SLOVENSKI STANDARD

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Medical electrical equipment - Requirements for the safety of radiotheraphy treatment planning systems (IEC 62083:2000)

ICS 11.040.60

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SIST EN 62083:2002(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62083

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English version

Medical electrical equipment
Requirements for the safety of radiotherapy treatment planning systems
(IEC 62083:2000)

Appareils électromédicaux
Règles particulières de sécurité
pour les systèmes de planification de
traitement en radiothérapie
(CEI 62083:2000)

Medizinische elektrische Geräte
Festlegungen für die Sicherheit von
Bestrahlungsplanungssystemen
(IEC 62083:2000)

This European Standard was approved by CENELEC on 2000-12-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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 62083:2001 E

Foreword

The text of document 62C/280/FDIS, future edition 1 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 2000-12-01

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)	2001-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2003-12-01

NOTE In this standard, the following print types are used:
- requirement: in roman type;
- *test specifications: in italic type;*
- notes: in smaller roman type.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes A, C and ZA are normative and annex B is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62083:2000 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 60601-2-1	NOTE: Harmonized as en 60601-2-1:1998 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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	[1)]	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990[2)]
IEC 60601-1-2	[1)]	Medical electrical equipment Part 1: General requirements for safety -- 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993[2)] 1997[2)]
IEC 60601-1-4	[1)]	Medical electrical equipment Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996[2)]
IEC 60788	[1)]	Medical radiology - Terminology	HD 501 S1	1988[2)]
IEC 60950 (mod)	[1)]	Safety of information technology equipment	EN 60950	2000[2)]
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	2000[2)]
IEC 61000-4-2	[1)]	Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995[2)]
IEC 61000-4-3 (mod)	[1)]	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996[2)]
IEC 61000-4-4	[1)]	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995[2)]

[1)] undated reference.

[2)] valid edition at date of issue.

Publication	Year	Title	EN/HD	Year
IEC 61217	1)	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996 2)
ICRU rapport 42	1987	Use of Computers in External Beam Radiotherapy Procedures with high Energy Photons and Electrons	-	-

NORME INTERNATIONALE

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

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Requirements for the safety of radiotherapy treatment planning systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 62083 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62C/280/FDIS	62C/288/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes A and C form an integral part of this standard.

Annex B is for information only.

In this standard, the following print types are used:

– Requirements, compliance with which can be tested, and definitions: in roman type.

– Notes, explanations, advice, general statements, and exceptions: in small roman type.

– *Test specifications: in italic type.*

– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN ANNEX C AND DEFINED IN CLAUSE 4, OR IN IEC 60601-1 AND ITS COLLATERAL STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

Certain defined terms have been abbreviated, namely:

Defined term	Abbreviation
RADIOTHERAPY TREATMENT PLANNING SYSTEM	RTPS
BEAM LIMITING DEVICE	BLD
COMPUTED TOMOGRAPHY	CT
MAGNETIC RESONANCE IMAGING	MRI
CENTRAL PROCESSING UNIT	CPU

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device, usually a PROGRAMMABLE ELECTRONIC 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, USER 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 USER to make informed choices during the TREATMENT PLANNING process.

NOTE As it is not used in the presence of PATIENTS, an RTPS 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. Clause 3 contains related information.