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

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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

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 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).