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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-64: Exigences particulières pour la sécurité de base et les performances essentielles des appareils électromédicaux par faisceau d'ions légers

IEC 60601-2-64:2014-09(en-fr)

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colour inside

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Particular requirements for the basic safety and essential performance of LIGHT ION BEAM ME EQUIPMENT

FOREWORD

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International Standard IEC 60601-2-64 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/594/FDIS	62C/600/RVD

Full information on the voting for the approval of this 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 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.

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- withdrawn,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

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INTRODUCTION

The use of LIGHT ION BEAM ME EQUIPMENT 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 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 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, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

Closely related to this standard 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 of IEC 62667 provides forms for presenting performance values, measured per the methods SPECIFIED.