IEC 62083

Edition 2.0 2009-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux – Exigences de sécurité pour les systèmes de planification de traitement en radiothérapie

IEC 62083:2009

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX U

ICS 11.040.60

ISBN 978-2-88910-617-2

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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International Standard IEC 62083 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 second edition replaces the first edition of IEC 62083, published in 2000. This edition constitutes a technical revision, which brings this standard in line with changes to the other standards referred to in this standard.

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

FDIS	Report on voting
62C/473/FDIS	62C/479/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 2.

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.

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- withdrawn;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

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.

3.1.7
SOURCE MODELLING
process of establishing the BRACHYTHERAPY SOURCE MODEL

3.1.8
TREATMENT PLAN
all patient and dosimetric information that is intended for use by appropriately qualified persons for the purpose of prescribing or administering RADIOTHERAPY, including any information to be transmitted to other equipment

NOTE A printed or plotted TREATMENT PLAN is referred to as a TREATMENT PLAN report.

3.1.9
TREATMENT PLANNING
process of establishing the TREATMENT PLAN

3.2 Abbreviations

Certain defined terms have been abbreviated in this document as follows:

Defined term	Abbreviation
RADIOTHERAPY TREATMENT PLANNING SYSTEM	RTPS
BEAM LIMITING DEVICE	BLD
COMPUTED TOMOGRAPHY	CT
Magnetic resonance imaging	MRI
Central processing unit	CPU

4 General

4.1 Development

Compliance with IEC 62304 requires identification of HAZARDS, assessment of their RISKS, and appropriate verification and validation of RISK CONTROLS. Demonstration of compliance with the requirements of this standard shall be included as part of the above processes, with explicit reference to each requirement of this standard. Compliance data shall be retained by the MANUFACTURER as a permanent record. Each test shall include a protocol containing all the necessary input data, sufficient detail to provide for exact reproducibility, and the expected result. A statement of compliance to this standard shall be included in the technical description.

Compliance is checked by inspection of the records of the MANUFACTURER.

4.2 Testing during installation

The MANUFACTURER shall provide an installation test document as part of the technical description that includes, as a minimum, performance of the ABSORBED DOSE distribution calculation algorithm tests given in 10.2 and tests of geometric relationships. The tests shall also demonstrate correct functioning of the RTPS hardware components and their ability to achieve predetermined results when performing TREATMENT PLANNING functions.

Due to the complexity of TREATMENT PLANNING functions and the possible use of configurations beyond those specified by the MANUFACTURERS, it is usually not possible for the MANUFACTURER to demonstrate complete fitness for use of the RTPS at time of installation. The technical description shall provide explicit warnings to the RESPONSIBLE ORGANIZATION to add additional tests specific for the installation of the RTPS at the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

5 ACCOMPANYING DOCUMENTS

The ACCOMPANYING DOCUMENTS shall include a technical description and the INSTRUCTIONS FOR USE, which shall contain the information as required by this standard (see Table 1 for references).

Table 1 – Clauses and subclauses in this standard that require the provision of information in the ACCOMPANYING DOCUMENTS and the technical description

Check reference	INSTRUCTIONS FOR USE	Technical description
1		4.1
2		4.2
3		6.4 a)
4	6.4 c)	
5	6.4 d)	
6	6.5	
7		6.7 a)
8		6.7 b)
9	6.8	
10	7.1 g)	
11	7.2 b)	
12		7.3 b)
13	8.1 a)	
14	8.2 a)	
15	8.2 c)	
16	8.3 c)	
17	9.2 a)	
18	9.5 a)	
19		10.1 a)
20	10.1 b)	
21		10.2 a)
22	10.2 c)	
23		10.2 c)
24	10.2 d)	
25		10.2 e)
26		12
27	13	
28	14 b)	
29	15 a)	
30	15 b)	
31	15 d)	
32	16	
33		A.1
34	A.3	
35		A.3
36		Annex B
NOTE The check reference is given as an aid for checking the availability of compliance documentation.		

6 General requirements for operational safety

6.1 Distances and linear and angular dimensions

Distance measurements and linear dimensions shall be indicated in centimetres or in millimetres but not both. Angular dimensions shall be indicated in degrees (°) All values of distance measurements and linear and angular dimensions requested, displayed, or printed shall include their units.

Compliance is checked by inspection of the DISPLAY and output information.

6.2 RADIATION quantities

All values of RADIATION quantities requested, displayed or printed shall include their units. Units of RADIATION quantities should conform to the SI convention.

Compliance is checked by inspection of the DISPLAY and output information.

6.3 Date and time format

When the date is displayed or printed, correct interpretation shall not depend upon the OPERATOR'S interpretation of format, and a DISPLAY of the year shall be in four digits.

NOTE 1 Examples acceptable: "03 Apr 2005", "03/04/2005 (dd/mm/yyyy)".

NOTE 2 Examples not acceptable: "03/04/05", "03 Apr 05".

When the time is requested, displayed or printed, it shall be represented on a 24 h clock basis, or the letters "a.m." and "p.m." shall be appropriately included. Measurements of time shall include units (hours, minutes, seconds).

NOTE 3 By convention, noon is 12:00 p.m. and midnight is 12:00 a.m.

When time is entered, displayed or printed, each denomination of time shall be labelled. To prevent confusion with numbers, single-letter abbreviations of time denomination shall not be used (for example h,m,s). Acceptable examples: 2,05 min; 1 hour 33 minutes; 1:43:15 (hr:min:sec).

It shall be possible to enter, display and print time together with an indication of the time zone and, where applicable, the use of daylight saving time. The OPERATOR should have the possibility to select or de-select this option.

Time-sensitive functions shall be performed correctly at transitions such as year boundaries, leap years, year 2000, etc.

Compliance is checked by testing and by inspection of the DISPLAY and output information.

6.4 Protection against unauthorized use

a) A PASSWORD protection feature, or the use of a key, shall be provided by the MANUFACTURER as a means for the RESPONSIBLE ORGANIZATION to ensure that only authorized persons operate the TREATMENT PLANNING system. A means to control PASSWORD access or key access shall be provided to ensure that these may be controlled by an individual designated by the RESPONSIBLE ORGANIZATION. The technical description shall describe how protection is implemented and how access is controlled.

   Protection against unauthorized use shall provide for selective access for different functions so that the RESPONSIBLE ORGANIZATION can specify the levels of protection for SPECIFIC OPERATORS.

EXAMPLE Not all OPERATORS qualified for TREATMENT PLANNING are likely to be qualified for BRACHYTHERAPY SOURCE MODELLING and EQUIPMENT MODELLING. Also, viewing TREATMENT PLANS, or printing out TREATMENT PLANS, may be permitted with fewer restrictions than for TREATMENT PLANNING.

Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.

b) Where network connection is permitted by the design, the following requirements apply:
   - access to the RTPS shall be provided only to authorized equipment or individuals who are authorized (for example, by a PASSWORD under the control of the RESPONSIBLE ORGANIZATION);
   - access to EQUIPMENT MODEL, BRACHYTHERAPY SOURCE MODEL, and PATIENT ANATOMY MODEL data, or to TREATMENT PLANS (with or without ABSORBED DOSE distribution calculation) through the network shall be restricted so as to prevent unauthorized access.

   Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.

c) The MANUFACTURER may employ copy protection to prevent the creation of a useable duplicate RTPS not intended by the MANUFACTURER to be used for TREATMENT PLANNING. If copy protection is employed, it shall permit backup of data. The existence of copy protection shall be stated in the INSTRUCTIONS FOR USE.

   Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.

d) Protection against unauthorized changes to software or data (e.g., viruses) shall be employed. The manufacturer shall state in the INSTRUCTIONS FOR USE the means of protection employed.

   Compliance is checked by testing and by inspection of the ACCOMPANYING DOCUMENTS.

6.5 Data limits

Data elements entered by the OPERATOR or acquired from a device or network shall be compared against pre-established limits. Operation shall be prevented if the data are outside these limits unless the OPERATOR overrides a cautionary message at the time the data are found to be outside the limits.

Limits for those data elements that are entered by the OPERATOR shall be provided in the INSTRUCTIONS FOR USE and/or shall be provided as part of the error messages displayed by the RTP when these limits are exceeded.

Other consistency checks on data should also be performed as appropriate to the expected nature of the data.

For TREATMENT PLANNING performed when the OPERATOR has overridden data limits, TREATMENT PLAN reports shall include the message "CAUTION: SOME DATA ELEMENTS USED WERE OUTSIDE NORMAL RANGE" or a similar statement.

NOTE The requirements in this subclause do not ensure that input data are correct or used appropriately by the OPERATOR. The limits define the maximum ranges of input data elements. Defining these ranges permits safe use of the system with input data, which the MANUFACTURER could not anticipate, and provides the MANUFACTURER with the means to test algorithms for correct behaviour at established boundaries. See also 10.2 b).

Compliance is checked by testing and by inspection of the output information and ACCOMPANYING DOCUMENTS.

6.6 Protection against unauthorized modification

See clause 13.

6.7 Correctness of data transfer

a) Data transferred to or from other devices shall use a communication protocol that verifies error-free data transmission. The MANUFACTURER shall specify these protocols in the technical description.

EXAMPLE DICOM 3 or FTP, each of which includes error detection.

Compliance is checked by inspection of the communication protocol specifications, and by inspection of the ACCOMPANYING DOCUMENTS.

b) If data are transmitted for use by another device, other than closed communication with a peripheral or a component of an integrated RTPS/delivery system that has been type tested by the MANUFACTURER, then

- the format of the output data shall be included in the technical description, including (but not limited to) identification of all data elements, data types, and data limits;
- the data output shall include the name of the OPERATOR, the date on which the data was written, and any relevant identifiers for the PATIENT, EQUIPMENT MODEL, BRACHYTHERAPY SOURCE MODEL, PATIENT ANATOMY MODEL and TREATMENT PLAN.

NOTE See Annex B concerning correctness of transferred data.

Compliance is checked by testing and by inspection of the output information and ACCOMPANYING DOCUMENTS.

6.8 Coordinate systems and scales

It shall be possible for the OPERATOR to perform all TREATMENT PLANNING functions with the scales and coordinates of RADIOTHERAPY TREATMENT ME EQUIPMENT displayed according to the IEC 61217 convention. It should also be possible for the OPERATOR to perform all TREATMENT PLANNING functions with the scales and coordinates of ME EQUIPMENT displayed according to the customization for the particular ME EQUIPMENT performed during EQUIPMENT MODELLING.

In either case, the TREATMENT PLAN reports used for RADIOTHERAPY TREATMENT prescription shall show the scales and coordinates of ME EQUIPMENT according to the customization for the particular ME EQUIPMENT performed during EQUIPMENT MODELLING.

The method of display of scales shall be explained in the INSTRUCTIONS FOR USE.

Compliance is checked by testing and by inspection of the DISPLAY, output information and ACCOMPANYING DOCUMENTS.

6.9 Saving and archiving data

Means shall be provided such that an EQUIPMENT MODEL, BRACHYTHERAPY SOURCE MODEL, TREATMENT PLAN, and other data critical to proper operation can be saved while work is in progress so that it can be retrieved in the case of a system malfunction.

Means shall be provided for archiving data onto a separate medium from the primary storage, such that it can be retrieved in the case of a failure of the data storage device or complete RTPS.

Compliance is checked by testing.