Irish Standard
I.S. EN 61217:2012

Radiotherapy equipment - Coordinates, movements and scales (IEC 61217:2011 (EQV))

I.S. EN 61217:2012

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EUROPEAN STANDARD

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Supersedes EN 61217:1996 + A1:2001 + A2:2008

English version

Radiotherapy equipment - Coordinates, movements and scales
(IEC 61217:2011)

Appareils utilisés en radiothérapie - Coordonnées, mouvements et échelles (CEI 61217:2011)

Strahlentherapie-Einrichtungen - Koordinaten, Bewegungen und Skalen (IEC 61217:2011)

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CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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Foreword

The text of document 62C/530/FDIS, future edition 2 of IEC 61217, 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 approved by CENELEC as EN 61217:2012.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-11
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-01-11

This document supersedes EN 61217:1996 + A1:2001 + A2:2008.

EN 61217:2012 constitutes a technical revision to include imager and focus coordinate systems in 3.12. Beyond this subclause, changes were only introduced where needed to include the above coordinate systems.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 61217:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified).
IEC 61168:1993	NOTE	Harmonized as EN 61168:1994 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 + corr. March	2008 2010
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	EN 60601-2-1	201X[1)]
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 60601-2-29	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	EN 60601-2-29 + A11	2008 2011
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 62083	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	EN 62083	2009

[1)] To be published.

Annex ZZ
(informative)

Coverage of Essential Requirements of EU 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 the relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC for ERs 9.1 and 11.2.1 last sentence only.

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.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

RADIOTHERAPY EQUIPMENT – COORDINATES, MOVEMENTS AND SCALES

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

International standard IEC 61217 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 1996, amendment 1, published in 2000 and amendment 2, published in 2007. This edition constitutes a technical revision to include imager and focus coordinate systems in Subclause 3.12. Beyond this Subclause, changes were only introduced where needed to include the above coordinate systems.

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

FDIS	Report on voting
62C/530/FDIS	62C/539/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 and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
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– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

The committee has decided that the contents of this publication will remain unchanged until the stability 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

RADIOTHERAPY is performed in medical centres where a variety of ME EQUIPMENT from different MANUFACTURERS is usually concentrated in the RADIOTHERAPY department. In order to plan and simulate the TREATMENT, set up the PATIENT and direct the RADIATION BEAM, such ME EQUIPMENT can be put in different angular and linear positions and, in the case of MOVING BEAM RADIOTHERAPY, can be rotated and translated during the IRRADIATION of the PATIENT. It is essential that the position of the PATIENT, and the dimensions, directions, and qualities of the RADIATION BEAM prescribed in the treatment plan, be set up or varied by programmes on the radiotherapy EQUIPMENT with accuracy and without misunderstanding. Standard identification and scaling of coordinates is required for ME used in RADIOTHERAPY, including RADIOTHERAPY SIMULATORS and ME EQUIPMENT used to take images during or in connection with RADIOTHERAPY, because differences in the marking and scaling of similar movements on the various types of ME EQUIPMENT used in the same department may increase the probability of error. In addition, data from ME EQUIPMENT used to evaluate the tumour region, such as ultrasound, X-ray, CT and MRI should be presented to the treatment planning system in a form which is consistent with the RADIOTHERAPY coordinate system. Coordinate systems for individual geometrical parameters are required in order to facilitate the mathematical transformation of points and vectors from one coordinate system to another.

A goal of this standard is to avoid ambiguity, confusion, and errors which could be caused when using different types of ME EQUIPMENT. Hence, its scope applies to all types of TELERADIOTHERAPY ME EQUIPMENT, RADIOTHERAPY SIMULATORS, information from diagnostic ME EQUIPMENT when used for RADIOTHERAPY, recording and verification equipment, and to data input for the TREATMENT PLANNING process.

Movement nomenclature is classified as defined terms according to IEC/TR 60788:2004 as well as terms defined in IEC 60601-2-1 and IEC 60601-2-29 (see index of defined terms).

This standard is issued as a publication separate from the IEC 60601 series of safety standards. It is not a safety code and does not contain performance requirements. Thus, the present requirements will not appear in future editions of the IEC 60601-2 series, which deals exclusively with safety requirements.

IEC 60601-2-1, IEC 60601-2-11, IEC 60601-2-29, IEC 60976, IEC 60977, IEC 61168 and IEC 61170 include ME EQUIPMENT movements and scale conventions. A number of changes and additions have been made in this standard.

A major value of a standard coordinate system is its contribution to safety in RADIOTHERAPY TREATMENT PLANNING. The scales that are demonstrated in this standard are consistent with the coordinate systems described herein. USERS may use other scale conventions. It is anticipated that MANUFACTURERS will normally employ the scale conventions of this standard for new ME EQUIPMENT.

It is anticipated that future amendments may address the following:

– three-dimensional RADIOTHERAPY SIMULATORS;

– CT type RADIOTHERAPY SIMULATORS.

Amendment 2, published in 2007, had extended the rotation of the PATIENT support devices around the Z-axis in the IEC fixed coordinate system to two additional rotations – rolling around the PATIENT'S longitudinal axis and pitching around the patient's transversal axis.

The use of the two new additional degrees of freedom (pitch and roll) generalizes the coordinate systems to include systematically 3 rotations and 3 translations, therefore supporting 6 degrees of freedom in a systematic way. Modern patient support devices with 6 degrees of freedom can use a combined translation and rotation to get the same result as the eccentric table top rotation. When changing table position data using the new IEC systems,

the definition of isocentric rotations is sufficient to transfer all treatment-related information. The eccentric table top coordinate system is however maintained for backward compatibility.

NOTE It is quite common in proton therapy to use a treatment chair, where the PATIENT can be rotated and tilted, while the beam line has a fixed direction.

RADIOTHERAPY EQUIPMENT – COORDINATES, MOVEMENTS AND SCALES

1 Scope and object

This International Standard applies to equipment and data related to the process of TELERADIOTHERAPY, including PATIENT image data used in relation with RADIOTHERAPY TREATMENT PLANNING SYSTEMS, RADIOTHERAPY SIMULATORS, isocentric GAMMA BEAM THERAPY EQUIPMENT, isocentric medical ELECTRON ACCELERATORS, and non-isocentric equipment when relevant.

The object of this standard is to define a consistent set of coordinate systems for use throughout the process of TELERADIOTHERAPY, to define the marking of scales (where provided), to define the movements of ME EQUIPMENT used in this process, and to facilitate computer control when used.

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 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

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 60601-2-29:2008, *Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*

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

IEC 62083:2009, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*

3 Coordinate systems

3.1 General

An individual coordinate system is assigned to each major part of the ME EQUIPMENT which can potentially be moved in relation to another part, as illustrated in Figure 1a and summarized in Table 1. Furthermore a fixed reference system is defined. Each major part (e.g. GANTRY, RADIATION HEAD) is always stationary with respect to its own coordinate system.