BS EN 60601-2-29:2008+A11:2011

BSI Standards Publication

Medical electrical equipment —

Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

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National foreword

This British Standard is the UK implementation of EN 60601-2-29:2008+A11:2011. It is identical to IEC 60601-2-29:2008. It supersedes BS EN 60601-2-29:2008 which will be withdrawn on 1 October 2014.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical equipment in medical practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments issued since publication

Date	Text affected
30 April 2012	Implementation of CENELEC amendment A11:2011. Modification of Annex ZZ.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-29:2008+A11

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English version

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

(IEC 60601-2-29:2008)

Appareils électromédicaux - Partie 2-29: Exigences particulières pour la sécurité de base et les performances essentielles des simulateurs de radiothérapie (CEI 60601-2-29:2008)

Medizinische elektrische Geräte - Teil 2-29: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Strahlentherapiesimulatoren (IEC 60601-2-29:2008)

CENELEC

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

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Foreword

The text of document 62C/423/CDV, future edition 3 of IEC 60601-2-29, 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 Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-29 on 2008-11-01.

This European Standard supersedes EN 60601-2-29:1999.

EN 60601-2-29:2008 constitutes a technical revision, which brings EN 60601-2-29 in line with EN 60601-1:2006 and its collateral standards.

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)	2009-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-11-01

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 93/42/EEC. See Annex ZZ.

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 DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-29:2008 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 60601-1-3	NOTE	Harmonized as EN 60601-1-3:2008 (not modified).
IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8:2007 (not modified).
IEC 60601-2-1	NOTE	Harmonized as EN 60601-2-1:1998 (not modified).

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Foreword to amendment A11

This document (EN 60601-2-29:2008/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

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.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Addition *to Annex ZA of EN 60601-1:2006:*

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61217	-[1)]	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996[2)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

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 except as follows:

– Essential Requirement 6a
– Essential Requirement 7.4
– Essential Requirement 7.5 paragraph 2 & 3
– Essential Requirement 13.6 (q)

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

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY SIMULATORS; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such ME EQUIPMENT. It places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists, for example a component failure, and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of RADIOTHERAPY SIMULATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for RADIOTHERAPY SIMULATORS [as defined in 201.3.204].

201.1.3 *Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

The following collateral standard does not apply:

– IEC 60601-1-10.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

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

ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Addition:

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

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC TR 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 23.

Addition:

201.3.201
DELINEATED RADIATION BEAM
that part of the RADIATION BEAM bordered by the shadow cast by the DELINEATORS

201.3.202
DELINEATED RADIATION FIELD
area of the DELINEATED RADIATION BEAM intercepted on a plane perpendicular to the REFERENCE AXIS

201.3.203
DELINEATOR(S)
means for defining the border(s) of the simulated radiation field

201.3.204
RADIOTHERAPY SIMULATOR
SIMULATOR
ME EQUIPMENT that uses X-RAY EQUIPMENT to simulate geometrically the parameters of movements and RADIATION FIELDS of RADIOTHERAPY ME EQUIPMENT to assist with the planning of PATIENT treatments

NOTE This definition does not include:

– CT-simulation devices and MR-simulation devices;

– virtual simulation computer programs;

– imaging modalities that form a part of gamma beam therapy equipment or of electron accelerators.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

– a sufficiently low internal impedance to prevent voltage fluctuations exceeding ±5 % between the on-load and off-load steady states.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows*:*

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 Provision of scales and indications for moving parts

a) The following shall be provided:
   - a numerical indication of the dimensions of the DELINEATED RADIATION FIELD at a SPECIFIED distance;
   - a visual indication of the RADIATION BEAM and the DELINEATED RADIATION FIELD;
   - an indication of the position of the ISOCENTRE;
   - means for indicating the FOCAL SPOT TO SKIN DISTANCE;
   - an indication of the position of the REFERENCE AXIS on entry to the PATIENT or X-RAY IMAGE RECEPTOR;
   - an indication to the OPERATOR, associated with the angular position of the DELINEATED RADIATION BEAM, of the possible WEDGE FILTER direction(s) for the RADIOTHERAPY ME EQUIPMENT being simulated;
   - a numerical indication of the distance from the FOCAL SPOT to the IMAGE RECEPTOR PLANE;
   - a numerical indication of the distance from the ISOCENTRE to the FOCAL SPOT when this parameter is adjustable;
   - scale readouts complying with the conventions of IEC 61217, for all available movements of GANTRY, RADIATION HEAD and BLSs (BEAM LIMITING SYSTEMS), DELINEATORS, X-RAY IMAGE RECEPTOR and PATIENT SUPPORT.

b) In order to reduce the possibility of error when transferring data between SIMULATORS and RADIOTHERAPY ME EQUIPMENT having other scale conventions, SIMULATORS may incorporate additional scale readouts supporting other scale conventions, in which case the scale convention then being DISPLAYED by the SIMULATOR shall be unambiguous.

Compliance is checked by inspection.

201.7.8.1 Colours of indicator lights

Addition:

Where indicator lights are used on the TREATMENT CONTROL PANEL (TCP), or other CONTROL PANELS, the colours of the lights shall be in accordance with the following:

- RADIATION BEAM "on" — yellow;
- READY STATE — green;
- urgent action required in response to an unintended state of operation — red;
- PREPARATORY STATE — other colour.

NOTE In the SIMULATOR room, or in other locations, the states "RADIATION BEAM on" and "READY STATE" may need urgent action or caution; different colours, in accordance with Table 2 of the general standard, may therefore be used in such locations.

Light emitting diodes (LEDs) are not considered to be indicator lights when:

– on any CONTROL PANEL, all indications for which no particular colour is required are given by LEDs of the same colour; and

– the indications for which particular colours are required are clearly distinguishable by attributes other than the light colour.

201.7.9.1 General

Addition:

See also Table 201.C.101

201.7.9.2.1 General

Addition:

See also Table 201.C.102

The instructions for use shall contain:

– an explanation of the function of all INTERLOCKS and other RADIATION safety devices;

– instructions for checking their correct operation;

– a recommendation of the frequency with which such checks should be made;

– the recommended inspection or replacement intervals for parts having a safety function that are subject to impairment caused, during NORMAL USE of the ME EQUIPMENT, by the effects of IONIZING RADIATION on the dielectric and/or mechanical properties of those parts;

201.7.9.2.15 Environmental protection

Addition:

– include data to assist the RESPONSIBLE ORGANIZATION's RADIOLOGICAL PROTECTION adviser regarding:

- the range of available DELINEATED RADIATION FIELD dimensions;
- the maximum available RADIATION FIELD dimensions and the distance from the FOCAL SPOT at which this is SPECIFIED;
- the available directions of the RADIATION BEAM;
- the location of the FOCAL SPOT referred to an accessible point on the X-RAY SOURCE ASSEMBLY/RADIATION HEAD;
- the maximum available X-RAY TUBE VOLTAGE.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

See also Table 201.C.103.

The technical description shall provide full details of the environmental conditions and power supply required for NORMAL USE.

Addition:

201.7.9.3.101 Installation

Where the requirements of this standard are wholly or partly met by measures taken during the course of installation, compliance test methods shall be SPECIFIED in the technical description.

Compliance at installation should be checked by inspection of the technical description and test.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.6.4 Impedance and current-carrying capability

Addition:

aa) The technical description shall contain advice that PROTECTIVE EARTH CONDUCTORS, permanently fixed at installation to connect PROTECTIVE EARTH TERMINALS of ME EQUIPMENT to an external protective system, should be adequately dimensioned according to the requirements of national regulations, for each installation and for the maximum fault current that may occur there.

Compliance is checked by inspection of the technical description

201.8.7.3 Allowable values

Replacement of item d):

The allowable values of the EARTH LEAKAGE CURRENT are 10 mA in NORMAL CONDITION and 20 mA in SINGLE FAULT CONDITION

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows*:*

201.9.2.1 General

Addition:

For the PATIENT SUPPORT system, the requirements shall apply when it is unloaded and when it is loaded with a uniformly distributed mass equal to the maximum specified patient load but not less than 135 kg.

NOTE 1 The phrase "to set-up automatically" or "automatic set-up" is used to denote the moving of ME EQUIPMENT parts automatically to the positions required for the start of a PATIENT treatment simulation.

NOTE 2 The term "pre-programmed movements" is used where movement of ME EQUIPMENT parts takes place according to a previously planned programme, without intervention by the OPERATOR, during PATIENT treatment simulation; this is referred to as "pre-programmed treatment simulation".

201.9.2.2.4.4 Protective measures

Addition:

– where any part of the ME SYSTEM is provided with a device designed to reduce, in NORMAL USE, the RISK of collision with the PATIENT, the operation and limitations of each device shall be described in the instructions for use.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.5 Continuous activation

Replacement of the existing text of the subclause:

201.9.2.2.5.101 General

It shall not be possible to adjust motorized movements of ME EQUIPMENT parts which may cause physical injury to the PATIENT without continuous simultaneous personal action by the OPERATOR on two switches.

NOTE Linear or angular adjustments of BLSs or DELINEATORS are not considered to be likely causes of injury to the PATIENT unless ACCESSORIES are fitted that do not have integral safety devices/touch guards or are otherwise considered to present a HAZARD.

For ME EQUIPMENT intended to be set-up automatically, it shall not be possible to initiate or maintain movements associated with this condition without continuous simultaneous personal action by the OPERATOR on the automatic set-up switch and a switch common to all movements.

All switches, when released, shall be capable of stopping movement within the limits given in 201.9.2.2.6. In each case, at least one of the required switches shall be HARD-WIRED.

Compliance is checked by inspection.

201.9.2.2.5.102 Operation of movements of ME EQUIPMENT parts from inside the simulator room

The switches required by 201.9.2.2.5.101 shall be located close to the PATIENT SUPPORT system, to allow the OPERATOR to observe the PATIENT during ME EQUIPMENT movement to avoid injury to the PATIENT.

GANTRY angular speed may be increased to a maximum of 12°/s, for positioning under manual control and, for ME EQUIPMENT that includes a computed tomography (CT) capability, during the checking of a pre-programmed CT scan, provided that in both cases there is personal action by the OPERATOR on a “fast speed” enabling switch, followed by continuous personal action by the OPERATOR on the GANTRY rotation switch and the switch common to all movements.

The instructions for use shall contain advice that when a remotely controlled movement from the TCP or a CT scan is intended, a check should be made of all intended or planned movements with the PATIENT finally positioned, before the OPERATOR leaves the SIMULATOR room.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.5.103 Operation of movements of ME EQUIPMENT parts from outside the simulator room

For ME EQUIPMENT that includes a computed tomography (CT) capability, GANTRY angular speed may be increased to a maximum of 12°/s, during pre-programmed CT scans, provided that there is continuous simultaneous personal action by the OPERATOR on the CT enabling switch and on the switch common to all movements.

The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR shall have an unobstructed view of the PATIENT before and during the treatment simulation.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.6 Speed of movement(s)

Replacement of the existing text of the subclause:

201.9.2.2.6.101 General

For automatic set-up, speed shall be reduced at least 5° before any planned stop angle and at least 25 mm before any planned stop position. The speed reduction shall be such that overshoot does not exceed 2° for angular displacements and 5 mm for linear displacements. Details of the speed reduction processes shall be included in the technical description.

Compliance is checked by measurement.

201.9.2.2.6.102 Angular movements

No speed shall exceed 7°/s, except for positioning under manual control or during the operation of a pre-programmed CT facility (see subclauses 201.9.2.2.5.102 and 201.9.2.2.5.103).

NOTE This requirement above shall not apply to the BEAM LIMITING SYSTEM (BLS)

When rotating at the speed nearest to, but not exceeding, 1°/s, the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 0,5°, and it shall not exceed 3° for speeds in excess of 1°/s.

201.9.2.2.6.103 Linear movements

No speed shall exceed 100 mm/s.

When moving at speeds not exceeding 25 mm/s, the distance between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 3 mm, and it shall not exceed 10 mm for speeds in excess of 25 mm/s.

Compliance is checked by measurement of the stopping distances. In order to eliminate the effects of variable personal reaction times, measurement shall start at the instant the personally actuated switch contacts open or close. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance.

201.9.2.3 Other HAZARDS associated with moving parts

Addition:

201.9.2.3.101 Interruption or failure

Interruption or failure of

a) the power supply/ies for powered movements or

b) the SUPPLY MAINS to the ME EQUIPMENT

shall cause any parts in motion to be stopped within the limits given in 201.9.2.2.6.

Compliance is checked by interruption of the SUPPLY MAINS a) to powered movements, b) to the ME EQUIPMENT, and measurement of stopping distances. In order to eliminate the effects of variable personal reaction times, measurement shall start at the instant the personally actuated the switch contacts that interrupt the SUPPLY MAINS. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance.

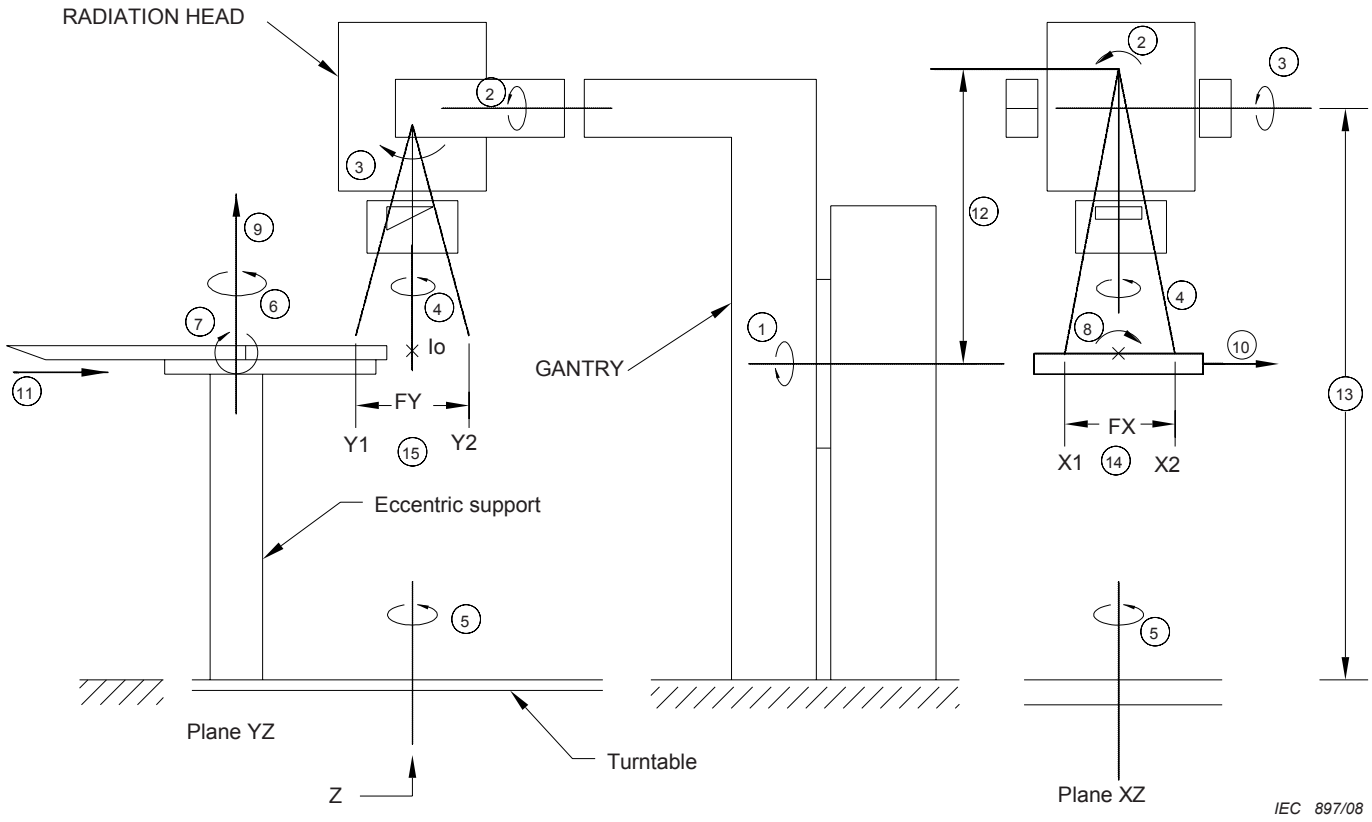
201.9.2.3.102 Accuracy of positioning

To allow the accurate positioning of the moving parts of the simulator, the minimum speeds of the movements shall comply with the following requirements:

– the minimum speed available for each angular movement shall not exceed 1°/s;

– the minimum speed available for displacements 20, 21, 22 and 23 of the DELINEATED RADIATION FIELD edges, 16, 17 and 18 of the X-RAY IMAGE RECEPTOR, and 9, 10 and 11 of the PATIENT SUPPORT system shall not exceed 10 mm/s (see Figures 101, 102 and 103).

Compliance is checked by inspection.



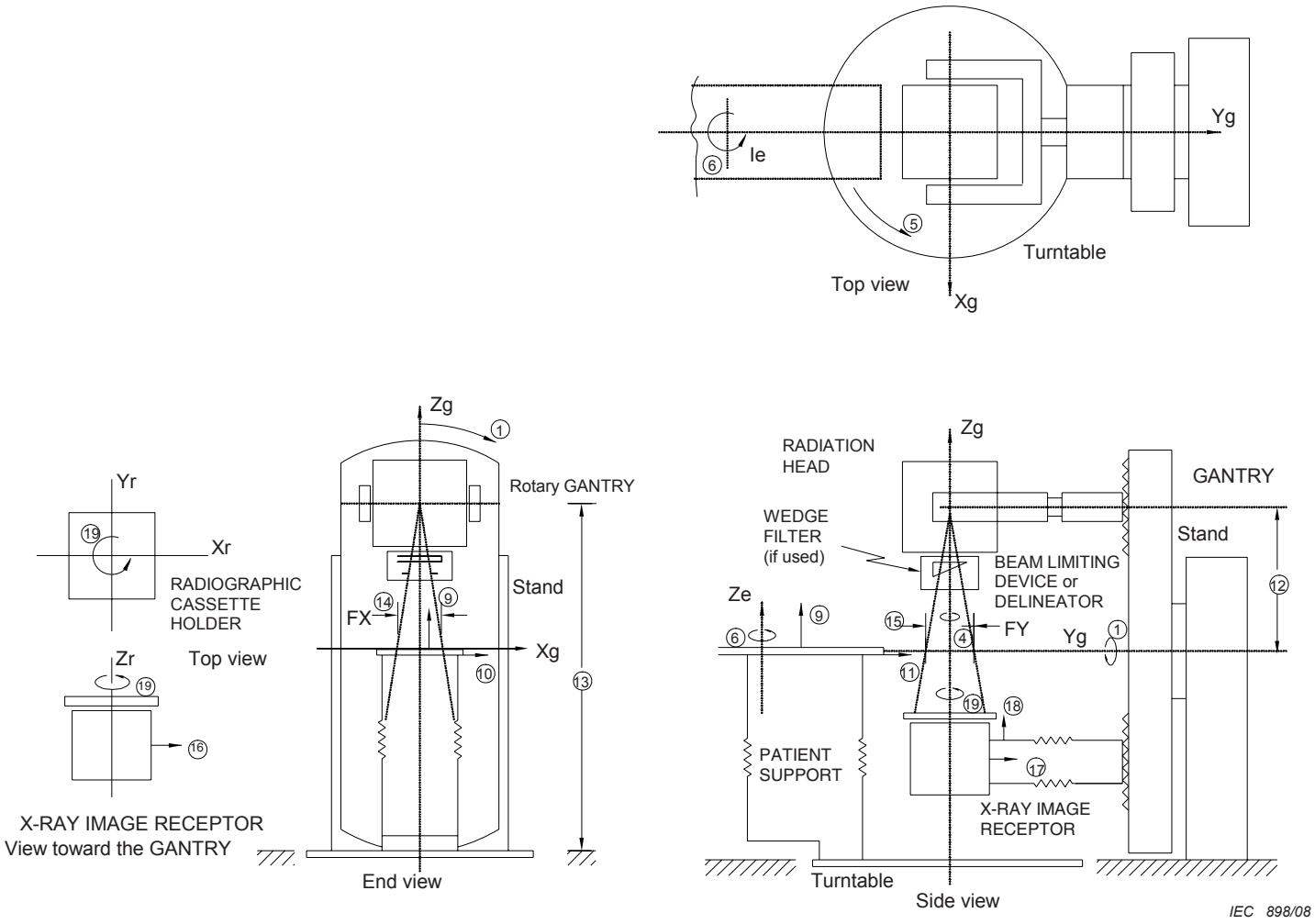
NOTE 1 The axes, directions and dimensions corresponding to the numbers on these figures are listed in the accompanying table.

NOTE 2 The elliptical arrows show clockwise rotations looking towards GANTRY for axes 1 and 8, away from GANTRY for axis 2, from right side of GANTRY for axes 3 and 7, up from ISOCENTRE, Io, for axis 4, up from ISOCENTRE for axis 5, up from table top for axis 6.

NOTE 3 Symbols X1, X2, Y1 and Y2 designate the edges of RADIATION FIELD or DELINEATED RADIATION FIELD according to 6.4.1 of IEC 61217.

NOTE 4 This figure is identical to Figure 13a in IEC 61217.

Figure 101 – Equipment movements and scales – Rotary GANTRY with identification of axes 1 to 8, directions 9 to 13, and dimensions 14 and 15
(see accompanying table)



NOTE 1 RADIOGRAPHIC CASSETTE HOLDER and/or X-RAY IMAGE RECEPTOR motions:

Direction 17: motion along Y-axis, parallel to axis 1;

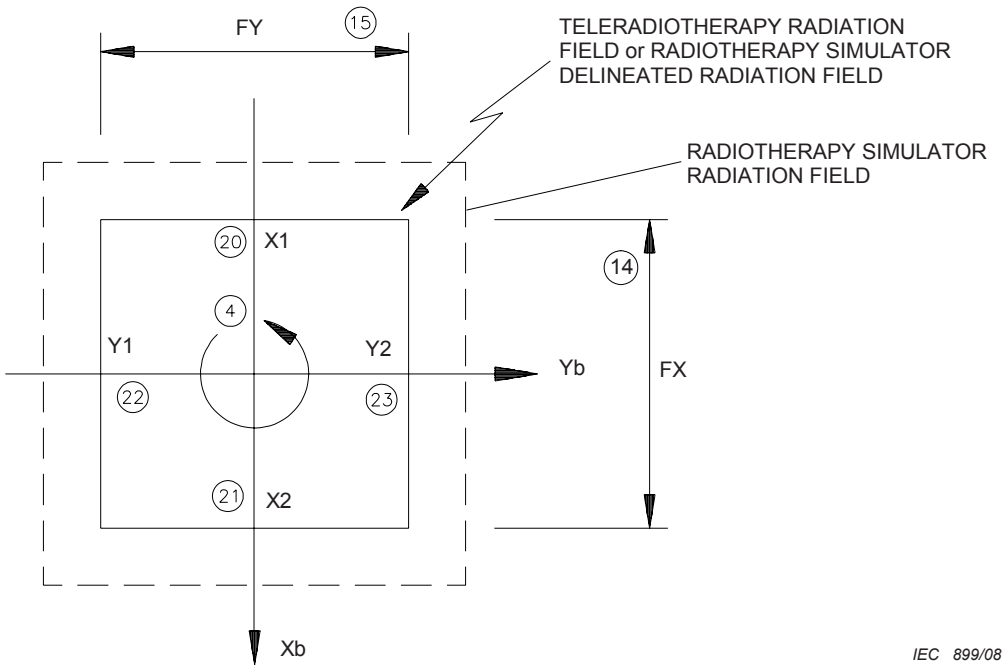
Direction 18: motion along Z-axis, parallel to axis 4;

Axis 19: rotation.

NOTE 2 Symbols Xr, Yr, Zr; Xg, Yg, Zg; and Ze are coordinates for X-RAY IMAGE RECEPTOR; GANTRY; and table top eccentric rotation coordinate systems respectively. Ie is the origin of the eccentric coordinate system.

NOTE 3 This figure is identical to Figure 13b in IEC 61217.

Figure 102 – Equipment movements and scales – ISOCENTRIC RADIOTHERAPY SIMULATOR or TELERADIOTHERAPY ME EQUIPMENT, with identification of axes 1; 4 to 6; 19, of directions 9 to 12; 16 to 18 and of dimensions 14; 15
(see accompanying table)



NOTE 1 This figure is identical to Figure 13c in IEC 61217.

Figure 103 – Equipment movements and scales – View from RADIATION SOURCE of TELERADIOTHERAPY RADIATION FIELD or RADIOTHERAPY SIMULATOR DELINEATED RADIATION FIELD
(see accompanying table)

Table 201.101 – Description of equipment movements

Axis 1	Rotation of GANTRY
Axis 2	Roll of the RADIATION HEAD
Axis 3	Pitch of the RADIATION HEAD
Axis 4	Rotation of the BEAM LIMITING SYSTEM or DELINEATOR
Axis 5	ISOCENTRIC rotation of the PATIENT SUPPORT
Axis 6	Rotation of the table top about the eccentric support
Axis 7	Pitch of the table top
Axis 8	Roll of the table top
Direction 9	Vertical displacement of the table top
Direction 10	Lateral displacement of the table top
Direction 11	Longitudinal displacement of the table top
Direction 12	Displacement of RADIATION SOURCE from axis 1
Direction 13	Displacement of RADIATION SOURCE from floor at GANTRY angular position zero
Dimension 14	Dimension FX of the RADIATION FIELD or DELINEATED RADIATION FIELD in the Xb direction indicated in Figure 103 at a SPECIFIED distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Dimension 15	Dimension FY of the RADIATION FIELD or DELINEATED RADIATION FIELD in the Yb direction indicated in Figure 103 at a SPECIFIED distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 16	X-RAY IMAGE RECEPTOR or RADIOGRAPHIC CASSETTE HOLDER motion along X axis perpendicular to axis 1 and axis 4
Direction 17	X-RAY IMAGE RECEPTOR or RADIOGRAPHIC CASSETTE HOLDER motion along Y axis parallel to axis 1
Direction 18	X-RAY IMAGE RECEPTOR or RADIOGRAPHIC CASSETTE HOLDER motion along Z axis parallel to axis 4
Axis 19	Rotation of the X-RAY IMAGE RECEPTOR or RADIOGRAPHIC CASSETTE HOLDER
Direction 20	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge X1 at a SPECIFIED distance from the RADIATION SOURCE (usually the NORMAL TREATMENT DISTANCE)
Direction 21	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge X2 at a SPECIFIED distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 22	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge Y1 at a SPECIFIED distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 23	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge Y2 at a SPECIFIED distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)

201.9.2.4 Emergency stopping devices

Replacement of the first sentence:

Emergency stopping devices shall be provided that comply with the following requirements:

Addition:

aa) The emergency stopping devices shall be provided in HARD-WIRED circuits near to, or on, the PATIENT SUPPORT system and the TCP, for emergency switching of all power to the movement systems. When operated, any movement shall stop within the limits given in 201.9.2.2.6.

bb) The means provided near to, or on, the TCP shall also TERMINATE IRRADIATION. The time to effect these disconnections shall not exceed 100 ms.

cc) When any of the means are to be incorporated on site by the RESPONSIBLE ORGANIZATION, the requirements and test procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTS.

Replacement of test specifications:

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, the MANUFACTURER's relevant information and by inspection and measurement of stopping distances and disconnection time using suitable measuring instruments; in order to eliminate the effects of variable personal reaction times, measurements shall start at the instant the personally actuated switch contacts open or close.

201.9.2.5 Release of PATIENT

Addition at the end of the clause:

The means provided for the release of the PATIENT shall be described in the instructions for use.

Compliance is checked by inspection of the instructions for use.

201.9.7.2 Pneumatic and hydraulic parts

Additional dash:

– If a HAZARD can arise from a change in the pressure of a system used to provide power for movements, all movement shall stop from any speed within the limits specified in 201.9.2.2.6.

  Compliance is checked by simulation of a fault condition, the operation of protective devices and measurement of stopping distances.

201.9.8.1 General

Additional dashes:

– Where means are provided to permit the attachment of ACCESSORIES supplied by the MANUFACTURER, in particular those for the shaping of the RADIATION BEAM, such means shall be designed to retain those ACCESSORIES securely under all conditions of NORMAL USE.

  Compliance is checked by inspection, and by consideration of design data and applied safety factors.

– The ACCOMPANYING DOCUMENTS shall contain maintenance requirements and define the conditions and limits of use for the means of ACCESSORIES; they shall include guidance regarding design limits for ACCESSORIES manufactured or commissioned by the RESPONSIBLE ORGANIZATION.

  Compliance is checked by inspection.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

The annexes of the general standard apply except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition at the end of the clause:

Table 201.C.101 – ACCOMPANYING DOCUMENTS, General

Description of requirement	Subclause
Emergency stopping devices	201.9.2.4
HAZARDS associated with support systems – General	201.9.8.1

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Addition at the end of the clause:

Table 201.C.102 – ACCOMPANYING DOCUMENTS, Instructions for use

Description of requirement	Subclause
Instructions for use – General	201.7.9.2.1
Environmental protection	201.7.9.2.15
Protective measures	201.9.2.2.4.4
Operation of movements of ME EQUIPMENT parts from inside the SIMULATOR room	201.9.2.2.5.102
Operation of movements of ME EQUIPMENT parts from outside the SIMULATOR room	201.9.2.2.5.103
Release of PATIENT	201.9.2.5

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition at the end of the clause:

Table 201.C.103 – ACCOMPANYING DOCUMENTS, technical description

Description of requirement	Subclause
Technical description – General	201.7.9.3.1
Installation	201.7.9.3.101
Impedance and current carrying capability	201.8.6.4
Speeds of movement(s) – General	201.9.2.2.6.101

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

The use of RADIOTHERAPY SIMULATORS may expose PATIENTS to danger if the ME EQUIPMENT design does not satisfy standards of electrical, mechanical and IONIZING RADIATION safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the IONIZING RADIATION adequately or if there are inadequacies in the design of the SIMULATOR room.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.3 – Collateral standards

Regarding IEC 60601-1-3:

The collateral standard has been generalised to be applicable for all modalities. This standard does not address RADIOTHERAPY SIMULATOR specific matter related to RADIATION PROTECTION.

When applying the IEC 60601-1-3 standard to RADIOTHERAPY SIMULATORS, MANUFACTURERS should balance the RISKS and controls associated with the relatively small amounts of IONIZING RADIATION used for imaging purposes against the RISKS and RISK CONTROLS associated with the relatively large amounts of IONIZING RADIATION used for therapy purposes. This could mean that RISK CONTROLS which are commonly used for diagnostic X-RAY EQUIPMENT may not be appropriate for RADIOTHERAPY SIMULATORS.

NOTE Attention is drawn to the existence, in some countries, of legislation containing requirements for:

– IONIZING RADIATION safety which may not align with the provisions of this Particular Standard, and

– maintenance, quality assurance and other related subjects, which are not covered by this standard.

Regarding IEC 60601-1-8:

Alarms are needed where they are identified as a RISK CONTROL measure. In the present standard, there are no alarms required. Information signals (RADIATION present) should be distinct from an alarm. See also 12.3 of the general standard.

Bibliography

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

[2] IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

[3] IEC 60601-2-1:1998, *Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV*

Index of defined terms used in this particular standard

PATIENT SUPPORT ..... IEC TR 60788:2004, rm-30-02
PREPARATORY STATE ..... IEC TR 60788:2004, rm-84-04
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... IEC 60601-1:2005, 3.90
PROTECTIVE EARTH CONDUCTOR ..... IEC 60601-1:2005, 3.93
PROTECTIVE EARTH TERMINAL ..... IEC 60601-1:2005, 3.95

RADIATION ..... IEC TR 60788:2004, rm-11-01
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TREATMENT CONTROL PANEL (TCP) ..... IEC TR 60788:2004, rm-33-05

WEDGE FILTER ..... IEC TR 60788:2004, rm-35-10

X-RAY EQUIPMENT ..... IEC TR 60788:2004, rm-20-20
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X-RAY TUBE VOLTAGE ..... IEC TR 60788:2004, rm-36-02

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