IEC 60601-2-1

Edition 4.0 2020-10

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 pour la sécurité de base et les performances essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV

IEC 60601-2-1:2020-10(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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International Standard IEC 60601-2-1 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 fourth edition cancels and replaces the third edition published in 2009 and Amendment 1:2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) alignment with the new relevant collateral standards;
b) addition of computer interface and control;
c) addition of new technologies in RADIOTHERAPY, including
   - BEAM GATING, and
   - ADAPTIVE RADIOTHERAPY.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62C/770/FDIS	62C/785/RVD

Full information on the voting for the approval of this document 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 document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 Clause 7 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 document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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.

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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment MANUFACTURERs and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose distribution to the PATIENT, or if the ME EQUIPMENT design fails to meet the requirements of BASIC SAFETY and ESSENTIAL PERFORMANCE. 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 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.

Clauses 201.10, 201.103, 201.104, 201.105 and 201.108 contain limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. In this document, the information in Clause 201.10 has either been reorganized or moved to other clauses in order to better reflect current usage and broaden the applicability of certain clauses to always apply to the ME EQUIPMENT when IRRADIATION is being produced and not just when a PATIENT is being treated. Annex AA provides a table showing the relationship between the clauses in IEC 60601-2-1:2009 and IEC 60601-2-1:2009/AMD1:2014 and the clauses in this document.

TYPE TESTS that are performed by the MANUFACTURER, 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 RESPONSIBLE ORGANIZATION.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, data obtained from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTATION, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

IEC 60601-2-1 was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. The third edition was prompted by the need to align IEC 60601-2-1 with the third edition of the general standard, IEC 60601-1:2005, and was amended in 2014. This fourth edition is prompted by the need to update IEC 60601-2-1 for the technology that is in current use as well as to bring it into alignment with IEC 60601-1:2005 and IEC 60601-2-1/AMD1:2012. This prompted the relabelling and organization of Clause 201.10 as well as the addition of Clauses 201.102 through 201.109.

IEC 60976:2007 and IEC TR 60977:2008 are closely related to the third edition of this document. 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 performance standard but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with technology available at the time of publication. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERs replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

When a stated requirement does not apply to a given piece of equipment because the function involved does not exist on that equipment, compliance with that requirement is not necessary. However, when that stated requirement addresses a RISK that could be caused by a substantially similar function of the equipment, the MANUFACTURER needs to address the RISK caused by that similar function in the RISK MANAGEMENT FILE.

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 part of IEC 60601 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.

NOTE 1 While ELECTRON ACCELERATORS used for TREATMENT of PATIENTS are always ME EQUIPMENT, there are times in this document where they are referred to as EXTERNAL BEAM EQUIPMENT (EBE). Usage of EBE does not remove the requirements placed on the ME EQUIPMENT but is meant to clarify that the ME EQUIPMENT being discussed is the EBE and not some other ME EQUIPMENT that may be part of the system configuration.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies to the manufacture and some installation aspects of ELECTRON ACCELERATORS and their included equipment used to increase the precision, accuracy and volumetric targeting of the TREATMENT delivery

– intended for RADIOTHERAPY in medical practice, including those in which the selection and DISPLAY of TREATMENT 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 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 the ERP from the RADIATION SOURCE, and
  - REFERENCE TREATMENT DISTANCES (RTDs) between 0,5 m and 2 m from the RADIATION SOURCE;

and

– intended to be

  - for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS appropriately licensed or having the required skills for a particular medical application, for particular SPECIFIED clinical purposes,
  - maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
  - subject to regular QUALITY ASSURANCE performance and calibration checks by a QUALIFIED PERSON.

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[1] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

NOTE 2 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 3 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

NOTE 4 The limits on maximum ABSORBED DOSE RATES are included for two reasons. The first is due to requirements related to time in this document. This restriction limits the total dose that could be delivered during a SPECIFIED time (examples: timer, TIME TO INTERRUPT or TERMINATE, LATENCY). The second is to limit the amount of RADIATION damage that can occur during the time required to take action (often as a follow up to an INTERRUPTION or TERMINATION OF IRRADIATION). Wherever requirements were made to limit the amount of dose delivered before action is taken, the RADIATION damage was considered to be independent of the dose rate and only dependent on the dose. This would largely hold true if the dose rate stayed within the range stated above.

IEC 61217 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 60976:2007 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS and is intended to facilitate comparisons of accelerator-based ME EQUIPMENTs of different manufacture. IEC 60976:2007 contains no safety requirements, and is not required to show compliance with this document. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

IEC TR 62926 provides guidance for integration of ELECTRON ACCELERATORS with other equipment.

IEC TR 63183 provides guidance on the construction of error and warning messages.

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 document helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- maintains OPERATOR and general public safety during ME EQUIPMENT NORMAL USE and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE, and
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, without causing unnecessary RISK to the PATIENT, the OPERATOR, other persons or the environment.

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 60601-1-2:2014 applies. IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clause 206. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013, IEC 60601-1-11 and IEC 60601-1-12 do not apply, and all other collateral standards in the IEC 60601-1 series do not apply.

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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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 3.147, additional definitions in this document 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, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" 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

NOTE Informative references are listed in the Bibliography.

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-68:2014, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 111.

Addition:

201.3.201
ADAPTIVE RADIOTHERAPY
RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

Note 1 to entry: IMAGE-GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY.

201.3.202
AMBIENT DOSE EQUIVALENT
$H^*(10)$
DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT that would be produced by the corresponding aligned and expanded RADIATION FIELD at a depth of 10 mm in the ICRU sphere on the radius opposing the direction of the aligned RADIATION FIELD

Note 1 to entry: 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 to entry: See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

201.3.203
BEAM GATING
allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

[SOURCE: IEC 60601-2-64:2014, 201.3.204]

201.3.204
BEAM GATING SIGNAL
signal generated for the purpose of BEAM GATING

EXAMPLE Examples include a respiratory spirometer, electrocardiogram, optical sensor, etc.

[SOURCE: IEC 60601-2-64:2014, 201.3.205]

201.3.205
BEAM GATING LATENCY
time between the assertion of the BEAM GATING SIGNAL and the inhibition or enabling of IRRADIATION

Note 1 to entry: The inhibition or enabling of IRRADIATION is measured at 90 % of dose rate change.

201.3.206
BEAM HOLD
condition, during IRRADIATION, in which the ME EQUIPMENT has minimized the TREATMENT IRRADIATION output

Note 1 to entry: BEAM HOLD is not the same as INTERRUPTION OF IRRADIATION where the ME EQUIPMENT is changed to the beam off state.

Note 2 to entry: BEAM HOLD is a subcondition of IRRADIATION for the purpose of rapid transition to intended TREATMENT IRRADIATION output.

Note 3 to entry: BEAM HOLD approximates the IRRADIATION off condition by inhibiting the IRRADIATION output.

Note 4 to entry: This is commonly used during gating, INTENSITY-MODULATED RADIATION THERAPY (IMRT), etc.

201.3.207
BEAM LIMITING DEVICE
BLD
<RADIOTHERAPY> structure, fixed or movable, intended to block or collimate IONIZING RADIATION, resulting in shielding the TREATMENT region from unintended X-RADIATION or ELECTRON RADIATION

Note 1 to entry: Examples are non-adjustable primary collimators, adjustable collimators, JAWS, MLCs, cones (non-adjustable BLD), etc.

[SOURCE: IEC 60976:2007, 3.2, modified – Note added.]