

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**



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CONTENTS

FOREWORD.....	5
INTRODUCTION.....	8
201.1 Scope, object and related standards	9
201.1.1 Scope	9
201.1.2 Object	10
201.1.3 Collateral standards	10
201.1.4 Particular standards	11
201.2 Normative references	12
201.3 Terms and definitions	2
201.4 General requirements.....	21
201.5 General requirements for testing ME EQUIPMENT.....	21
201.5.1 TYPE TESTS.....	21
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	22
201.7 ME EQUIPMENT identification, marking and documents.....	22
201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	23
201.7.4 Marking of controls and instruments	23
201.7.9 ACCOMPANYING DOCUMENTS.....	25
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	31
201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS.....	31
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	32
201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure	38
201.9.8 MECHANICAL HAZARDS associated with support systems	38
201.10 Protection against unwanted and excessive RADIATION HAZARDS	39
201.10.2 Alpha, beta, gamma, neutron and other particle RADIATION	39
201.10.101 ME EQUIPMENT intended to produce therapeutic X-RADIATION and ELECTRON RADIATION	39
201.11 Protection against excessive temperatures and other HAZARDS.....	80
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	80
201.12.3 ALARM SYSTEMS	80
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	81
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	81
201.14.101 PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)	81
201.15 Construction of ME EQUIPMENT	82
201.16 ME SYSTEMS.....	82
201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM	82
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS.....	83
201.17.101 Additional requirements	83
201.17.102 Radio-frequency EMISSIONS	83
201.17.103 IMMUNITY to radio-frequency electromagnetic fields	83
201.101 * ELECTRONIC IMAGING DEVICES (e.g. EPID)	84
201.102 Date and time format.....	84
201.103 EXTERNAL MONITORING DEVICES	84
201.103.1 Selection, VERIFICATION, and DISPLAY of EXTERNAL MONITORING DEVICES	84
201.103.2 BEAM GATING	85

201.104 * LATENCY.....	86
201.105 Interfaces.....	87
201.105.1 Correctness of data transfer.....	87
201.105.2 VERIFICATION of data coherence and selection of TREATMENT PARAMETERS.....	87
201.105.3 Interface data requirements.....	88
201.106 TREATMENT PLAN retrieval.....	89
201.107 Recording of TREATMENT delivery.....	89
201.108 ADAPTIVE RADIOTHERAPY.....	90
201.108.1 OFFLINE ADAPTIVE RADIOTHERAPY.....	90
201.108.2 ONLINE ADAPTIVE RADIOTHERAPY.....	90
201.108.3 REAL-TIME ADAPTIVE RADIOTHERAPY.....	91
201.109 Imaging dose delivery.....	92
201.110 Operation of ME EQUIPMENT from outside the facility.....	92
206 USABILITY.....	93
206.101 Usability of ELECTRON ACCELERATORS.....	93
Annexes.....	94
Annex B (informative) Sequence of testing.....	95
B.1 General.....	95
Annex AA (informative) Particular guidance and rationale.....	96
AA.1 General guidance.....	96
AA.1.1 Overview.....	96
AA.1.2 Mapping of the clauses in IEC 60601-2-1:2009 and IEC 60601-2-1:2009/AMD1:2014 (edition 3.1) to this document (edition 4.0).....	96
AA.2 Rationale for particular clauses and subclauses.....	101
Annex BB (informative) Electronic imaging devices (e.g. epid).....	104
BB.1 General guidance.....	104
BB.2 ELECTRONIC IMAGING DEVICES (e.g. EPID) (Clause 201.101 of IEC 60601-2-1:2009).....	104
BB.2.1 Image coordinates and orientation (201.101.1 of IEC 60601-2-1:2009).....	104
BB.2.2 Image scale factor (201.101.2 of IEC 60601-2-1:2009).....	104
BB.2.3 Image field of view and alignment (201.101.3 of IEC 60601-2-1:2009).....	104
BB.2.4 EID PATIENT clearance (201.101.4 of IEC 60601-2-1:2009).....	104
BB.2.5 Artefacts (201.101.5 of IEC 60601-2-1:2009).....	104
Annex CC (informative) Latency and accuracy of dose delivery between CONTROL POINTS.....	106
Annex DD (informative) Radiobiology considerations.....	108
Bibliography.....	109
Index of defined terms.....	111
Figure 201.101 – Flattened area within the RADIATION FIELD.....	19
Figure 201.102 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION.....	59
Figure 201.103 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION.....	61
Figure 201.104 – Elevation view – Application of LEAKAGE RADIATION requirements.....	64
Figure 201.105 – 24 measurement points for averaging LEAKAGE RADIATION during X- RADIATION.....	67

Figure 201.106 – Limits of LEAKAGE RADIATION through the BEAM LIMITING DEVICES during ELECTRON IRRADIATION	69
Figure 201.107 – Measurement points for averaging LEAKAGE RADIATION during ELECTRON IRRADIATION	71
Figure 201.108 – 24 measurement points for averaging LEAKAGE RADIATION outside area <i>M</i>	73
Figure 201.109 – ME EQUIPMENT movements and scales	74
Figure AA.1 – Closed-loop control dose delivery system	102
Figure AA.2 – Dynamic dose-positioning.....	102
Figure CC.1 – Diagram to measure the BEAM GATING LATENCY at disabling IRRADIATION	106
Figure CC.2 – Diagram to measure the BEAM GATING LATENCY at enabling IRRADIATION	107
Figure CC.3 – BEAM HOLD and beam restart response times.....	107
Table 201.101 – Dimensions defining the flattened area according to Figure 201.101.....	19
Table 201.102 – Data required in the technical description to support Clause 201.10 SITE TEST compliance	26
Table 201.103 – Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description	28
Table 201.105 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (see Figure 201.103)	60
Table AA.1 – Items of consideration in the generation of this document.....	96
Table AA.2 – Mapping of clauses in edition 3.1 to clauses in this document (excluding Clause 201.10)	97
Table AA.3 – New clauses in this document.....	99
Table AA.4 – Mapping of clauses in edition 3.1 to clauses in this document (Clause 201.10)	100

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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

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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/AMD1:2014. 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 standard¹ 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 $0,001 \text{ Gy} \times \text{s}^{-1}$ and $1 \text{ Gy} \times \text{s}^{-1}$ 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.

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*.