Elektrilised meditsiiniseadmed. Nõuded kiiritusravi planeerimissüsteemide ohutusele

Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 62083:2010 sisaldab Euroopa standardi EN 62083:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 62083:2010 consists of the English text of the European standard EN 62083:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.03.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.03.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 11.12.2009.	Date of Availability of the European standard text 11.12.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62083

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Supersedes EN 62083:2001

English version

Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

(IEC 62083:2009)

Appareils électromédicaux - Exigences de sécurité pour les systèmes de planification de traitement en radiothérapie (CEI 62083:2009)

Medizinische elektrische Geräte - Festlegungen für die Sicherheit von Bestrahlungsplanungssystemen (IEC 62083:2009)

This European Standard was approved by CENELEC on 2009-11-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 62083:2009 E

Foreword

The text of document 62C/473/FDIS, future edition 2 of IEC 62083, 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 62083 on 2009-11-01.

This European Standard supersedes EN 62083:2001.

EN 62083:2009 constitutes a technical revision, which brings this standard in line with changes to the other standards referred to in this standard.

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)	2010-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-11-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

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

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

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 62083:2009 was approved by CENELEC as a European Standard without any modification.

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

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-2 (mod)	-[1)]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007[2)]
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 60601-2-11	1997	Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment	EN 60601-2-11	1997
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60950-1 (mod)	-[1)]	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1 + A11	2006[2)] 2009
IEC 61000-4-1	-[1)]	Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series	EN 61000-4-1	2007[2)]
IEC 61000-4-2	-[1)]	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	2009[2)]
IEC 61000-4-3	-[1)]	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006[2)]
IEC 61000-4-4	-[1)]	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2004[2)]
IEC 61217	-[1)]	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996[2)]
IEC 62304	-[1)]	Medical device software - Software life-cycle processes	EN 62304 + corr. November	2006[2)] 2008

[1)] Undated reference.

[2)] Valid edition at date of issue.

Publication	Year	Title	EN/HD	Year
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
ICRU Report 42	1987	Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

INTRODUCTION

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device, usually a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM that is used to simulate the application of RADIATION to a PATIENT for a proposed RADIOTHERAPY TREATMENT. It usually, but not necessarily, provides estimates of ABSORBED DOSE distribution in human tissue using a particular algorithm or algorithms. These estimations, referred to in this International Standard as ABSORBED DOSE distributions, are used by a QUALIFIED PERSON in planning a course of RADIOTHERAPY.

The output of an RTPS is used by appropriately QUALIFIED PERSONS as important information in RADIOTHERAPY TREATMENT PLANNING. Inaccuracies in the input data, the limitations of the algorithms, errors in the TREATMENT PLANNING process, or improper use of output data, may represent a safety HAZARD to PATIENTS should the resulting data be used for TREATMENT purposes. This standard defines requirements to be complied with by MANUFACTURERS in the design and construction of an RTPS in order to provide protection against the occurrence of such HAZARDS.

SPECIFIC types of input data and calculation algorithms are not addressed in this standard. These are dependent on many factors, such as available technology, RESPONSIBLE ORGANIZATION preference, and the type of TREATMENT being planned. However, this standard establishes the safety requirements that are common to algorithms. It also establishes the minimum requirements for the contents of the ACCOMPANYING DOCUMENTS that will permit the OPERATOR to make informed choices during the TREATMENT PLANNING process.

Generally, an RTPS is not used in the presence of PATIENTS, so it is not MEDICAL ELECTRICAL EQUIPMENT as defined by IEC 60601-1. Consequently, this standard is written in an independent format rather than as a particular standard to IEC 60601-1.

- Relationship to other standards

The BASIC SAFETY of hardware, such as for protection against electric shock and fire, and for assuring ELECTROMAGNETIC COMPATIBILITY requires that these subjects be addressed by the MANUFACTURER through compliance with an appropriate standard, depending upon the nature and environment of the hardware used for the RTPS. See Annex A for hardware safety standards.

A RTPS is principally a software application for medical purposes. IEC 62304 applies (see Clause 14).

IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero position and the direction of movement with increasing value. The means of applying IEC 61217 are SPECIFIED in appropriate clauses and subclauses of this standard.

IEC 62366 applies (see Clause 16).

MEDICAL ELECTRICAL EQUIPMENT – REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY TREATMENT PLANNING SYSTEMS

1 Scope

This International Standard applies to the design, manufacture and some installation aspects of a radiotherapy treatment planning systems(RTPS)

– for use in RADIOTHERAPY TREATMENT PLANNING in human medical practice;
– that imports data either through input by the OPERATOR or directly from other devices;
– that outputs data either in printed form for review or directly to other devices;
– and which is intended to be
  – for NORMAL USE, under the authority of appropriately licensed or QUALIFIED PERSONS, by OPERATORS having the required skills and training;
  – maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
  – used within the environmental and electrical supply conditions SPECIFIED in the technical description.

2 Normative references

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.

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

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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 60601-2-11:1997, *Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment*

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

IEC 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

IEC 61000-4-1, *Electromagnetic compatibility (EMC) – Part 4-1: Testing and measurement techniques – Overview of IEC 61000-4 series*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61217, *Radiotherapy equipment – Coordinates, movements and scales*

IEC 62304, *Medical device software – Software life cycle processes*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

ICRU Report 42:1987, *Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE See the Index of defined terms for a full list of terms used in this standard and their source.

3.1.1
ANATOMY MODELLING
process of establishing the PATIENT ANATOMY MODEL

3.1.2
BRACHYTHERAPY SOURCE MODEL
all physical, geometric and RADIATION parameters required to plan a course of RADIOTHERAPY for a particular BRACHYTHERAPY RADIOACTIVE SOURCE

3.1.3
EQUIPMENT MODEL
all physical, geometric and RADIATION parameters required to plan a course of RADIOTHERAPY for particular ME EQUIPMENT

3.1.4
EQUIPMENT MODELLING
process of establishing the EQUIPMENT MODEL

3.1.5
PATIENT ANATOMY MODEL
all physical and anatomical parameters required to plan a course of RADIOTHERAPY for a particular patient

3.1.6
RADIOTHERAPY TREATMENT PLANNING SYSTEM
RTPS
device, usually a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM including its associated peripherals, that is used to simulate the application of RADIATION to a patient for a proposed RADIOTHERAPY TREATMENT

NOTE It usually, but not necessarily, provides estimations of ABSORBED DOSE distribution in human tissue using a particular algorithm or algorithms. These algorithms provide simulations of RADIATION that is typically from, but not necessarily limited to, MEDICAL ELECTRON ACCELERATORS, GAMMA BEAM THERAPY EQUIPMENT, or in BRACHYTHERAPY from RADIOACTIVE SOURCES.