IEC 60601-2-1

Edition 3.0 2009-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-1: Exigences particulières de sécurité de base et de performances essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 60601-2-1 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 third edition cancels and replaces the second edition published in 1998 and its Amendment 1 (2002). It constitutes a technical revision.

This third edition addresses the following issues not covered in previous editions:

– alignment with the new relevant collateral standards;
– new technologies in radiotherapy, including:
  • stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT);
  • intensity modulated radiotherapy (IMRT);
  • electronic imaging devices (e.g. EPID);
  • moving beam radiotherapy (dynamic therapy).

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

FDIS	Report on voting
62C/474/FDIS	62C/480/RVD

Full information on the voting for the approval of this particular 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 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.

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 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

The use of ELECTRON ACCELERATORS 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 and/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 ELECTRON ACCELERATORS for use in RADIOTHERAPY; 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 and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and end user.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, 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 at installation.

This International Standard was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. This third edition is prompted by the need to align this particular standard with the third edition of the general standard, IEC 60601-1:2005.

IEC 60976 and IEC/TR 60977 are closely related to this standard. The former specifies test methods and reporting formats for performance tests of ELECTRON ACCELERATORS for use in RADIOTHERAPY, with the aim of providing uniform methods for conducting such tests. The latter is not a standard per se, but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with present technology.

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

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 ELECTRON ACCELERATORS, hereafter referred to as ME EQUIPMENT, in the range 1 MeV to 50 MeV, used for treatment of PATIENTS.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of ELECTRON ACCELERATORS

– intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),

– that, under NORMAL CONDITIONS and in NORMAL USE, deliver a RADIATION BEAM of X-RADIATION and/or ELECTRON RADIATION having

- NOMINAL ENERGY in the range 1 MeV to 50 MeV,
- maximum ABSORBED DOSE RATES between 0,001 Gy × s^{-1} and 1 Gy × s^{-1} at 1 m from the RADIATION SOURCE,
- NORMAL TREATMENT DISTANCES (NTDs) between 0,5 m and 2 m from the RADIATION SOURCE,

and

– intended to be

- for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular specified clinical purposes, e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises.

NOTE 2 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

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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*.

IEC 61271 gives guidance on the designation of ME EQUIPMENT movements; the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

IEC 60676 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS. The standard is intended to facilitate comparisons of accelerator-based ME EQUIPMENTs of different manufacture. IEC 60676 contains no safety requirements, and is therefore not required for compliance with this particular standard. It should also be noted (as stated in the Introduction to IEC 60976:2007) that tests specified in IEC 60976 are not necessarily appropriate for ensuring that any individual medical ELECTRON ACCELERATOR conforms to the declared functional performance during the course of its working lifetime.

NOTE 3 IEC/TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*, is a related technical report that provides performance guidelines. It shall not be construed as a standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTRON ACCELERATORS in the range 1 MeV to 50 MeV and to specify tests to check compliance to those requirements.

NOTE The adoption of this standard helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE,
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, by utilizing STATIONARY RADIOTHERAPY, MOVING BEAM RADIOTHERAPY, RADIATION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

201.1.3 Collateral standards

Addition:

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

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 60601-1-6 apply as modified in Clauses 206. IEC 60601-1-3, IEC 60601-1-8 and 60601-1-10[2] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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.

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2 IEC 60601-1-10, Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers

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, 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:

NOTE Informative references are listed in the bibliography on page 60.

Addition:

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available in English only)

IEC 61217:1996, *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 to be found at the end of the document.

Addition:

201.3.201
AMBIENT DOSE EQUIVALENT
$H^*(10)$
DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT which would be generated in the associated oriented and expanded RADIATION FIELD at a depth of 10 mm on the radius of the ICRU sphere which is oriented opposite to the direction of incident RADIATION

NOTE 1 An oriented and expanded RADIATION FIELD is an idealized RADIATION FIELD which is expanded and in which the radiation is additionally oriented in one direction.

NOTE 2 See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

201.3.202
CONTROLLING TIMER
device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, TO TERMINATE IRRADIATION

201.3.203
ELECTRON BEAM APPLICATOR
BEAM LIMITING DEVICE for ELECTRON RADIATION beams

201.3.204
ELECTRONIC IMAGING DEVICE
EID
device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

[IEC 60976:2007, definition 3.5]

201.3.205
ELECTRONIC PORTAL IMAGING DEVICE
EPID
device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed substantially normal to the RADIATION BEAM AXIS, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen, using the medical ELECTRON ACCELERATOR'S RADIATION BEAM as the RADIATION SOURCE

NOTE 1 The primary function of an EPID is in verification of PATIENT set-up, and so replaces the need for port films for this same purpose.

[IEC 60976:2007, definition 3.6]

NOTE 2 This definition is not included in IEC/TR 60788.

201.3.206
GANTRY
part of the ME EQUIPMENT supporting the RADIATION HEAD

201.3.207
GEOMETRICAL RADIATION FIELD
geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window; the GEOMETRICAL RADIATION FIELD may be defined at any distance from the front surface of the TARGET for X-RADIATION, or from the ELECTRON RADIATION window for ELECTRON RADIATION

201.3.208
HARD-WIRED
term used where the features of a system can be modified only by physically removing and re-routing wires

201.3.209
INTENSITY MODULATION RADIATION THERAPY
IMRT
treatment procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the PATIENT, and beam size of the external beam, either in a continuous or a discrete manner, and as pre-determined by a treatment plan

NOTE The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned TARGET VOLUME, while minimizing dose to surrounding healthy tissue.

201.3.210
INTERRUPTION OF IRRADIATION/TO INTERRUPT IRRADIATION
stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

201.3.211
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

201.3.212
NOMINAL ENERGY
ENERGY
<ELECTRON RADIATION> ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

<X-RADIATION> ENERGY stated by the MANUFACTURER to characterize the radiation BEAM

201.3.213
NORMAL TREATMENT DISTANCE
NTD
<ELECTRON RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane

<X-RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for ME EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

201.3.214
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

201.3.215
PATIENT SUPPORT
<RADIOTHERAPY> assembly of ME EQUIPMENT that supports the PATIENT

201.3.216
PRIMARY/SECONDARY DOSE MONITORING COMBINATION
utilization of two DOSE MONITORING SYSTEMS where one is arranged to be the PRIMARY and the other the SECONDARY DOSE MONITORING SYSTEM

201.3.217
QUALIFIED PERSON
person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

201.3.218
RADIATION TYPE
nature of the waves or corpuscles comprising the RADIATION

NOTE E.g. whether the RADIATION is X-RADIATION or ELECTRON RADIATION.

201.3.219
REDUNDANT DOSE MONITORING COMBINATION
utilization of two DOSE MONITORING SYSTEMS where both systems are arranged TO TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

201.3.220
RELATIVE SURFACE DOSE
ratio of the ABSORBED DOSE on the REFERENCE AXIS, at the depth of 0,5 mm, to the maximum ABSORBED DOSE on the REFERENCE AXIS, both measured in a PHANTOM with its surface at a SPECIFIED distance

201.3.221
SITE TEST
after installation, test of an individual device or ME EQUIPMENT to establish compliance with SPECIFIED criteria

201.3.222
STEREOTACTIC RADIOTHERAPY
SRT
treatment procedure in which RADIATION BEAMS of generally small size are oriented from various angles, and precisely positioned relative to a TARGET VOLUME within the PATIENT

NOTE Precise location of the TARGET VOLUME is enabled by use of a three-dimensional frame of reference, which may include anatomical registration points or markers, and immobilisation methods, or imaging techniques.

201.3.223
STEREOTACTIC RADIOSURGERY
SRS
SPECIFIC version of STEREOTACTIC RADIOTHERAPY, in which a single high dose of RADIATION is delivered to the TARGET VOLUME, using a STEREOTACTIC FRAME OF REFERENCE in conjunction with anatomical registration points

201.3.224
STEREOTACTIC FRAME OF REFERENCE
three-dimensional coordinate system for numerical specification of the position of those parts of a PATIENT anatomy intended for SRS/SRT treatment