

ELEKTRILISED MEDITSIINISEADMED. OSA 2-17:
ERINÕUDED AUTOMAATJÄRELLAADIMISEGA
BRAHHÜTERAAPIASEADMETE ESMASELE OHUTUSELE
JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-17:2015 sisaldab Euroopa standardi EN 60601-2-17:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-17:2015 consists of the English text of the European standard EN 60601-2-17:2015.
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 22.05.2015.	Date of Availability of the European standard is 22.05.2015.
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 11.040.60

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Medical electrical equipment - Part 2-17: Particular requirements
for the basic safety and essential performance of automatically-
controlled brachytherapy afterloading equipment
(IEC 60601-2-17:2013)**

Appareils électromédicaux - Partie 2-17: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils projecteurs de sources
radioactives à chargement différé automatique utilisés en
brachythérapie
(IEC 60601-2-17:2013)

Medizinische elektrische Geräte - Teil 2-17: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von ferngesteuerten,
automatisch betriebenen Afterloading-Geräten für die
Brachytherapie
(IEC 60601-2-17:2013)

This European Standard was approved by CENELEC on 2015-04-14. 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

Foreword

The text of document 62C/575/FDIS, future edition 3 of IEC 60601-2-17, 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 60601-2-17:2015.

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) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-17:2004.

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 60601-2-17:2013 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 60601-2-28:2010	NOTE	Harmonized as EN 60601-2-28:2010 (not modified).
IEC 61217:2011	NOTE	Harmonized as EN 61217:2012 (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.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition to Annex ZA of EN 60601-1:2006:</i>				
IEC 60601-1	2005	Medical electrical equipment -	EN 60601-1	2006
-	-	Part 1: General requirements for basic safety and essential performance	+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A1/AC	2014
-	-		+ A12	2014
IEC 60601-2-1	2009	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	-	-
IEC 60601-2-8	2010	Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	EN 60601-2-8	¹⁾
IEC 60601-2-11	2013	Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	EN 60601-2-11	2015
IEC 61005 (mod)	2003	Radiation protection instrumentation - Neutron ambient dose equivalent (rate) meters	EN 61005	2004

1) To be published.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 62083	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	EN 62083	2009
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions	10
201.4 General requirements.....	12
201.5 General requirements for testing ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	12
201.7 ME EQUIPMENT identification, marking and documents.....	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	18
201.10 Protection against unwanted and excessive radiation HAZARDS.....	18
201.11 Protection against excessive temperatures and other HAZARDS.....	37
201.12 Accuracy of controls and instruments and protection against hazardous outputs	37
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	40
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	40
201.15 Construction of ME EQUIPMENT	40
201.16 ME SYSTEMS.....	40
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	40
Annex A (informative) General guidance and rationale.....	41
Bibliography.....	42
Index of defined terms used in this particular standard.....	43
Table 201.101 – Colours of lights and their meanings	14

INTRODUCTION

The delivery of RADIOTHERAPY over short distances is called BRACHYTHERAPY. BRACHYTHERAPY is delivered by positioning RADIATION SOURCES within or adjacent to the tissue to be treated. Historically, RADIOACTIVE SOURCES were handled manually, resulting in IRRADIATION of the OPERATOR'S hands. AFTERLOADING generally refers to the technique of placing an applicator into or adjacent to the tissue to be treated, and introducing one or more RADIATION SOURCE(S) only after the applicator position has been confirmed. This procedure minimizes the time during which the operator is exposed to the RADIATION SOURCE(S). Manual AFTERLOADING techniques were developed in the 1950s and are used routinely today for permanent implants, but less frequently for temporary implants.

Temporary implants require the use of higher dose rates, to ensure that the treatment can be completed in a length of time easily tolerated by the PATIENT. In the 1980s, automatic remote AFTERLOADING techniques were developed, that could move a RADIOACTIVE SOURCE or SOURCES through connecting tubes from a shielded safe to the applicators implanted in the patient. Because the SOURCE(S) could be moved remotely, the risk of exposure to personnel could be eliminated.

In 2007 an automatic remote afterloader was introduced that replaced the conventional RADIOACTIVE SOURCE(S) with an X-ray source. This device otherwise performed similarly to AFTERLOADERS containing RADIOACTIVE SOURCES. However, the X-ray source could be disabled when not in use, removing any risk of IRRADIATION. BRACHYTHERAPY devices that employ X-ray source(s) are subject to the requirements of IEC 60601-2-8, in addition to those of this standard.

The use of AFTERLOADING ME EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose to the PATIENT, or if the ME EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S), if the X-RAY TUBE is energized inappropriately, or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of AFTERLOADING ME EQUIPMENT for use in temporary BRACHYTHERAPY procedures; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such ME EQUIPMENT. It places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists and at which an INTERLOCK then operates to disable the X-RAY TUBE(S) or return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard applies to automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT used for treatment or alleviation of disease.

This standard specifies requirements

a) for automatically-controlled AFTERLOADING ME EQUIPMENT

- 1) which contains and uses only beta, gamma, or NEUTRON-emitting SEALED RADIOACTIVE SOURCES, or BRACHYTHERAPY X-RAY SOURCES designed and constructed for use with automatically-controlled AFTERLOADING ME EQUIPMENT,
- 2) which automatically drives the RADIATION SOURCE(S) from a STORAGE CONTAINER or, in the case of BRACHYTHERAPY X-RAY SOURCES, a reference location outside the PATIENT, to a treatment position inside the SOURCE APPLICATOR(S) and returns the RADIATION SOURCE(S) to the STORAGE CONTAINER or the BRACHYTHERAPY X-RAY SOURCE(S) to the reference location,
- 3) which is designed for connection to a PATIENT, and
- 4) with which movements of the RADIATION SOURCE(S) are carried out automatically by the ME EQUIPMENT according to a prescribed programme using a powered mechanism whose changes are controlled by the CONTROLLING TIMER(S) and TIMING DEVICES that are either PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) (computer or microprocessors) or non-programmable systems and

b) for ME EQUIPMENT intended to be

¹ The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*