SLOVENSKI STANDARD
SIST EN 60601-2-17:2004

01-maj-2004

Nadomešča:
SIST EN 60601-2-17:1998
SIST EN 60601-2-17:1998/A1:1998

Medicinska električna oprema - 2-17. del: Posebne varnostne zahteve za avtomatsko krmiljeno napravo za brahiterapijo z naknadnim polnjenjem (IEC 60601 -2-17:2004)

Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (IEC 60601-2-17:2004)

Medizinische elektrische Geräte - Teil 2-17: Besondere Festlegungen für die Sicherheit ferngesteuerter, automatisch betriebener Afterloading-Geräte für die Brachytherapie (IEC 60601-2-17:2004)

Appareils électromédicaux - Partie 2-17: Règles particulières de sécurité des appareils projecteurs de brachythérapie avec contrôles automatiques (CEI 60601-2-17:2004)

Ta slovenski standard je istoveten z: **EN 60601-2-17:2004**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-17:2004 **en**

EUROPEAN STANDARD **EN 60601-2-17**

NORME EUROPÉENNE

EUROPÄISCHE NORM April 2004

ICS 11.040.60; 19.100 Supersedes EN 60601-2-17:1996 + A1:1996

English version

Medical electrical equipment
Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment
(IEC 60601-2-17:2004)

Appareils électromédicaux
Partie 2-17: Règles particulières
de sécurité des appareils projecteurs
de brachythérapie
avec contrôles automatiques
(CEI 60601-2-17:2004)

Medizinische elektrische Geräte
Teil 2-17: Besondere Festlegungen
für die Sicherheit ferngesteuerter,
automatisch betriebener
Afterloading-Geräte für die Brachytherapie
(IEC 60601-2-17:2004)

This European Standard was approved by CENELEC on 2004-03-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-17:2004 E

Foreword

The text of document 62C/363/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-17 on 2004-03-01.

This European Standard supersedes EN 60601-2-17:1996 + A1:1996.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2004-12-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2007-03-01

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: small roman type;

– *test specifications: italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH ARE DEFINED IN CLAUSE 2 OR IN THE GENERAL STANDARD EN 60601-1, ITS COLLATERAL OR PART 2 STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-17:2004 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-1-3 NOTE Harmonized as EN 60601-1-3:1994 (not modified).

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996
A1	2000		A1	2001
IEC 62083	2000	Medical electrical equipment Requirements for the safety of radiotherapy treatment planning systems	EN 62083	2001
Replacement in Annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2	1995
			A13	1996
IEC 60601-1-1	2000	Medical electrical equipment Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	2001
IEC 60601-1-2	2001	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	1999		A1	1999

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-17

Deuxième édition
Second edition
2004-01

Appareils électromédicaux –

Partie 2-17:
Règles particulières de sécurité des appareils projecteurs de sources radioactives à chargement différé automatique utilisés en brachythérapie

Medical electrical equipment –

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

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Международная Электротехническая Комиссия

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For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-17: Particular requirements for the safety 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 subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989, and its Amendment 1 (1996). 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 edition.

This bilingual version (2005-09) replaces the English version.

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

FDIS	Report on voting
62C/363/FDIS	62C/366/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.

The French version of this standard has not been voted upon.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: small roman type;

– *test specifications: italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH ARE DEFINED IN CLAUSE 2 OR IN THE GENERAL STANDARD IEC 60601-1, ITS COLLATERAL OR PART 2 STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

NOTE Attention is drawn to the existence, in some countries, of legislation containing requirements for:

– IONIZING RADIATION safety which may not align with the provisions of this Particular Standard, and

– maintenance, quality assurance and other related subjects, which are not covered by this Standard.

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 use of AFTERLOADING EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S) and/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 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 EQUIPMENT. It places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

1.1.101 This Particular Standard specifies requirements for the safety of automatically-controlled EQUIPMENT for BRACHYTHERAPY of patients using AFTERLOADING techniques.

1.1.102 This Standard specifies requirements for automatically-controlled AFTERLOADING EQUIPMENT

– which contains and uses only beta, gamma, and NEUTRON-emitting SEALED RADIOACTIVE SOURCES,
– which automatically drives the sealed radioactive source(s) from a storage container to a treatment position inside the source applicator(s) and returns the source(s) to the storage container,
– which is designed for connection to a PATIENT, and
– with which movements of the RADIOACTIVE SOURCE(S) are carried out automatically by the 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.

1.1.103 This Standard specifies requirements for EQUIPMENT intended to be

– used under the supervision of QUALIFIED PERSONS;
– maintained at predetermined intervals;
– subject to regular checks by the user.

This Standard does not specify requirements for SEALED RADIOACTIVE SOURCES used with the EQUIPMENT. Such requirements are specified in other standards (see 6.8.3).

1.1.104 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) of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT is (are) known.

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

– the selected RADIOACTIVE 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 RADIOACTIVE SOURCE configuration for the selected duration;
– IRRADIATION is performed by the EQUIPMENT without causing unnecessary risk to the OPERATOR or other persons in the immediate surroundings.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for safety of automatically-controlled BRACHYTHERAPY AFTERLOADING EQUIPMENT and the compliance test specifications. It presents the general functional requirements of the demand for safety rather than particular technological means of implementation.

1.3 Particular Standards

ADDITION:

1.3.101 Relationship to the General Standard

This Particular Standard is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, with its Amendments 1 (1991) and 2 (1995) – hereinafter referred to as the General Standard – which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General and Collateral Standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General 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;

"Amendment" means that the clause or subclause of the General 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 101: additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term “this Standard “ is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.