MEASURING ASSEMBLY

The MEASURING ASSEMBLY shall conform to field class instruments of IEC 60731, unless stated otherwise.

4.3 Source types

4.3.1 General

The BRACHYTHERAPY source determines the insert used in the WELL-TYPE IONIZATION CHAMBER. For each BRACHYTHERAPY source type, the MANUFACTURER of the WELL-TYPE IONIZATION CHAMBER shall specify the insert type to be used. The tests below shall be made with the insert type specified by the MANUFACTURER of the WELL-TYPE IONIZATION CHAMBER.

4.3.2 Beta particle-emitting sources

Measurements on beta particle-emitting sources of the same radionuclide and activity will vary greatly with insert composition (for example glass versus plastic) and wall thickness. Some inserts depend on a measure of BREMSSTRAHLUNG produced by the deceleration of the beta particles in the insert material; other inserts are designed to measure the betas directly. Reproducible measurements depend upon consistent insert selection and consistency in the manner in which the instrument is used.

4.3.3 Low-energy-photon-emitting sources

The wall thickness of the insert plus the thickness of the interior wall of the WELL-TYPE IONIZATION CHAMBER may cause a significant attenuation for low-energy photons. Wide variations in wall materials and source materials may result in variations in RESPONSE.

4.4 Quantity to be measured

The following quantities are used: AIR KERMA STRENGTH in units of Gy m^2/s, ABSORBED DOSE RATE TO WATER at a specified distance from the source in units of Gy/s, REFERENCE AIR KERMA RATE in units of Gy/s.

NOTE In practice the units Gy m^2/h and Gy/h are used frequently.

4.5 Reference and STANDARD TEST CONDITIONS

The values of the reference and STANDARD TEST CONDITIONS are given in Table 1.

Table 1 – REFERENCE and STANDARD TEST CONDITIONS

INFLUENCE QUANTITY	REFERENCE VALUES	STANDARD TEST VALUES
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
Air pressure	101,3 kPa	Atmospheric pressure
STABILIZATION TIME	15 min after switch-on	≥ 15 min after switch-on
Polarizing voltage	Stated by MANUFACTURER	REFERENCE VALUE ±5 %
STRAY RADIATION	Zero	As small as possible
Saturation losses	Full saturation	≤ 1 % saturation loss
Electromagnetic fields	Zero	Insignificant

4.6 General test conditions

4.6.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS listed in Table 1 shall be met during the test procedure except

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

4.6.2 STABILIZATION TIME

Before the start of the compliance test, the instrument under test shall be switched on for at least the STABILIZATION TIME.

In addition, the WELL-TYPE IONIZATION CHAMBER should be allowed to attain thermal equilibrium with the environment and should have the polarizing voltage applied for a period of time equal to or greater than the specified STABILIZATION TIME.

4.6.3 Adjustments during test

Compliance tests shall be performed with the instrument under test 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.

4.6.4 Batteries

Battery-operated instruments under test shall be equipped with fully charged batteries, of the type specified by the MANUFACTURER, unless operating on an external power source.

4.7 Constructional requirements as related to performance

4.7.1 General

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

4.7.2 Components

If a MEASURING ASSEMBLY has several ranges or scales, all ranges, scales and components shall be unmistakably and unambiguously identified.

4.7.3 Display

4.7.3.1 Quantities of measurement

The indicated unit shall be that of the measuring quantity: AIR KERMA STRENGTH, ABSORBED DOSE TO WATER, REFERENCE AIR KERMA RATE, amperes (which can be converted to AIR KERMA STRENGTH) i.e. Gy m^2/h, or A respectively, with SI prefix e.g. m or μ.

4.7.3.2 Indication of battery condition

Battery-operated MEASURING ASSEMBLIES shall be provided with a low battery indication for any battery voltage below the RATED RANGE.

4.7.3.3 Indication of polarizing voltage failure

MEASURING ASSEMBLIES intended for use with WELL-TYPE IONIZATION CHAMBERS shall be provided with a means of indicating if the polarizing voltage does not meet the MANUFACTURER'S requirement for satisfactory operation.

4.7.4 Inserts

The MANUFACTURER shall supply inserts for the type of sources for which the WELL-TYPE IONIZATION CHAMBER is to be used. The inserts shall be constructed in a way that the source can be located at the REFERENCE POINT OF A WELL-TYPE IONIZATION CHAMBER to within ±1 mm. The MANUFACTURER shall specify for which types of sources a given insert may be used.

NOTE In some calibrations, the insert is an integral part of the calibration arrangement. Use of an alternative insert voids the calibration.

4.7.5 STABILIZATION TIME

The STABILIZATION TIME shall not be greater than 15 min.

4.8 Test of components

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

a) tests on the MEASURING ASSEMBLY shall be carried out using a current or charge source of sufficient characteristics to meet the objective of the test;

b) tests on the WELL-TYPE IONIZATION CHAMBER shall be performed using a MEASURING ASSEMBLY with sufficient characteristics to meet the objective of the test.

Some tests should be carried out using the complete WELL-TYPE CHAMBER SYSTEM. In particular, this is the preferred method for investigating the effects of radio-frequency electromagnetic fields and electrostatic discharges on a cable-connected WELL-TYPE 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 quadrate sum of the separate LIMITS OF VARIATION may be taken as an overall LIMIT OF VARIATION.

When a WELL-TYPE IONIZATION CHAMBER 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 ±0,5 % of the overall RESPONSE calculated from the RESPONSES of the separate assemblies.

5 Limits of performance characteristics

5.1 Position of source in insert and repeatability

Repetitive positioning of the source at the REFERENCE POINT OF A WELL-TYPE CHAMBER shall give a standard deviation of the readings of 1 % or less.

Compliance shall be checked by inserting the source repeatedly at least ten times and determining the standard deviation of the readings. The test shall be conducted with a source in which the radioactive material remains in a stable position, e.g. a ^{192}Ir-source.

5.2 USABLE LENGTH

The USABLE LENGTH shall be considered to be the length where the relative RESPONSE falls to 97 % of the maximum.

Compliance shall be checked by stepping a small source 5 mm or less, using the centre of the source as the point of reference) through the axis of the chamber and determining the relative RESPONSE.

5.3 RESOLUTION OF THE DISPLAY

Within the whole EFFECTIVE RANGE of INDICATED VALUES the RESOLUTION OF THE DISPLAY shall be equal to or better than 0,5 % of the reading.

Compliance with this performance requirement shall be checked by inspection.

5.4 STABILIZATION TIME

After the STABILIZATION TIME, the LIMITS OF VARIATION of RESPONSE shall be within ±0,5 % of the steady state value of the RESPONSE.

Compliance with this performance requirement shall be checked by determining the RESPONSE of the instrument under the same conditions as at calibration, after the STABILIZATION TIME and 30 min, 45 min and 1 h after the MEASURING ASSEMBLY has been switched on.

5.5 LEAKAGE CURRENT

5.5.1 In AIR KERMA STRENGTH measuring mode

On all AIR KERMA STRENGTH ranges, the LEAKAGE CURRENT of a WELL-TYPE CHAMBER SYSTEM shall not exceed 1,0 % of the current corresponding to the minimum AIR KERMA STRENGTH of the range in use for at least 1 min, after any compensation adjustment has been made.

Compliance with this performance requirement shall be checked for each allowable combination of AIR KERMA STRENGTH range and CHAMBER ASSEMBLY, by measuring the LEAKAGE CURRENT in the "measure" condition with the relevant WELL-TYPE IONIZATION CHAMBER connected.

5.5.2 In charge measuring mode

On all charge measuring ranges, when the MEASURING ASSEMBLY is left in the "measure" condition after being exposed to greater than 75 % of full scale, the INDICATED VALUE shall not change by more than 0,5 % per minute.

Compliance with this performance requirement shall be checked for each allowable combination of AIR KERMA STRENGTH range and DETECTOR ASSEMBLY, by exposing the well-type chamber detector until the display reads just below the stated full scale, then observing the rate of change of scale reading whilst keeping the MEASURING ASSEMBLY in the "measure" condition. (This is for charge measuring mode, add req. that current reading has to go down to 1,0 % of minimum AIR KERMA STRENGTH range, see 5.6.1.)

5.6 Stability

5.6.1 Long term stability

The VARIATION of RESPONSE when the WELL-TYPE IONIZATION CHAMBER is irradiated under REFERENCE CONDITIONS shall not be greater than ±1,0 % per year (chamber alone).

Compliance with this performance requirement shall be verified by retaining a representative MEASURING ASSEMBLY and CHAMBER ASSEMBLY(IES), stored under STANDARD TEST CONDITIONS, and investigating their combined long-term stability by making measurements under REFERENCE CONDITIONS at one month intervals over a period of not less than six months and then using regression analysis to extrapolate these readings to obtain the change in RESPONSE over one full year. It is permissible to perform the tests on the MEASURING and CHAMBER ASSEMBLIES separately. (Sealed chamber should be kept at a pressure different from that in the interior by at least a factor of two.)The same source shall be used. ^{137}Cs or ^{60}Co is recommended for the source.

5.6.2 MANUFACTURER method to check long term stability

The MANUFACTURER shall provide a test method as a means to check long term stability.

6 LIMITS OF VARIATION for effects of influence quantities

6.1 General

The LIMITS OF VARIATION $\pm L$ due to the effects of INFLUENCE QUANTITIES are summarized in Table 2. For any change of an INFLUENCE QUANTITY within its RATED RANGE the change of the MEASURING ASSEMBLIES RESPONSE shall not be greater than the values in column 4 of Table 2.

Table 2 – LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES

INFLUENCE QUANTITY	Minimum RATED RANGE	REFERENCE CONDITIONS	LIMITS OF VARIATION L	Sub-clause
Operating voltage mains batteries	–15 % to +10 % as stated by the MANUFACTURER	Nominal voltage	±0,5 %	6.3
Air pressure, temperature, and relative humidity	80,0 to 106,0 kPa +15 to +35°C ≤ 80 % (maximum 20 g/m^3)	101,3 kPa +20 °C 50 %	±1 % [a)]	6.4 and 6.6
Change of air pressure	±10,0 %	Atmospheric pressure	0,5 %	6.5
Electromagnetic immunity (as in IEC 60731)	As in IEC 61000-4-X	Without any disturbance	See IEC 60731	6.8

[a)] after correction

6.2 IONIZATION CHAMBER – recombination losses

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTS the AIR KERMA STRENGTH at which the ion collection efficiency of the IONIZATION CHAMBER falls to 98 % when the normal polarizing voltage is applied.

Compliance in the case of AIR KERMA STRENGTH shall be checked by irradiating the IONIZATION CHAMBER in continuous radiation at a known AIR KERMA STRENGTH and then measuring the ion collection efficiency by observing changes in the INDICATED VALUE for known changes in the polarizing voltage.

6.3 Operating voltage

6.3.1 Mains operated MEASURING ASSEMBLY

For a mains-operated MEASURING ASSEMBLY the LIMIT OF VARIATION of RESPONSE due to variation of the operating voltage between +10 % and –15 % of the nominal voltage, shall not be greater than the limit stated in Table 2, over the RATED RANGE of mains voltage, stated by the MANUFACTURER.

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

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.3.2 Battery operated MEASURING ASSEMBLY

For a battery-operated MEASURING ASSEMBLY, a low battery condition shall be indicated if the instrument is operating when the battery voltage is outside the RATED RANGE stated by the MANUFACTURER. Over this RATED RANGE of battery voltage, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 2.

Compliance with this performance requirement shall be checked as follows: the batteries shall be replaced by a stable DC. power supply producing a voltage equivalent to the voltage produced by a set of fresh batteries of the type specified by the MANUFACTURER. A set of reference readings shall be taken and the voltage decreased until the battery power indicator begins to show low battery condition. A second set of readings shall then be taken and compared with the REFERENCE VALUE.

NOTE In some instruments, connection to an external supply with a cable may compromise the instrument shield, or batteries may not be at chassis ground. In these cases, the MANUFACTURER should provide proper guidance on the test method.

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.3.3 Rechargeable MEASURING ASSEMBLY

For mains rechargeable, battery-operated MEASURING ASSEMBLY in addition to the requirements on the battery-powered MEASURING ASSEMBLY, the LIMIT OF VARIATION of RESPONSE shall not be greater than the limit stated in Table 2 when the MEASURING ASSEMBLY is operated under the following conditions or MANUFACTURER-stated operating conditions, e.g. system is not to be used when connected to charging assembly:

a) mains disconnected, battery fresh;

b) mains connected, battery fresh;

c) mains connected, battery low.

Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with the mains disconnected and a set of fresh batteries of the type specified by the MANUFACTURER fitted. The mains shall then be connected, and a second set of readings taken and compared with the reference reading. Finally, a set of used batteries, which are just spent enough to cause the low battery indication to show, shall be fitted and, with the mains connected, a third set of readings shall be taken and compared with the reference reading.

A standard, gamma-emitting radioactive source with a long half life, such as ^{137}Cs, may be used when carrying out these measurements.

6.4 Air pressure

The LIMITS OF VARIATION of RESPONSE shall not be greater than those given in Table 2 when the air pressure changes over its RATED RANGE. If a VENTED WELL-TYPE IONIZATION CHAMBER is used, 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. Note that for low energy sources an air density correction may overcorrect for vented chambers. The MANUFACTURER shall state the additional corrections to be applied. There is also a small correction for SEALED WELL-TYPE IONIZATION CHAMBERS that may or may not be ignored by the MANUFACTURER.

Compliance with this performance requirement shall be checked by making measurements at an ambient air pressure of 80,0 kPa and 106 kPa and comparing these measurements with those for the reference air pressure of 101,3 kPa. For VENTED WELL-TYPE IONIZATION CHAMBERS all readings shall be corrected for air density before this comparison is made.

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.5 Change of air pressure and EQUILIBRATION TIME of the radiation detector

6.5.1 VENTED WELL TYPE IONIZATION CHAMBERS

If the RESPONSE of the VENTED WELL TYPE IONIZATION CHAMBERS is influenced by air density, the 90 % EQUILIBRATION TIME for pressure differences (change of air pressure of 10 % within the RATED RANGE of pressure in 15 s) between the exterior and interior of the WELL-TYPE IONIZATION CHAMBER shall not be greater than 1 min of application of pressure change.

Compliance with this performance requirement shall be checked by irradiating the WELL-TYPE IONIZATION CHAMBER ASSEMBLY at constant AIR KERMA RATE, then monitoring the change with time of the electrical signal from the ASSEMBLY when the WELL-TYPE IONIZATION CHAMBER

ASSEMBLY is subjected to a sudden change in air pressure of between 8 % and 12 %. The test shall be carried out for pressure changes in both directions.

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.5.2 SEALED WELL TYPE IONIZATION CHAMBERS

These chambers shall meet the requirements in 6.4.

The LIMITS OF VARIATION of RESPONSE shall not be greater than 0,3 % after accounting for decay over a period of one year.

Compliance with this performance requirement shall be checked by investigating the long-term stability by making measurements under REFERENCE CONDITIONS at one month intervals over a period of not less than six months and then using linear regression analysis to extrapolate these readings to obtain the change in RESPONSE over one full year. It is permissible to perform the tests on the MEASURING and DETECTOR ASSEMBLIES separately.

Alternatively, compliance with this performance requirement shall be checked by observing the calibration after at least one year so that it would not change by greater than 0,5 %.

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.6 Temperature and humidity

The LIMITS OF VARIATION of the MEASURING ASSEMBLY'S RESPONSE shall not be greater than the value given in Table 2, for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity (absolute humidity not to exceed 20 g/m^3). If a VENTED WELL TYPE IONIZATION CHAMBER is used, the MEASURED VALUE shall be corrected for the air density, by manual calculation if not made by the instrument, before this requirement is met.

Compliance with this performance requirement shall be checked by carrying out the following test: the NEASURING ASSEMBLY shall be exposed to varying temperature and air humidity. 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

For VENTED WELL-TYPE IONIZATION CHAMBERS all readings shall be corrected for air density before this comparison is made if this has not been made automatically.

The WELL TYPE IONIZATION CHAMBER ASSEMBLY shall be exposed to each different temperature and humidity condition for at least 24 h before the instrument is tested.

The MANUFACTURER shall provide a test method as a means to check these measurements.

6.7 Length RESPONSE

The RESPONSE along the length of the well chamber shall be checked to verify it meets MANUFACTURER stated requirements. For train type sources with lengths greater than 1 cm,

the RESPONSE shall be flat, ±3 % over the range of the USABLE LENGTH (e.g. 100 mm). Trains longer than 90 % of the USABLE LENGTH of the chamber shall not be measured.

Compliance with this performance requirement shall be checked by employing a small source, not greater than 5 mm, that is moved through the length.

6.8 Electromagnetic immunity

The electromagnetic immunity shall be tested for WELL-TYPE CHAMBER SYSTEMS and compliance shall be shown according to the requirements on electromagnetic immunity as described in IEC 60731:1997.

Stated uncertainty is OVERALL UNCERTAINTY for all electromagnetic tests.

7 Marking

7.1 WELL-TYPE IONIZATION CHAMBER ASSEMBLY

The WELL-TYPE IONIZATION CHAMBER ASSEMBLY shall be provided with the following permanently affixed and clearly legible markings:

a) indication of origin, i.e. name and/or trade-mark of the MANUFACTURER or supplier;

b) type number and serial number, to enable the relation between separated parts of the instrument, as specified in the ACCOMPANYING DOCUMENTS, to be recognized.

Compliance shall be checked by inspection.

7.2 MEASURING ASSEMBLY

The MEASURING ASSEMBLY shall be provided with the following permanently affixed and clearly legible markings:

a) indication of origin, i.e. name and/or trade-mark of the MANUFACTURER or supplier;

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

c) RATED mains supply potential or potentials and RATED mains supply frequency or frequencies required to ensure 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.

8 ACCOMPANYING DOCUMENTS

8.1 General

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

8.2 Use of the instrument

The MANUFACTURER shall provide adequate information describing the correct use and maintenance of the instrument. The MANUFACTURER shall state the BRACHYTHERAPY sources that are intended for use and the range of strengths to be measured.

8.3 Documentation

The ACCOMPANYING DOCUMENTS shall contain a description of the WELL-TYPE IONIZATION CHAMBERS, including its type number and MANUFACTURER. In addition the ACCOMPANYING DOCUMENTS shall contain the following information applicable to each type of DETECTOR ASSEMBLY supplied:

a) dimensions of detector(s) and construction; a diagram is considered to be useful;

b) data giving typical dependence of RESPONSE on radiation quality;

c) usable length and position of the reference point of a well-type ionization chamber;

   1) EFFECTIVE RANGES of measurement and resolution in SI-units;

   2) RATED RANGE of use for atmospheric pressure;

   3) RATED RANGE of use for temperature;

   4) RATED RANGE of use for air humidity;

   NOTE If there is a pressure effect for low energy photon sources at high altitudes, which is not corrected for by the normal density air correction, the MANUFACTURER shall document this effect.

d) STABILIZATION TIME;

e) polarizing voltage;

f) dimension of USABLE LENGTH;

g) RATED RANGE of use for operating voltage and, for battery-operated instruments, typical battery life;

h) RATED RANGE of use for USABLE LENGTH; furthermore, the ACCOMPANYING DOCUMENTS shall recommend that the USER make measurements only with a USABLE LENGTH at least 5 mm greater, on each side of the USABLE LENGTH, than the minimum rated USABLE LENGTH;

i) table, diagram or formula for air density correction (if required);

j) for battery-operated MEASURING ASSEMBLIES, type of batteries required to ensure the performance of the instrument complies with Clauses 5 and 6.

The MANUFACTURER shall state the REFERENCE VALUES and STANDARD TEST VALUES in the instructions for use or in the test sheets.

Compliance shall be checked by inspection.

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