

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

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	11
201.4 General requirements	14
201.5 General requirements for testing ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	15
201.7 ME EQUIPMENT identification, marking and documents	15
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	21
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	22
201.10 Protection against unwanted and excessive radiation HAZARDS.....	25
201.11 Protection against excessive temperatures and other HAZARDS	47
201.12 Accuracy of controls and instruments and protection against hazardous outputs	47
201.13 HAZARDOUS SITUATIONS and fault conditions	47
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	47
201.15 Construction of ME EQUIPMENT.....	48
201.16 ME SYSTEMS	48
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	48
206 Usability.....	50
Annexes	59
Annex B (informative) Sequence of testing.....	59
Annex I (informative) ME SYSTEMS aspects.....	59
Bibliography.....	60
Index of defined terms	61
Figure 201.101 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION (201.10.1.2.102.1)	51
Figure 201.102 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (201.10.1.2.102.2)	52
Figure 201.103 – Elevation view – Application of LEAKAGE RADIATION requirements (201.10.1.2.103 and 201.10.1.2.104)	53
Figure 201.104 – 24 measurement points for averaging LEAKAGE RADIATION during X-RADIATION (201.10.1.2.103.2.1)	54
Figure 201.105 – Limits of LEAKAGE RADIATION through the BEAM LIMITING DEVICES during ELECTRON IRRADIATION (201.10.1.2.103.2.2).....	55
Figure 201.106 – Measurement points for averaging LEAKAGE RADIATION during ELECTRON IRRADIATION (201.10.1.2.103.2.2).....	56
Figure 201.107 – 24 measurement points for averaging LEAKAGE RADIATION outside area <i>M</i> (201.10.1.2.103.3).....	57
Figure 201.108 – ME EQUIPMENT movements and scales	58
Table 201.101 – Colours of indicator lights and their meaning for ME EQUIPMENT.....	16

Table 201.102 – Data required in the technical description to support Clause 201.10 SITE TEST compliance	18
Table 201.103 – Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and the technical description	20
Table 201.104 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION (see Figure 201.101)	39
Table 201.105 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (see Figure 201.102)	39

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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 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.

Withdrawn

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.