IEC 62467-1

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Dosimetric instruments as used in brachytherapy –
Part 1: Instruments based on well-type ionization chambers

Appareils électromédicaux – Instruments de dosimétrie utilisés en curiethérapie –
Partie 1: Instruments conçus pour les chambres d'ionisation à puits

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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- withdrawn,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 $d\bar{\varepsilon}$ by dm where $d\bar{\varepsilon}$ is the mean energy imparted by IONIZING RADIATION to water of mass dm

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.