ELEKTRILISED MEDITSIINISEADMED. BRAHHÜTERAAPIAS KASUTATAVAD DOSIMEETRILISED INSTRUMENDID. OSA 1: KAEVU-TÜÜPI IONISATSIOONIKAMBRITEL PÕHINEVAD INSTRUMENDID

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 62467-1:2015 sisaldab Euroopa standardi EN 62467-1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 62467-1:2015 consists of the English text of the European standard EN 62467-1:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.10.2015.	Date of Availability of the European standard is 23.10.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62467-1

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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)

This European Standard was approved by CENELEC on 2015-09-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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

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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

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.

CONTENTS

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.