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Medical electrical equipment -
Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

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CONTENTS

FOREWORD 2
INTRODUCTION 1
201.1 Scope, object and related standards 6
201.2 Normative references 8
201.3 Terms and definitions 8
201.4 General requirements 16
201.5 General requirements for testing ME EQUIPMENT 16
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 17
201.7 ME EQUIPMENT identification, marking and documents 18
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 21
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 21
201.10 Protection against unwanted and excessive radiation HAZARDS 27
201.11 Protection against excessive temperatures and other HAZARDS 49
201.12 Accuracy of controls and instruments and protection against hazardous outputs 49
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 49
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 50
201.15 Construction of ME EQUIPMENT 50
201.16 ME SYSTEMS 50
201.17 ELECTROMAGNETIC DISTURBANCES of ME EQUIPMENT and ME SYSTEMS 52
201.101 ELECTRONIC IMAGING DEVICES (EID) 53
201.102 Operation of ME EQUIPMENT parts from outside the facility 53
206 Usability 53
Annexes 57
Annex B (informative) Sequence of testing 57
Annex I (informative) ME SYSTEMS aspects 57
Bibliography 58
Index of defined terms used in this document 59

Figure 201.101 – PATIENT ~~SUPPORT~~ POSITIONER movements 54
Figure 201.102 – Diagram illustrating example RADIATION HEAD components and possible PATIENT position for NON-PRIMARY RADIATION REQUIREMENTS 55
Figure 201.103 – Diagram illustrating distance along PATIENT plane to measure NON-PRIMARY RADIATION ABSORBED DOSE 56

Table 201.101 – Data required in the technical description to support Clause 201.10 ~~– SITE TEST~~ compliance 19

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Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

FOREWORD

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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-64:2014. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 60601-2-64 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This second edition cancels and replaces the first edition published in 2014. This edition constitutes a technical revision.

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

a) harmonization with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2011 and IEC 60601-1:2005/AMD2:2020;

b) harmonization with IEC 62667:2017 for defined terms and definitions;

c) address revision to neutrons outside the field of irradiation.

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

Draft	Report on voting
62C/954/FDIS	62C/964/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, 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.

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 webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,
– withdrawn, or
– revised.

INTRODUCTION

The use of LIGHT ION BEAM ME EQUIPMENT for RADIOTHERAPY purposes ~~may~~ can 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~~ can 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 LIGHT ION BEAM ME EQUIPMENT 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, cause INTERRUPTION OF IRRADIATION or cause TERMINATION OF IRRADIATION in order to insure that ESSENTIAL PERFORMANCE is maintained and to avoid an unsafe condition. 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 should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

Closely related to this document is IEC 62667 ~~which is currently being developed~~. It specifies test methods and reporting formats for performance tests of LIGHT ION BEAM ME EQUIPMENT for use in RADIOTHERAPY, with the aim of providing uniform methods of doing so. ~~The annex~~ Annex A of IEC 62667:2017 provides forms for presenting performance values, measured per the methods SPECIFIED.

201.1 Scope, object and related standards

Clause 1 of ~~the general standard~~ [1] IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LIGHT ION BEAM ME EQUIPMENT, hereafter referred to as ME EQUIPMENT, used for treatment of PATIENTS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

This document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the ~~manufacture~~ MANUFACTURER and ~~some~~ SPECIFIED installation aspects of LIGHT ION BEAM ME EQUIPMENT

– 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, in NORMAL USE, deliver a RADIATION BEAM of LIGHT IONS having ENERGY PER NUCLEON in the range 10 MeV/n to 500 MeV/n,

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 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 document, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

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

NOTE 3 Information regarding x-ray image guidance can be found in IEC 60601-2-68 ~~(under development)~~.

NOTE 4 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).

201.1.2 Object

Replacement:

[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*~~

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LIGHT ION BEAM ME EQUIPMENT in the range 10 MeV/n to 500 MeV/n 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;
- delivers the pre-selected RADIATION TYPE, ENERGY PER NUCLEON, LIGHT ION species, and ABSORBED DOSE;
- delivers pre-selected LIGHT ION BEAMS to the PATIENT, by utilizing LIGHT ION 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~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 applies as modified in Clause 206. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-9 [1]~~2~~ and IEC 60601-1-10~~3~~ [2] ~~4~~ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE Collateral standards published after the date of publication of this document will only apply subject to further amendment to this document.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ~~or~~ 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~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

~~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 clauses and subclauses of this document corresponds to that of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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

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~~2 IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*~~

~~3 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*~~

4 Numbers in square brackets refer to the Bibliography.

Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text in this document.

"*Addition*" means that the text of this document is additional to the requirements of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.~~139~~154, 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, 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 document, the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 compatibility – Requirements and tests*~~

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 60601-1:2005/AMD2:2020

IEC 60601-2-1:~~2009~~2020, *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*

~~IEC 60601-2-11:2013, *Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*~~

IEC 60601-2-68:2014, *Medical electrical equipment - Part 2-68: 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*[5]

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

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

~~ISO/IEC 14165-321:2009, *Information technology – Fibre channel – Part 321: Audio video (FC-AV)*~~

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

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5 A newer edition of IEC 60601-2-68 was published in 2025.

Bibliography

~~[1] International Commission on Radiation Units and Measurements (ICRU). *ICRU Report 33: Radiation quantities and units*. ICRU Publications: Bethesda, Maryland, 1980~~

~~[3] IEC 60601-2-68, *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*[6]~~

[1] IEC 60601-1-9, *Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design*

[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*

[3] International Commission on Radiation Units and Measurements (ICRU). *Report 85a: Fundamental quantities and units for ionizing radiation* (revised). Journal of the ICRU, 11(1), Oxford University Press: Oxford, UK, 2011

[4] Void

[5] International Commission on Radiological Protection (ICRP) Publication 116:2010. *Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures*. ICRP Publication 116, Ann. ICRP 40(2-5)

[6] IEC 62667:2017, *Medical electrical equipment - Medical light ion beam equipment - Performance characteristics*

[7] IEC 60601-2-11:2013, *Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*

[8] ISO/IEC 80079-34:2018, *Explosive atmospheres - Part 34: Application of quality systems for ex product manufacture*

~~[6] To be published.~~