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

IEC 62667:2017-08(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-4734-1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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- withdrawn,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.

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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

IEC 60601-2-64:2014, *Medical electrical equipment – Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60580:2000, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-2-1:2009, IEC 60601-2-1:2009/AMD1:2014, IEC 60601-2-64:2014, IEC TR 60788:2004, and the following, apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp.

3.1
ACCEPTANCE TEST
test carried out at a USER facility after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

Note 1 to entry: During or immediately after acceptance testing, reference data are collected to be used as a standard for comparison with future routine tests.

[SOURCE: IEC TR 60788:2004, rm-70-01, modified – Addition of the words "at a USER facility".]

3.2
ACCOMPANYING DOCUMENTATION
materials accompanying a MEDICAL DEVICE and containing information for the USER or those accountable for the installation, use and maintenance of the MEDICAL DEVICE, particularly regarding safe use

Note 1 to entry: The ACCOMPANYING DOCUMENTATION can consist of the INSTRUCTIONS FOR USE, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: ACCOMPANYING DOCUMENTATION could include auditory, visual, or tactile materials and multiple media types.

Note 3 to entry: The performance characteristics provided by this document are intended to be disclosed to potential customers to allow meaningful comparison of products prior to purchasing.

[SOURCE: IEC 62366-1:2015, 3.2, modified – Replacement of Notes to entry 2 and 3.]

3.3
APERTURE
PATIENT and RADIATION FIELD specific BEAM LIMITING DEVICE with a non-attenuating opening that allows RADIATION to reach a PATIENT

3.4
APPLICATOR CARRIAGE
the most distal part of the RADIATION HEAD that cannot be removed without using tools to which interchangeable LIGHT ION BEAM APPLICATORS are attached and which may extend toward and retract away from the ISOCENTRE or ERP

Note 1 to entry: Colloquially the APPLICATOR CARRIAGE has sometimes been called a snout.

[SOURCE: IEC 60601-2-64:2014, 201.3.201]

3.5
DOSE MONITOR UNIT
parameter, reported by the DOSE MONITORING SYSTEM, from which, through a calibration procedure and with additional information, the ABSORBED DOSE delivered can be calculated

[SOURCE: IEC 60601-2-64:2014, 201.3.207]

3.6
DOSE MONITOR UNIT RATE
DOSE MONITOR UNIT per unit time

[SOURCE: IEC 60601-2-64:2014, 201.3.208]

3.7
ELECTRONIC IMAGING DEVICE
EID
device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

[SOURCE: IEC 60976:2007, 3.5]

3.8
ENERGY PER NUCLEON
total kinetic energy of the ion divided by the number of nucleons in the nucleus at the point where the ion enters the RADIATION HEAD before passing through any beam modifiers

[SOURCE: IEC 60601-2-64:2014, 201.3.211]

3.9
ENTRANCE-TO-PEAK DOSE RATIO
ratio of the ABSORBED DOSE on the LIGHT ION REFERENCE AXIS at the water-equivalent depth of 10 mm to the peak ABSORBED DOSE on the LIGHT ION REFERENCE AXIS both measured in a water equivalent PHANTOM with its surface at a SPECIFIED distance from the ISOCENTRE or ERP for a NON-RANGE MODULATED PORTAL

Note 1 to entry: An example method to measure the ABSORBED DOSE at a depth of 10 mm is to place a parallel plate ionization chamber, RADIOGRAPHIC FILM, diode, etc. in a plastic PHANTOM.

Note 2 to entry: See Figure 1 for description of measurement points.

3.10
EQUIPMENT REFERENCE POINT
ERP
point in space used for referencing dimensions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the EQUIPMENT REFERENCE POINT is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC EQUIPMENT, then the centre of the PATIENT alignment system may be used.

Note 2 to entry: The corresponding note to entry in the French text indicates that the abbreviation "ERP" stands for "EQUIPMENT REFERENCE POINT" in English.

[SOURCE: IEC 60601-2-64:2014, 201.3.212]

3.11
FLUENCE
the quotient of dN by da, where dN is the number of particles incident on a sphere of cross-sectional area da, thus

$$\Phi = \frac{dN}{dA}$$

Note 1 to entry: Definition from ICRU 85a.

3.12
FLUX
the quotient of dN by dt, where dN is the increment of the particle number in the time interval dt, thus

$$N = \frac{dN}{dt}$$

Note 1 to entry: Definition from ICRU 85a.

[SOURCE: IEC 60601-2-64:2014, 201.3.214, modified – New definition.]

3.13
GANTRY
part of the ME EQUIPMENT supporting the RADIATION HEAD

Note 1 to entry: Types of GANTRIES may include rotational ISOCENTRIC, rotational eccentric, stationary, multiple-discrete angles (one RADIATION HEAD moved between two or more angles).

Note 2 to entry: The GANTRY is any mechanical device that supports the RADIATION HEAD regardless of movement limitations.

[SOURCE: IEC 60601-2-1:2009/AMD1:2014, 201.3.206, modified – Addition of a new Note 1 to entry and new Note 2 to entry.]

3.14
INITIATION OF IRRADIATION
INITIATION
commencing IRRADIATION from the READY STATE when the READY STATE was attained by carrying out the selection and confirmation of the operating conditions and not by NTERRUPTION OF IRRADIATION

[SOURCE: IEC 60601-2-17:2013, 201.3.207]

3.15
INTERRUPTION OF IRRADIATION
TO INTERRUPT IRRADIATION
stopping of / to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

[SOURCE: IEC 60601-2-1:2009, 201.3.210]

3.16
IRRADIATION
exposing of a living being or matter to RADIATION. In RADIOLOGY, exposing of a living being or matter to IONIZING RADIATION

Note 1 to entry: Examples of ionizing RADIATION include: X-RAYS, GAMMA-RAYS, ELECTRONS, NEUTRONS, and LIGHT IONS.

[SOURCE: IEC TR 60788:2004, rm-12-09 modified – moved examples of IONIZING RADIATION to a note.]

3.17
IRRADIATION TIME
duration of an IRRADIATION determined according to specific methods, usually the time a rate of a RADIATION quantity exceeds a SPECIFIED level

[SOURCE: IEC TR 60788:2004, rm-36-11]

3.18
ISOCENTRIC
when used in combination with radiological techniques or equipment, refers to the use or presence of an ISOCENTRE

[SOURCE: IEC TR 60788:2004]

3.19
ISOCENTRIC EQUIPMENT
equipment for RADIOTHERAPY designed and constructed in such a manner that it has an ISOCENTRE

[SOURCE: IEC 60976:2007, 3.11]

3.20
ISOCENTRIC TREATMENT

<RADIOTHERAPY> TREATMENT of a PATIENT in which the position of the TARGET VOLUME is referred to the ISOCENTRE

[SOURCE: IEC 60976:2007, 3.12]

3.21
LATERAL SPREADING DEVICE
LSD
device used to increase the lateral (X_g, Y_g) dimensions of a small diameter LIGHT ION BEAM produced by an accelerator

EXAMPLE Examples of spreading devices include a thin metal foil for scattering the ions or a magnet to defocus the beam or to scan the beam laterally across the intended TARGET VOLUME.

Note 1 to entry: The definition was taken from IEC 60601-2-64:2014 but further review after publication of the standard showed that the GANTRY frame of reference would be more appropriate.

[SOURCE: IEC 60601-2-64:2014, 201.3.217, modified – In the definition, "(X_b, Y_b)" has been replaced by "(X_g, Y_g)". The Note 1 to entry has been rephrased.]

3.22
LEAF CARRIAGE
device for simultaneously translating all leaves of one side of a multi-element BEAM LIMITING DEVICE

Note 1 to entry: A major purpose of a LEAF CARRIAGE is to enable TREATMENT of an effectively larger IRRADIATION FIELD SIZE.

3.23
LIGHT ION
species of ion with an atomic number less than or equal to that of neon ($Z \leq 10$) and SPECIFIED by its number of protons, number of nucleons, and ionization state