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

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 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 ensure 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*.