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.

Published by BSI Standards Limited 2015

ISBN 978 0 580 57216 6
ICS 11.040.50; 11.040.60

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2015.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62467-1

October 2015

ICS 11.040.50; 11.040.60

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
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 62467-1:2015 E

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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*