IEC 60601-2-11

Edition 3.0 2013-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment

Appareils électromédicaux –
Partie 2-11: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de gammathérapie

IEC 60601-2-11:2013

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment

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 60601-2-11 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 third edition cancels and replaces the second edition of IEC 60601-2-11 published in 1997 and its Amendment 1:2004. This edition constitutes a technical revision which brings this standard in line with the third edition of IEC 60601-1 and its collateral standards.

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

FDIS	Report on voting
62C/552/FDIS	62C/558/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 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 collateral 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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

The use of GAMMA BEAM THERAPY EQUIPMENT for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME equipment fails to deliver the required dose to the PATIENT, or if the ME equipment design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME equipment itself fails to contain the RADIATION adequately or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of gamma beam therapy equipment. Subclause 201.10.2 states tolerance limits beyond which INTERLOCKS must prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition. TYPE TESTS which are performed by the MANUFACTURER, or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are specified for each requirement.

Subclause 201.10.2 does not attempt to define the optimum performance requirements for a GAMMA BEAM THERAPY EQUIPMENT for use in RADIOTHERAPY. Its purpose is to identify those features of design which 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 at which it can be presumed that a fault condition applies, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the ME EQUIPMENT after installation.

The relationship of this particular standard with IEC 60601-1 (including the amendments) and the collateral standards is explained in 201.1.3 and 201.1.4.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment

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 GAMMA BEAM THERAPY EQUIPMENT, including MULTI-SOURCE STEREOTACTIC RADIOTHERAPY equipment, 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 GAMMA BEAM THERAPY EQUIPMENT.

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 201.2 of this particular standard.

IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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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.*

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 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 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 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, figures or tables 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, figures or tables 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 clause or subclause in this particular standard, the 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:

Replacement:

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*

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 46.

Addition:

201.3.201
BEAM OFF
condition in which the RADIATION SOURCE(S) is(are) fully shielded, and are also in a position in which they can be secured

201.3.202
BEAM ON
condition in which the RADIATION SOURCE(s) is(are) fully exposed for RADIOTHERAPY

201.3.203
CONTROLLING TIMER
TIMER
device to measure the time during which IRRADIATION occurs and, when a predetermined time is reached, to TERMINATE IRRADIATION

201.3.204
GAMMA BEAM THERAPY EQUIPMENT
RADIONUCLIDE BEAM THERAPY EQUIPMENT, in which the RADIONUCLIDE is a gamma emitter

201.3.205
GANTRY
that part of the ME EQUIPMENT supporting and allowing possible movements of the RADIATION HEAD

Note 1 to entry: MULTI-SOURCE STEREOTACTIC RADIOTHERAPY (MSSR) equipment usually is not equipped with a gantry.

201.3.206
GEOMETRICAL FIELD SIZE
geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the RADIATION BEAM AXIS, as seen from the centre of the front surface of the RADIATION SOURCE

Note 1 to entry: The RADIATION FIELD is thus of the same shape as the aperture of the beam limiting device. The geometrical field size may be defined at any distance from the RADIATION SOURCE.

201.3.207
HELMET
three dimensional multi-source ISOCENTRIC BEAM LIMITING SYSTEM used in MSSR for TREATMENT VOLUMES within the head or neck

201.3.208
INTERRUPTION OF IRRADIATION
INTERRUPTION
TO INTERRUPT IRRADIATION
TO INTERRUPT
stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

Note 1 to entry: I.e. a return to the READY STATE.

201.3.209
IRRADIATION FIELD SIZE
FIELD SIZE
<radiotherapy> dimensions of an area in a plane perpendicular to the radiation beam axis at a specified distance from the RADIATION SOURCE or at a specified depth in the irradiated object and defined by specified isodose lines

[SOURCE: IEC TR 60788:2004, rm-37-11]

201.3.210
MOVING BEAM RADIOTHERAPY
RADIOTHERAPY with any planned displacement of the RADIATION FIELD or PATIENT relative to each other or with any planned change of ABSORBED DOSE distribution

[SOURCE: IEC TR 60788:2004, rm-42-41]

201.3.211
MULTI-SOURCE STEREOTACTIC RADIOTHERAPY
MSSR
RADIOTHERAPY using STEREOTACTIC RADIOTHERAPY procedure using more than one RADIATION SOURCE

201.3.212
NORMAL TREATMENT DISTANCE
SPECIFIED distance measured along the RADIATION BEAM AXIS from the RADIATION SOURCE to the ISOCENTRE or, for ME EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

201.3.213
PRIMARY/SECONDARY TIMER COMBINATION
PRIMARY/SECONDARY COMBINATION
combination of two TIMERS in which one is arranged to be the PRIMARY TIMER and the other is to be the SECONDARY TIMER

201.3.214
PRIMARY TIMER
controlling timer which is intended to TERMINATE IRRADIATION at the pre-selected time

201.3.215
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS
system based on one or more central processing units, including their software and interfaces

Note 1 to entry: These devices may contain one or more central processing units connected to sensors or actuators, for the purpose of control, protection or monitoring.

[SOURCE: IEC 60601-1:2005, 3.91, modified – a note to entry has been added to the definition.]

201.3.216
QUALIFIED PERSON
person recognised by a competent authority as having the requisite knowledge and training to perform specified duties

201.3.217
REDUNDANT TIMER COMBINATION
REDUNDANT COMBINATION
combination of two CONTROLLING TIMERS in which both are arranged to TERMINATE IRRADIATION at the pre-selected time

201.3.218
RELATIVE SURFACE DOSE
<individual source> ratio of the ABSORBED DOSE on its RADIATION BEAM AXIS at the depth of 0,5 mm to its maximum ABSORBED DOSE on its RADIATION BEAM AXIS, both measured in a PHANTOM with its surface at a specified distance

<MSSR equipment> ratio of the ABSORBED DOSE on each single RADIATION BEAM AXIS at the depth of 0,5 mm to the maximum ABSORBED DOSE on the RADIATION BEAM AXIS, both measured in a PHANTOM with its surface at a specified distance, when all other RADIATION SOURCES are blocked

201.3.219
REPOSITIONING
movement and adjustment of the STEREOTACTIC frame with respect to the HELMET to alter the intended TREATMENT VOLUME

201.3.220
REPOSITIONING POINT
retracted position of the HELMET where REPOSITIONING of the frame is possible

201.3.221
REPOSITIONING TIME
added time the ME EQUIPMENT needs to move from the BEAM ON condition to the REPOSITIONING POINT, to achieve REPOSITIONING and to return from the REPOSITIONING POINT to the BEAM ON condition

201.3.222
SECONDARY TIMER
CONTROLLING TIMER which is intended to TERMINATE IRRADIATION in the event of failure of the PRIMARY TIMER

201.3.223
SITE TEST
test of the individual device or ME EQUIPMENT to establish compliance with specified criteria after installation

201.3.224
STEREOTAXIS
STEREOTACTIC
method for locating points within the human body using an external, three-dimensional frame of reference

201.3.225
TERMINATION OF IRRADIATION
TERMINATION
TO TERMINATE IRRADIATION
TO TERMINATE
stopping of IRRADIATION with no possibility of re-starting without the re-selection of all operating conditions

Note 1 to entry: This is the case when

– the pre-selected value of elapsed time is reached; or
– the IRRADIATION was terminated:
  - by deliberate manual act;
  - by the operation of an INTERLOCK;
  - by pre-selected value of gantry angular position in MOVING BEAM RADIOTHERAPY.

201.3.226
TRANSITION TIME
time between when BEAM OFF condition is left until the BEAM ON condition is achieved or vice versa

201.3.227
TRANSITION RADIATION
dose received during the TRANSITION TIME

201.3.228
TREATMENT
application of a prescribed procedure, or a part thereof, for therapeutic purposes

201.3.229
TREATMENT FIELD
<RADIOTHERAPY> area at the PATIENT'S surface which is to be IRRADIATED

201.3.230
TYPE TEST
test on a representative sample of the equipment with the objective of determining whether the equipment, as designed and manufactured, can meet the requirements of this standard

[SOURCE: IEC 60601-1:2005, 3.135]

201.3.231
ZERO APPLICATOR
means to bypass the INTERLOCK in a system which includes an interlock against IRRADIATION without a BEAM APPLICATOR

201.3.232
PASSWORD
<RADIOTHERAPY> sequence of keystrokes that permits OPERATOR access for NORMAL USE or to reset INTERLOCKS and, with a different sequence of keystrokes, permits access for adjustment and maintenance

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.1 TYPE TESTS

Addition:

201.5.1.101 Test grades

Test procedures described in this particular standard are classified into three grades of TYPE TEST and two grades of SITE TEST. Their requirements are as follows:

– TYPE TEST grade A: an analysis of ME EQUIPMENT design, as related to the SPECIFIED RADIATION safety provisions, and inspection of the RISK MANAGEMENT FILE, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled.

– TYPE TEST/SITE TEST grade B: visual inspection or functional test or measurement of the ME EQUIPMENT. The test shall be carried out in accordance with the procedure SPECIFIED IN this particular standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the ME EQUIPMENT.

– TYPE TEST/SITE TEST grade C: functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this particular standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with circuitry or the construction of the ME EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER or his agent.

NOTE 1 The division between TYPE TEST and SITE TEST enables the testing of the entire functionality including aspects of the final assembly and installation of the individual EQUIPMENT with and without radioactive sources loaded .

NOTE 2 The distinction between grade B and grade C tests is that this standard specifies the PROCEDURES for grade B tests whereas, for grade C tests, the PROCEDURES need to be decided by the MANUFACTURER according to the design of the particular ME EQUIPMENT, and this standard specifies only the principles.

NOTE 3 It may be beneficial to perform TYPE TEST grade A during the design of the EQUIPMENT.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement:

ME EQUIPMENT within the scope of this standard shall be CLASS I.

ME EQUIPMENT within the scope of this standard shall have TYPE B APPLIED PART or TYPE BF APPLIED PART.

NOTE Generally ME EQUIPMENT other than MSSR will have TYPE B APPLIED PARTS but TYPE BF APPLIED PARTS are not prohibited.

201.6.3 Protection against harmful ingress of water or particulate matter

Replacement:

Unless otherwise SPECIFIED, ME EQUIPMENT within the scope of this standard shall be ordinary ME EQUIPMENT (enclosed ME EQUIPMENT without protection against ingress of water).

201.6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT

Replacement:

ME EQUIPMENT within the scope of this standard is not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies except as follows:

201.7.2.13 Physiological effects (safety signs and warning statements)

Addition:

The RADIATION HEAD shall be clearly and permanently marked on its outer surface with a RADIATION warning sign according to IEC TR 60878.

SITE TEST – *Grade B – Procedure: visually inspect the* RADIATION HEAD.

201.7.2.20 Removable protective means

Addition:

Where the requirements of this item are wholly or partly met by the nature of the installation, compliance at installation should be checked by inspection in order to prove that all parts are delivered and installed correctly. The results should be included in the SITE TEST report.

201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.3.101 RADIATION HEAD

Removal of the covers of the RADIATION HEAD shall expose symbol 10 of Table D.2 of the general standard, “Follow operating instructions”.

Subassemblies that are exposed with the removal of covers and containing radioactive sources should be marked with RADIATION warning signs according to IEC TR 60878.

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 Therapy equipment

The following shall be provided:

a) a mechanical scale or a numerical indication for each available movement. This does not apply in the case of MSSR during the set-up of the PATIENT.

NOTE For MSSR, during set-up of the PATIENT, the PATIENT SUPPORT is not in the position it will be in during TREATMENT.

b) when applicable, a LIGHT FIELD, with an indication of the position of the REFERENCE AXIS. This item is not applicable for MSSR;