IEC 62667

Edition 1.0 2017-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment – Medical light ion beam equipment – Performance characteristics

Appareils électromédicaux – Appareils médicaux par faisceau d'ions légers – Caractéristiques de performances

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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FOREWORD

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International standard IEC 62667 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/693/FDIS	62C/699/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, compliance with which can be tested, and definitions: in roman type;
– explanations, advice, general statements, exceptions and notes: in small roman type;
– *test specifications and headings of subclauses: in italic type;*
– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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- withdrawn,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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

Standards containing safety requirements for LIGHT ION BEAM ME EQUIPMENT have been published separately by the IEC, details of which will be found in Clause 2.

This document specifies methods of testing and methods of disclosure of performance of LIGHT ION BEAM ME EQUIPMENT intended for RADIOTHERAPY. It permits a direct comparison between the performance data of equipment of different MANUFACTURERS.

This document was published subsequent to IEC 60601-2-64, *Medical electrical equipment – Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment.* Many concepts useful to the reader of this document were described in that standard.

Since this document does not contain safety requirements, it has not been numbered in the IEC 60601 publication series. It describes aspects of performance of LIGHT ION BEAM ME EQUIPMENT and the way in which they should be presented. It also includes test methods and conditions suitable for TYPE TESTS. These test methods are suggested test methods and alternative methods may be equally appropriate, but the SPECIFIED performance characteristics of LIGHT ION BEAM ME EQUIPMENT are related to these test methods and conditions. Tests SPECIFIED in this document are not necessarily appropriate for ensuring that any individual LIGHT ION BEAM ME EQUIPMENT conforms to the declared performance during the course of its working lifetime. In recognition of the diversity of equipment produced by MANUFACTURERS in each of these technologies, this edition has SPECIFIED performance standards, methods of test, and methods of disclosure of performance, that are as basic and generic as possible. MANUFACTURERS may add more detailed information and special tests of performance characteristics to each performance category, in their ACCOMPANYING DOCUMENTATION.

MEDICAL ELECTRICAL EQUIPMENT –
MEDICAL LIGHT ION BEAM EQUIPMENT –
PERFORMANCE CHARACTERISTICS

1 Scope

This document applies to LIGHT ION BEAM ME EQUIPMENT when used, for therapy purposes, in human medical practice.

This document applies to LIGHT ION BEAM ME EQUIPMENT which delivers LIGHT ION BEAMS with an ENERGY PER NUCLEON in the range 10 MeV/n to 500 MeV/n.

This document describes measurements and test procedures to be performed by the MANUFACTURER of LIGHT ION BEAM ME EQUIPMENT but does not specify ACCEPTANCE TESTS.

This document specifies test procedures for the determination and disclosure of performance characteristics, knowledge of which is necessary for proper selection, application, and use of LIGHT ION BEAM ME EQUIPMENT and which are to be declared in the ACCOMPANYING DOCUMENTATION together with the greatest deviation or variation to be expected under specific conditions in NORMAL USE. A format for presentation of performance values is given in Annex A.

It is recognized that inaccuracies in the test methods can occur when assessing performance. However, it was felt preferable not to combine the errors into an overall performance tolerance but rather to keep them separate in the expectation that more accurate test methods will evolve.

It is not intended that this document in any way inhibit the future development of new designs of equipment which may have operating modes and parameters different from those described herein, provided that such equipment achieves equivalent or better levels of performance for the TREATMENT of PATIENTS.

This document applies to both ISOCENTRIC and non-ISOCENTRIC GANTRIES but many of the tests assume that the LIGHT ION BEAM ME EQUIPMENT has an ISOCENTRIC GANTRY. Where the equipment is non-ISOCENTRIC, the description of performance and test methods may be suitably adapted.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60580:2000, *Medical electrical equipment – Dose area product meters*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-1:2009, *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 60601-2-1:2009/AMD1:2014