ICS 11.040.60 SLOVENSKÁ TECHNICKÁ NORMA December 2015

STN	**Zdravotnícke elektrické prístroje. Časť 2-17: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti automaticky riadených afterloadingových prístrojov na brachyterapiu.**	**STN EN 60601-2-17** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/15

Obsahuje: EN 60601-2-17:2015, IEC 60601-2-17:2013

Oznámením tejto normy sa od 14.04.2018 ruší
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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)

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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 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.

EN 60601-2-17:2015

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

IEC 60601-2-17:2013

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IEC 60601-2-17

Edition 3.0 2013-11

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COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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.
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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

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

1) for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular specified clinical purposes, e.g. remote AFTERLOADING BRACHYTHERAPY;
2) maintained in accordance within the recommendations given in the INSTRUCTIONS FOR USE;
3) subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

This standard does not specify requirements for SEALED RADIOACTIVE SOURCES. Requirements for the design of X-RAY TUBES used with the ME EQUIPMENT are specified in other IEC standards. See for example: IEC 60601-2-28:2010.

The requirements of this standard are based on the assumptions that:

– a TREATMENT PLAN is available that prescribes appropriate values of the TREATMENT PARAMETERS, and
– the SOURCE STRENGTH(S) or the REFERENCE AIR-KERMA RATE of the RADIATION SOURCE(S) used by the ME EQUIPMENT is (are) known.

This standard includes requirements intended to ensure that the prescribed values of the TREATMENT PARAMETERS can be achieved by the ME EQUIPMENT, in particular that:

– the selected RADIATION SOURCE(S) is (are) positioned or moved within the SOURCE APPLICATOR in the selected configuration relative to the SOURCE APPLICATOR;
– IRRADIATION is performed by the selected RADIATION SOURCE configuration for the selected duration;
– IRRADIATION is performed by the ME EQUIPMENT without causing unnecessary RISK to the OPERATOR or other persons in the immediate surroundings.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this standard.

IEC 60601-1-3 and IEC 60601-1-10[2] do not apply. All other published collateral standards in the IEC 60601 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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2 IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+A1:2012, is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 42.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012[3]

[3] A consolidated edition 3.1 exists, including IEC 60601-1:2005 and its Amendment 1:2012.

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*

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*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61005:2003, *Radiation protection instrumentation – Neutron ambient dose equivalent (rate) meters*

IEC 62083:2009, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*