SLOVENSKI STANDARD
SIST EN 60601-2-17:2015

01-september-2015

Nadomešča:
SIST EN 60601-2-17:2004

Medicinska električna oprema - 2-17. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za brahiterapijo z avtomatičnim krmiljenjem naknadnega polnjenja

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

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-17:2015**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-17:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-17

May 2015

ICS 11.040.60

Supersedes EN 60601-2-17:2004

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

Ref. No. EN 60601-2-17:2015 E

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:

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:2006:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ 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.

Publication	Year	Title	EN/HD	Year
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.

IEC 60601-2-17

Edition 3.0 2013-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX

X

ICS 11.040.60

ISBN 978-2-8322-1214-1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-17 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition, published in 2004. Consideration has been given to new IEC standards, amendments to existing IEC standards, developments in technology and clinical usage, and various hazards encountered and envisaged since the preparation of the first and second editions. This edition constitutes a technical revision which brings this standard in line with IEC 60601-1:2005+A1:2012 and its collateral standards.

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

FDIS	Report on voting
62C/575/FDIS	62C/579/RVD

Full information on the voting for the approval of this particular 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.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201.7 includes subclauses 201.7.1, 201.7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *MEDICAL ELECTRICAL EQUIPMENT*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability 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 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 standard[1] 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*