

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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;
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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 INTERRUPTION 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

[SOURCE: IEC 60601-2-64:2014, 201.3.218]

3.24

LIGHT ION BEAM

collection of LIGHT IONS travelling in the same general direction

[SOURCE: IEC 60601-2-64:2014, 201.3.219]

3.25

LIGHT ION BEAM APPLICATOR

device for holding a BEAM LIMITING DEVICE or ACCESSORY close to the PATIENT'S skin during delivery of LIGHT ION BEAM

Note 1 to entry: Several LIGHT ION BEAM APPLICATORS may be available to reduce the weight of APERTURES lifted by the OPERATOR, decrease the APERTURE/ACCESSORY to skin distance, and reduce leakage RADIATION.

Note 2 to entry: ACCESSORIES that may be held by the LIGHT ION BEAM APPLICATOR include but are not limited to range shifters, alignment cross-wires, ridge filters, mirror or camera for viewing the PATIENT, and a beam monitor.

[SOURCE: IEC 60601-2-64:2014, 201.3.220, modified – Note 1 to entry has been rephrased, and a new Note 2 to entry has been added.]

3.26

LIGHT ION BEAM APPLICATOR LENGTH

distance between the most distal surface of the APPLICATOR CARRIAGE and the most distal surface of the LIGHT ION BEAM APPLICATOR when the LIGHT ION BEAM APPLICATOR is installed

3.27

LIGHT ION BEAM RANGE

depth in a water equivalent PHANTOM most distant from its surface at which the ABSORBED DOSE of a NON-RANGE MODULATED PORTAL is 80 % of the ABSORBED DOSE at the depth of peak ABSORBED DOSE, measured on the LIGHT ION REFERENCE AXIS in a SPECIFIED RADIATION FIELD and with the surface of the PHANTOM at a SPECIFIED distance from the ERP without RANGE SHIFTERS or ACCESSORIES installed in the RADIATION HEAD downstream of the ENERGY PER NUCLEON or range monitoring system

3.28

LIGHT ION REFERENCE AXIS

for a LIGHT ION BEAM, the line in the REFERENCE DIRECTION through the centre of the LIGHT ION VIRTUAL SOURCE

3.29

MODULATED SCANNING

SCANNING MODE wherein a small diameter LIGHT ION BEAM is scanned across a target to create a field large enough to cover the target such that the intended FLUENCE delivered to the PATIENT can be different at different lateral locations

Note 1 to entry: Various spatial and temporal SCANNING PATTERNS may be used to generate the modulated FLUENCE distribution.

[SOURCE: IEC 60601-2-64:2014, 201.3.223]

3.30

NOMINAL RANGE MODULATION WIDTH

NRMW

for a RANGE MODULATED PORTAL the difference in LIGHT ION BEAM RANGES for the highest and lowest ENERGY PER NUCLEON components

Note 1 to entry: See Figure 2 for additional information.

3.31**NON-RANGE MODULATED PORTAL****NRMP**

LIGHT ION PORTAL which does not use a RANGE MODULATION DEVICE (RMD) or program to vary the penetration of the LIGHT ION BEAM

3.32**PORTAL**

collection of one or more pre-programmed TREATMENT segments treated automatically with a single PATIENT set-up

Note 1 to entry: Segments may consist of IRRADIATION, motion of devices, or imaging.

[SOURCE: IEC 60601-2-64:2014, 201.3.228, modified – In Note 1 to entry, replacement of "TREATMENT BEAM IRRADIATION" by "IRRADIATION".]

3.33**PROGRAMMABLE RANGE MODULATED PORTAL****PRMP**

LIGHT ION PORTAL in which a program is used, with or without a RANGE MODULATION DEVICE (RMD), to tailor the DEPTH DOSE distribution by varying the penetration and weighting factors of several component segments

Note 1 to entry: Typically the DEPTH DOSE distribution is tailored to give a uniform dose distribution over the depths where the TARGET VOLUME (tumour) resides.

[SOURCE: IEC 60601-2-64:2014, 201.3.231, modified – In Note 1 to entry, replacement of "target" by "TARGET VOLUME".]

3.34**RADIATION HEAD**

structure from which the RADIATION BEAM emerges

[SOURCE: IEC TR 60788:2004, rm-20-06]

3.35**RANGE MODULATED PORTAL****RMP**

LIGHT ION PORTAL in which a RANGE MODULATION DEVICE or program is used to tailor the DEPTH DOSE distribution

[SOURCE: IEC 60601-2-64:2014, 201.3.231, modified – The term and the definition have been modified. Note to entry has been deleted.]

3.36**RANGE MODULATION DEVICE****RMD**

device used to modulate the penetration of a RADIATION BEAM into a PATIENT to tailor the DEPTH DOSE distribution during the delivery of one PORTAL

Note 1 to entry: The device may consist of a propellor shaped material that spins in the beam, a filter containing a repeating pattern of metallic ridges (e.g. ridge filter, mini-ridge filter, ripple filter), a cone or set of cones, or a set of uniform thickness blocks programmable in a binary fashion. Sub-types include discrete and programmable.

[SOURCE: IEC 60601-2-64:2014, 201.3.233, modified – In the definition, "beam" has been replaced by "RADIATION BEAM".]

3.37**SCANNING MODE**

method of delivering a scanned RADIATION BEAM to generate a laterally broad field

Note 1 to entry: Types of SCANNING MODES include none, UNIFORM SCANNING, or MODULATED SCANNING.

[SOURCE: IEC 60601-2-64:2014, 201.3.236, modified – In the definition, "RADIATION" has been added, and in the Note 1 to entry "none" has been added.]

3.38

SCANNING PATTERN SYNCHRONIZATION TYPE

method used to start the scanning of the SPOT through the SCANNING PATTERN

Note 1 to entry: SCANNING PATTERN SYNCHRONIZATION TYPES include: none, synchronized with energy layer, synchronized with spill, synchronized with breathing, synchronized with BEAM GATING signal, or USER defined.

3.39

SPOT

area of intersection between a narrow LIGHT ION BEAM and a plane perpendicular to the LIGHT ION REFERENCE AXIS

3.40

TABLE TOP

device attached to the PATIENT SUPPORT to which registration and immobilization devices are attached and upon which the PATIENT is placed

Note 1 to entry: TABLE TOPS are often exchangeable to hold PATIENTS or equipment in different orientations, for instance a flat board or a chair.

[SOURCE: IEC 60601-2-64:2014, 201.3.238, modified – In the definition "exchangeable device" has been replaced by "device" and a new Note 1 to entry has been added.]

3.41

TAIL-TO-PEAK DOSE RATIO

ratio of the ABSORBED DOSE at the depth of 30 mm distal to the LIGHT ION BEAM RANGE to that at the depth of peak ABSORBED DOSE, both measurements made on the LIGHT ION REFERENCE AXIS and 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: See Figure 1 for description of measurement points.

3.42

TARGET VOLUME

in RADIO THERAPY region in the PATIENT, to which it is desired to deliver an ABSORBED DOSE

[SOURCE: IEC TR 60788:2004, rm-37-20]

3.43

TERMINATION OF IRRADIATION

TERMINATE IRRADIATION

stopping of/to stop IRRADIATION and movements, with no possibility of restarting without returning to the PREPARATORY STATE

Note 1 to entry: Events that TERMINATE IRRADIATION and stop movements include the following events:

- when the pre-selected value of DOSE MONITOR UNITS is reached;
- when the pre-selected value is reached in the termination system independent of the DOSE MONITORING SYSTEM;
- by a deliberate manual act;
- by the operation of an INTERLOCK;
- in MODULATED SCANNING when the pre-programmed SCANNING PATTERN is completed.

[SOURCE: IEC 60601-2-1:2009, 201.3.225, modified – The definition and the notes to entry have been rephrased.]

3.44**TYPE TEST**

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this document

[SOURCE: IEC 60601-1:2005, 3.135]

3.45**UNIFORM SCANNING**

SCANNING MODE wherein a RADIATION BEAM is scanned laterally in a pre-defined pattern to produce a field large enough to treat the target such that the FLUX of the RADIATION BEAM is not intentionally changed throughout the lateral scan so that the resultant dose distribution within the field is uniform

Note 1 to entry: The scanning may be accomplished by changing the current in electromagnets through which the RADIATION BEAM passes or the use of permanent magnets mechanically rotated and/or translated.

[SOURCE: IEC 60601-2-64:2014, 201.3.243, modified – In the definition, addition of "RADIATION".]

3.46**UNIFORM SCANNING PATTERN**

pre-defined lateral pattern that the SPOT follows in UNIFORM SCANNING MODE

Note 1 to entry: Types of UNIFORM SCANNING PATTERNS include: Lissajous, repeated rectilinear, repeated triangular, repeated circular, repeated spiral, or USER defined.

3.47**VIRTUAL SOURCE-TO-AXIS DISTANCE****VSAD**

distance from the VIRTUAL SOURCE to the ISOCENTRE (i.e. the GANTRY axis of rotation) or the ERP

Note 1 to entry: This distance can be used for manufacturing PATIENT specific devices and for scaling scanning RADIATION BEAM positions to the PATIENT.

Note 2 to entry: A RADIATION BEAM may have more than one VSAD in the case of scanning magnets located at different distances from the ISOCENTRE.

3.48**WATER EQUIVALENT THICKNESS****WET**

thickness of water that results in, for a photon or neutron beam, the same attenuation or, for a charged particle beam, the same integral loss of energy due to the electronic stopping power, as the thickness of material being measured

Note 1 to entry: On a RADIOTHERAPY TREATMENT PLANNING SYSTEM, the WET is the integral of the relative linear electronic stopping power for charged particle beams or relative linear attenuation coefficient for x-ray or neutron beams for all voxels along a sampled line. The WET is calculated for the type and energy of the active beam at the time of sampling.

4 Environmental conditions**4.1 General**

The MANUFACTURER shall include in the ACCOMPANYING DOCUMENTATION the range of environmental conditions in which the achieved performances listed in the ACCOMPANYING DOCUMENTATION are achieved. These conditions shall include but not be limited to the ambient temperature (stated in degrees Celsius), relative humidity, and atmospheric pressure (stated in Pa).

4.2 Transport and storage

The allowable environmental conditions for transport and storage shall be stated in the ACCOMPANYING DOCUMENTATION.

4.3 Facility stability

The ACCOMPANYING DOCUMENTATION shall provide maximum allowable facility deformations to maintain the performance characteristics of the equipment without maintenance.

NOTE The values of maximum allowable facility deformations due to settling, earthquakes, vibrations, etc. can come from calculations.

5 Presentation of information to the USER

5.1 General

The information to the USER required by this document shall be provided in the format shown in Annex A.

5.2 Intended parameters

The ACCOMPANYING DOCUMENTATION shall describe the MANUFACTURER'S intended combinations of beam parameters.

NOTE Examples include maximum DOSE MONITOR UNITS (MU) per SPOT aiming location, scatterer and LIGHT ION BEAM APPLICATOR compatibility, etc.

6 Beam delivery

6.1 LIGHT ION species

The ACCOMPANYING DOCUMENTATION shall provide the following information for each LIGHT ION species that may be accelerated by the LIGHT ION BEAM accelerator and delivered to each of the GANTRIES:

- a) common name,
- b) number of protons in the nucleus,
- c) number of nucleons in the nucleus.

NOTE The LIGHT ION BEAM entering the RADIATION HEAD is expected to consist of LIGHT IONS with all electrons removed (fully stripped).

6.2 Energy

6.2.1 Method of selection of ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE

The ACCOMPANYING DOCUMENTATION shall state the method used to provide the selected ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE to the RADIATION HEAD of each GANTRY.

NOTE Examples of methods of selection include accelerator extraction, continuous range-shifted, or discrete range-shifted.

6.2.2 Range of available ENERGIES PER NUCLEON OR LIGHT ION BEAM RANGES

The ACCOMPANYING DOCUMENTATION shall state the maximum and minimum ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE available for each LIGHT ION species and the number of ENERGY PER NUCLEON levels or LIGHT ION BEAM RANGES available between the maximum ENERGY PER NUCLEON and the minimum ENERGY PER NUCLEON or between the maximum LIGHT ION BEAM RANGE and the minimum LIGHT ION BEAM RANGE without ACCESSORIES installed.

6.2.3 Methods of ensuring the ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE

The ACCOMPANYING DOCUMENTATION shall state the primary and backup methods used for ensuring the correct ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE of the LIGHT ION BEAM while it is being delivered.

6.2.4 Accuracy of ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE

The ACCOMPANYING DOCUMENTATION shall state the accuracy in MeV/n or millimetres of water of the ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE of the LIGHT ION BEAM while it is being delivered.

6.3 BEAM GATING

6.3.1 Method of BEAM GATING

The ACCOMPANYING DOCUMENTATION shall provide a description of the method used to enable/disable beam delivery during TREATMENT if BEAM GATING is available.

6.3.2 BEAM GATING required input trigger

The ACCOMPANYING DOCUMENTATION shall provide a description of the compatible input device or a description of the interface for the input devices.

6.4 GANTRIES

6.4.1 GANTRY types

For each LIGHT ION species that may be accelerated by the LIGHT ION BEAM accelerator and delivered to each of the GANTRIES, the ACCOMPANYING DOCUMENTATION shall provide the following information:

- a) the types of GANTRIES available;

NOTE Figure 3 gives an example of a rotational GANTRY type.

- b) the maximum number of each type of GANTRY available for a single system for each LIGHT ION species.

6.4.2 GANTRY configurations

For each rotational type GANTRY, the ACCOMPANYING DOCUMENTATION shall provide a list of supported LIGHT IONS. For each supported LIGHT ION, the ACCOMPANYING DOCUMENTATION shall provide:

- a) the maximum and minimum achievable GANTRY angles using the IEC 61217:2011 coordinate system;
- b) if the GANTRY provides a rotational overlap, the minimum and maximum angles of the sector that defines the rotational overlap;

NOTE Typically the minimum angle is larger than the maximum angle when there is an overlap.

- c) the minimum and maximum ENERGIES PER NUCLEON OR LIGHT ION BEAM RANGES that are available in the GANTRY;
- d) the maximum rotation speed in degrees per second ($^{\circ} \cdot \text{s}^{-1}$);
- e) the maximum angular acceleration and deceleration rates;
- f) the maximum angular rotation travelled after initiation of an emergency motion stop.

For each stationary type GANTRY, the ACCOMPANYING DOCUMENTATION shall provide the GANTRY angle given in IEC 61217:2011 fixed reference coordinates.

For each multiple-discrete angle type GANTRY, the ACCOMPANYING DOCUMENTATION shall provide the beam pointing angles given in IEC 61217:2011 fixed reference coordinates.

6.4.3 GANTRY angle readout

The ACCOMPANYING DOCUMENTATION shall state the accuracy of the angular readout for rotational and multiple-discrete angle type GANTRIES.

The accuracy should be stated in decimal degrees.

This clause does not apply to stationary type GANTRIES.

6.5 APPLICATOR CARRIAGE

The ACCOMPANYING DOCUMENTATION shall provide the following information for the APPLICATOR CARRIAGE:

- a) the distances between the LIGHT ION BEAM APPLICATOR mounting interface and the ISOCENTRE or ERP when the APPLICATOR CARRIAGE is fully retracted and extended;
- b) the accuracy of the APPLICATOR CARRIAGE retraction/extension readout;
- c) the minimum and maximum translation speeds;
- d) the maximum distance travelled after initiation of an emergency motion stop.

6.6 LIGHT ION BEAM APPLICATORS

The ACCOMPANYING DOCUMENTATION shall provide the following information for each available LIGHT ION BEAM APPLICATOR for each type of GANTRY:

- a) common name;
- b) ID;
- c) shape (circular, square, rectangular);
- d) LIGHT ION BEAM APPLICATOR LENGTH;
- e) distance from the distal end of the LIGHT ION BEAM APPLICATOR to the ISOCENTRE or ERP at full APPLICATOR CARRIAGE extension;
- f) outside dimensions of allowable APERTURES;
- g) outside dimensions of LIGHT ION BEAM APPLICATOR perpendicular to the LIGHT ION REFERENCE AXIS at the distal end and 300 mm proximal to the distal end or, if the LIGHT ION BEAM APPLICATOR LENGTH is shorter than 300 mm, then provide the maximum dimensions.
- h) if a LIGHT ION BEAM APPLICATOR is intended to be exchanged by the USER, the approximate time (in minutes) to exchange LIGHT ION BEAM APPLICATORS using the method described in the INSTRUCTIONS FOR USE;
- i) the mass (in kg);
- j) the dimensions of the maximum LIGHT ION IRRADIATION FIELD SIZE supported by the LIGHT ION BEAM APPLICATOR, in millimetres, with coordinates stated along axes Xb and Yb.

6.7 Adjustable BEAM LIMITING DEVICES (BLDS)

6.7.1 Information to the USER

For adjustable BEAM LIMITING DEVICES the ACCOMPANYING DOCUMENTATION shall state:

- a) the maximum range of motion possible, in millimetres at the adjustable BLD, including corresponding coordinates along the axes Xb and Yb (see IEC 61217:2011) for all adjustable LIGHT ION BEAM field-defining BLDS;
- b) the maximum speed, in mm/s at the adjustable BLD by which any BLD can move;

- c) in addition, for nominally rectangular LIGHT ION fields defined by BLDS other than the multi-element type:
 - 1) the maximum angular deviation, in degrees, from parallelism of the opposing edges and

NOTE 1 In addition, the USER may require shape information.
 - 2) the maximum angular deviation, in degrees, from perpendicularity of the adjacent edges;
- d) the maximum and minimum angles, in degrees, of rotation of the BLD about the LIGHT ION REFERENCE AXIS in the BLD reference system (see IEC 61217:2011);
- e) in addition, for multi-element BLDS:
 - 1) the ACCOMPANYING DOCUMENTATION shall include an equipment layout drawing with all dimensions indicated in millimetres and indication of materials;
 - 2) BLD configuration (examples: 2 bank (opposing pair), 4 bank (2 perpendicular opposing pairs));
 - 3) leaf end shape: curved, zigzag, straight, diverging

NOTE 2 A zigzag BLD is one in which the ends of the leaves are not perpendicular to the sides and the angle relative to the sides alternates.
 - 4) the number of elements and their dimensions parallel to Xb and Yb (see IEC 61217:2011) at the mechanical device;
 - 5) the thicknesses of the leaves parallel to the Zb axis;
 - 6) the dimensions of the available LIGHT ION IRRADIATION FIELD SIZES at the adjustable BLD without LEAF CARRIAGE travel in centimetres, with coordinates stated along axes Xb and Yb (see IEC 61217:2011);
 - 7) if the multi-element BLD has a LEAF CARRIAGE, the travel range of the LEAF CARRIAGE;
 - 8) element-end position accuracy at the adjustable BLD, in centimetres;
 - 9) element-end position reproducibility at the adjustable BLD, in centimetres;
 - 10) minimum and maximum SPECIFIED element speed at the adjustable BLD, in mm/s;
 - 11) the resolution of the leaf readouts at the adjustable BLD;
 - 12) the ability to simultaneously use demountable or fixed RADIATION FIELD shaping devices such as LIGHT ION BEAM APPLICATORS, APERTURES, ACCESSORIES, OR RMD;
 - 13) the criteria governing the use of any back-up adjustable BLDS;
 - 14) the average ABSORBED DOSE in the PATIENT plane behind adjustable or interchangeable BEAM LIMITING DEVICES (region P in IEC 60601-2-64:2014, Figure 201.103) relative to the ABSORBED DOSE delivered at the ERP on the central axis of the field at a depth coincident with the centre-of-modulation depth for a NRMW of 60 mm when the BEAM LIMITING DEVICES are not present. If the maximum NRMW available is less than 60 mm, then the maximum NRMW should be used. The area P over which this requirement applies is from the beam axis to 150 mm lateral to the projected edge of the maximum IRRADIATION FIELD SIZE defined by the 50 % isodose level supported by the LIGHT ION BEAM APPLICATOR or multi-element BLD.

NOTE 3 Test procedures are identical to those in 60601-2-64.

6.7.2 Test

Inspect the ACCOMPANYING DOCUMENTATION to verify that the information is included.

6.8 ISOCENTRE

6.8.1 Information to the USER

For ISOCENTRIC GANTRIES which are designed for ISOCENTRIC TREATMENT, the ACCOMPANYING DOCUMENTATION shall state the maximum displacement of the LIGHT ION REFERENCE AXIS from the ISOCENTRE for each RADIATION HEAD and LIGHT ION BEAM APPLICATOR. When software is used to provide a displacement correction, the reported displacement shall be made for a

measurement obtained using the correction if the correction is automatically applied and reported without software correction when the USER has the option to apply or reject the software provided correction.

The maximum displacement shall be given in millimetres.

For rotational GANTRIES, the displacements shall be measured for GANTRY angles not exceeding 45° between adjacent angles.

For multiple-discrete GANTRIES, the displacements shall be measured at each available GANTRY angle. More than 8 GANTRY angles need not be measured.

The reported value shall be the maximum displacement observed from any of the measurements for the defined set of angular positions of the GANTRY, BEAM LIMITING SYSTEM and for beams at both the maximum ENERGY PER NUCLEON and the minimum ENERGY PER NUCLEON.

For equipment with APPLICATOR CARRIAGES, the maximum displacement shall be reported for each available LIGHT ION BEAM APPLICATOR with the APPLICATOR CARRIAGE positioned at its closest approach to the ISOCENTRE.

For BEAM LIMITING SYSTEMS with continuous rotation, the displacements shall be measured for BEAM LIMITING SYSTEM angles not exceeding 45° between adjacent angles.

For BEAM LIMITING SYSTEMS without continuous rotation, the displacements shall be measured at each available BEAM LIMITING SYSTEM angle.

The maximum displacement shall be given separately for each LIGHT ION species.

The maximum displacement shall be given separately for each SCANNING MODE.

The test method to assess the deviation of the LIGHT ION REFERENCE AXIS from the expected ISOCENTRE shall be provided in the ACCOMPANYING DOCUMENTATION.

NOTE Correlation of the imaging system used for PATIENT localization and the TREATMENT system frame of reference is discussed in IEC 60601-2-68:2014, 201.101.9.1.

6.8.2 Test

Inspect the ACCOMPANYING DOCUMENTATION to verify that the test method to assess the deviation of the LIGHT ION REFERENCE AXIS from the ISOCENTRE for GANTRIES which are designed for ISOCENTRIC TREATMENT is provided.

Inspect the ACCOMPANYING DOCUMENTATION to verify that the deviation of the LIGHT ION REFERENCE AXIS from the ISOCENTRE is provided.

6.9 LATERAL SPREADING DEVICES (LSDs)

6.9.1 Type and order of lateral SPREADING DEVICES in the RADIATION HEAD

If the LSDs are selectable by the USER for IRRADIATION, the ACCOMPANYING DOCUMENTATION shall provide the following information for each LATERAL SPREADING DEVICE for each available GANTRY type:

- a) order in RADIATION HEAD from upstream to downstream;
- b) LSD type;
- c) LSD subtype.

NOTE 1 Example types of LATERAL SPREADING DEVICES are: continuous scatterer, discrete scatterer, or magnetic.

NOTE 2 Example subtypes of continuous scatterer LSD types are: double wedge, spiral wedge, or variable column.

NOTE 3 Example subtypes of discrete scatterer LSD types are: discrete, binary, contoured, or ring.

NOTE 4 Example subtypes of magnetic LSD types are: Xg sweep, Yg sweep, combo Xg, Yg sweep, or focussing.

NOTE 5 Most scanning magnets sweep the SPOT in only one direction, either vertically or horizontal. A combo sweep magnet can sweep the SPOT in both directions simultaneously.

6.9.2 SCANNING MODES for laterally spreading the beam

The ACCOMPANYING DOCUMENTATION shall list the available SCANNING MODES.

NOTE A scatterer type LSD can be used in combination with any SCANNING MODE.

6.9.3 UNIFORM SCANNING

If a UNIFORM SCANNING MODE is available, the ACCOMPANYING DOCUMENTATION shall provide the following information:

- a) all UNIFORM SCANNING PATTERN types available;
- b) shape of the scanned field with any adjustable BLDS fully open and without the presence of any removable BLD as defined by the 50 % isodose curve relative to the ABSORBED DOSE at the centre of the scanned field;

NOTE 1 Shapes can be square, rectangular, circular, other.

- c) the distances relative to the BLD or LIGHT ION BEAM APPLICATOR projected to the ISOCENTRE or ERP in both the Xg and Yg directions (see IEC 61217:2011) beyond which the LIGHT ION BEAM SPOT is scanned;

NOTE 2 This distance is often referred to as the overscan distance.

- d) the minimum ABSORBED DOSE required, for the largest IRRADIATION FIELD SIZE available and SPECIFIED conditions, to achieve better than or equal to $\pm 3\%$ lateral dose flatness within a plane perpendicular to the LIGHT ION REFERENCE AXIS that contains the ERP. If lateral dose flatness better than or equal to $\pm 3\%$ cannot be achieved, information on the achieved lateral dose flatness and the minimum ABSORBED DOSE to achieve that flatness shall be provided;
- e) if a UNIFORM SCANNING PATTERN is not recommended by the MANUFACTURER for use with BEAM GATING.

6.9.4 Synchronization types for scanning the beam

The ACCOMPANYING DOCUMENTATION shall list all available SCANNING PATTERN SYNCHRONIZATION TYPES.

6.9.5 VIRTUAL SOURCE-TO-AXIS DISTANCES (VSADS)

6.9.5.1 Information for the USER

For each combination of SCANNING MODE and LSD, the ACCOMPANYING DOCUMENTATION shall list the minimum VIRTUAL SOURCE-TO-AXIS DISTANCE relative to the ISOCENTRE or ERP for each GANTRY. Values of the VSAD shall be given for scanning in both the Xg and Yg directions (see IEC 61217:2011). In addition, for RADIATION BEAMS spread laterally with scatterers, the values should be given for each LIGHT ION BEAM APPLICATOR (scattering field diameter). This subclause does not require disclosure of information for every possible combination of settings for multiple LSDs but rather information for each RADIATION HEAD configuration.

NOTE Some MANUFACTURERS colloquially refer to these major RADIATION HEAD configurations as “options”.

6.9.5.2 Test

- a) For scattered or UNIFORM SCANNING RADIATION BEAMS, place a 2-D dosimeter in a PHANTOM that corresponds with the water equivalent depth of the centre of modulation for a medium sized modulation. Install an APERTURE with a size approximately 80 % of the maximum size supported for the LIGHT ION BEAM APPLICATOR. Extend the APPLICATOR CARRIAGE to place the APERTURE 50 mm upstream of the PHANTOM when the PHANTOM is placed in its most upstream position. Expose the 2-D dosimeter with the PHANTOM placed to locate the dosimeter at least 150 mm in front of the ISOCENTRE, at the ISOCENTRE, and at least 150 mm behind the ISOCENTRE. Determine the 50 to 50 % field widths from the lateral dose profiles. Plot the field widths versus the distance from the ISOCENTRE. Plot the APERTURE width versus the distance from the ISOCENTRE. Determine the best linear fit through the points and extrapolate to the distance from the ISOCENTRE to determine the VSAD. In addition, for RADIATION BEAMS spread laterally with scatterers the test should be repeated for each LIGHT ION BEAM APPLICATOR (scattering field diameter).
- b) For MODULATED SCANNING RADIATION BEAMS, instead of producing a uniform field, program a field consisting of detached SPOTS in different areas of the field. Expose a 2-D dosimeter free-in-air at the ISOCENTRE or ERP. Repeat the exposure with the 2-D dosimeter located at least 150 mm in front of the ISOCENTRE or ERP, at the ISOCENTRE or ERP, and at least 150 mm behind the ISOCENTRE or ERP. Determine the lateral distances between the SPOTS from the images at each distance. Plot the distances between SPOTS versus the distance from the ISOCENTRE or ERP and analyse similarly to a).

NOTE Scanning RADIATION BEAMS with sequential scanning magnets can have different VSADS in perpendicular directions.

6.10 Time constraints

6.10.1 General

The test conditions in this subclause apply to the system for NORMAL USE only. The device “timer” is to be understood as any device providing a time between events.

NOTE Example timers are oscilloscopes, counters, stopwatches, etc.

6.10.2 Maximum IRRADIATION TIME

If the LIGHT ION BEAM ME EQUIPMENT cannot provide continuous IRRADIATION, the ACCOMPANYING DOCUMENTATION shall state the estimated maximum IRRADIATION TIME in minutes without INTERRUPTION OF IRRADIATION for each LIGHT ION species at FLUX normally used for TREATMENT.

Values shall be reported for both the highest available ENERGY PER NUCLEON and the lowest available ENERGY PER NUCLEON.

Values shall be reported for each available LIGHT ION species.

NOTE 1 This information is useful primarily for testing procedures. This information is based upon equipment performance and not RADIATION safety issues of a given facility.

NOTE 2 The IRRADIATION TIME is considered to be the time between INITIATION OF IRRADIATION and TERMINATION OF IRRADIATION ignoring the temporal distribution due to pulsed accelerators, scanning beams, energy stacking, or range modulation. The IRRADIATION TIME does not include the time during which beam delivery is disabled due to a BEAM GATING signal (or lack thereof) or the time between an INTERRUPTION OF IRRADIATION and a repeated INITIATION OF IRRADIATION intended to finish the original intended IRRADIATION.

6.10.3 Time to switch between IRRADIATIONS in different rooms

6.10.3.1 Information for the USER

In the case of a multiple room configuration, the ACCOMPANYING DOCUMENTATION shall state the average time in seconds to obtain IRRADIATION in one room after TERMINATION OF IRRADIATION in a different room.

6.10.3.2 Test

Set up simulated PATIENT TREATMENTS in two different rooms and prepare both rooms for IRRADIATION. Launch an INITIATION OF IRRADIATION in one room at a given ENERGY PER NUCLEON. Immediately after TERMINATION OF IRRADIATION, start a timer and launch an INITIATION OF IRRADIATION in a different room with an ENERGY PER NUCLEON that differs from the ENERGY PER NUCLEON used in the first room by at least 100 MeV/n or if a 100 MeV/n difference is not available for the equipment, the largest difference available. Record the time indicated on the timer when IRRADIATION starts in the second room. Repeat the test 5 times and calculate the average switching time.

6.10.4 Time to switch beam between RADIATION HEADS with a common ERP

6.10.4.1 Information for the USER

If more than one RADIATION HEAD is provided with a common ERP, the ACCOMPANYING DOCUMENTATION shall state the delay in seconds from INITIATION OF IRRADIATION in one RADIATION HEAD in one room after TERMINATION OF IRRADIATION in a different RADIATION HEAD in the same room with a common ERP.

6.10.4.2 Test

Start IRRADIATION in one RADIATION HEAD in one room at a given ENERGY PER NUCLEON. Immediately after TERMINATION OF IRRADIATION, start a timer and start IRRADIATION in another RADIATION HEAD in the same room with an ENERGY PER NUCLEON that differs from the previous energy by at least 100 MeV/n or, if a 100 MeV/n difference is not available for the equipment, the largest difference available. Record the time indicated on the timer when IRRADIATION starts in the second RADIATION HEAD. Repeat the test 5 times and calculate the average switching time.

6.10.5 Time to switch between two ENERGY PER NUCLEON levels

6.10.5.1 Information for the USER

The ACCOMPANYING DOCUMENTATION shall state the time in seconds between IRRADIATION at one ENERGY PER NUCLEON and IRRADIATION at another ENERGY PER NUCLEON of at least 10 MeV/n difference using conditions SPECIFIED by the MANUFACTURER.

6.10.5.2 Test

Program a PORTAL with two or more ENERGY PER NUCLEON levels that differ by at least 10 MeV/n. Start a timer immediately when the IRRADIATION at the first ENERGY PER NUCLEON stops. Stop the timer when the IRRADIATION at the second ENERGY PER NUCLEON starts.

The test should be performed both near the maximum and minimum available ENERGY PER NUCLEON levels and each LIGHT ION species.

6.10.6 Time to switch between two LIGHT ION species

6.10.6.1 Information for the USER

If the LIGHT ION BEAM ME EQUIPMENT can deliver more than one LIGHT ION species, then the ACCOMPANYING DOCUMENTATION shall state the time in seconds between the end of IRRADIATION with one LIGHT ION species and the start of IRRADIATION with another LIGHT ION species and the change of equipment conditions SPECIFIED by the MANUFACTURER.

6.10.6.2 Test

Start a timer immediately when the IRRADIATION with the first LIGHT ION species stops. Stop the timer when the IRRADIATION with the second LIGHT ION species starts.

6.10.7 Time to TERMINATE and INTERRUPT IRRADIATION

6.10.7.1 Information for the USER

The ACCOMPANYING DOCUMENTATION shall state the time in seconds between a TERMINATION OF IRRADIATION event generation and end of beam delivery to the RADIATION HEAD and between an INTERRUPTION OF IRRADIATION event generation and end of beam delivery to the RADIATION HEAD.

6.10.7.2 Test

Start a timer immediately when the TERMINATION OF IRRADIATION event is generated. Stop the timer at the end of beam delivery to the RADIATION HEAD. Start a timer immediately when the INTERRUPTION OF IRRADIATION event is generated. Stop the timer at end of beam delivery to the RADIATION HEAD.

6.10.8 Time to restart IRRADIATION

6.10.8.1 Information for the USER

The ACCOMPANYING DOCUMENTATION shall state the average time in seconds required to restart IRRADIATION after a USER initiated INTERRUPTION OF IRRADIATION.

6.10.8.2 Test

INTERRUPT an ongoing IRRADIATION. Start a timer when the USER resumes IRRADIATION at the TREATMENT CONTROL PANEL (TCP). Stop the timer when LIGHT IONS enter the RADIATION HEAD. Repeat the test 5 times and calculate the average time.

NOTE 1 USER manipulations such as rescanning barcodes, securing the room, and pushing buttons performed before restart of IRRADIATION are not considered part of the time to restart IRRADIATION.

NOTE 2 Software sequences after a restart command is issued, such as reconfirmation of IRRADIATION devices, are considered part of the time to restart IRRADIATION.

6.10.9 Start-up time

6.10.9.1 Information for the USER

The ACCOMPANYING DOCUMENTATION shall state the time in minutes necessary to reach the READY STATE from the stand-by state as defined by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION.

The INSTRUCTIONS FOR USE shall include the procedures for entering and exiting the stand-by state.

6.10.9.2 Test

Start a timer when the procedure to put the equipment into the READY STATE, as defined by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION, is initiated. Stop the timer when IRRADIATION is possible in any arbitrary room.

6.10.10 Time for shutdown

6.10.10.1 Information for the USER

The ACCOMPANYING DOCUMENTATION shall state the time in minutes necessary to shut down the LIGHT ION BEAM ME EQUIPMENT to stand-by state as defined by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION.

6.10.10.2 Test

Start a timer when the OPERATOR begins to shut down the equipment. Stop the timer when the LIGHT ION BEAM ME EQUIPMENT is in the stand-by state as defined by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION.

6.11 Maintenance

The ACCOMPANYING DOCUMENTATION shall provide a schedule of preventive inspection, maintenance, and calibration procedures.

7 DOSE MONITORING SYSTEM

7.1 General

The ACCOMPANYING DOCUMENTATION shall state the information to the USER required in Clause 7 as follows:

- a) in the case of a PRIMARY-SECONDARY DOSE MONITORING SYSTEM: for the PRIMARY DOSE MONITORING SYSTEM;
- b) in the case of a REDUNDANT DOSE MONITORING SYSTEM: for both systems.

The ACCOMPANYING DOCUMENTATION shall state, for all intended modes of operation, the range of DOSE MONITOR UNITS and DOSE MONITOR UNIT RATES over which the DOSE MONITORING SYSTEM is working in compliance with the data provided according to this document.

7.2 Standard test conditions for testing DOSE MONITORING SYSTEMS

The measurements for this clause shall be performed with a RADIATION DETECTOR:

- a) from whose SCALE READINGS relative ABSORBED DOSE can be determined, and
- b) has adequate spatial resolution in regions of high dose gradients, and
- c) whose performance characteristics for proportionality of ABSORBED DOSE reading, ABSORBED DOSE RATE dependence and stability are established for the LIGHT ION BEAMS to be tested.

7.3 Reproducibility of MU delivery

7.3.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the reproducibility of DOSE MONITOR UNIT DELIVERY expressed as the maximum COEFFICIENT OF VARIATION and the maximum deviation from the average value of the ratio of the measured RADIATION DETECTOR response and the delivered DOSE MONITOR UNITS for LIGHT ION RADIATION when the same value of DOSE MONITOR UNITS is set under otherwise identical conditions for IRRADIATION.

The maximum COEFFICIENT OF VARIATION and the deviation from the average value shall be expressed as a percentage.

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION the reference IRRADIATION FIELD SIZE used for these measurements.

7.3.2 Test

Measurements to determine the reproducibility of DOSE MONITOR UNIT DELIVERY shall be performed for:

- a) each LIGHT ION species if the system has the capability to deliver more than one LIGHT ION species;

- b) each beam delivery mode available;
- c) highest and lowest available DOSE MONITOR UNIT RATE if the system has the capability of delivering more than one dose rate.

The reproducibility s is determined as a COEFFICIENT OF VARIATION using the formula:

$$s = \frac{100}{\bar{R}} \left[\sum_{i=1}^n \frac{(\bar{R} - R_i)^2}{n-1} \right]^{1/2} \%$$

where

R_i is the ratio of measured RADIATION DETECTOR response, D , to delivered DOSE MONITOR UNITS, U , of the i^{th} measurement,

$\bar{R}$ is the average value of the ratios R_i determined from $\bar{R} = \frac{1}{n} \sum_{i=1}^n R_i$,

n is the number of measurements.

For each set of test conditions given in Table 1, ten consecutive IRRADIATIONS are made under otherwise identical conditions. The requested number of DOSE MONITOR UNITS should result in an ABSORBED DOSE of about 2 Gy to a hypothetical small water volume if located at the test detector position. The location of the test detector shall coincide with the plane passing through the ISOCENTRE or ERP and normal to the LIGHT ION REFERENCE AXIS. These measurement conditions shall apply for all measurements of R .

Table 1 – Standard test conditions for testing reproducibility

Angular position of		Combination of SCANNING MODE and LSD	RADIATION FIELD mm × mm	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
GANTRY Axis ① ^{a,c}	BEAM LIMITING SYSTEM ^d Axis ④ ^a					
0°	0°	Each combination if selectable	Reference size ^b	Highest (and lowest if selectable)	Each LIGHT ION species	One ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE ^e
^a See Figure 3. ^b MANUFACTURER'S reference IRRADIATION FIELD SIZE described in ACCOMPANYING DOCUMENTATION. ^c For stationary GANTRY type, the test is performed at the available stationary angle. ^d For systems with a rotating BEAM LIMITING SYSTEM. ^e Either a NON-RANGE MODULATED PORTAL or RANGE MODULATED PORTAL is acceptable. For RANGE MODULATED PORTALS, only the highest ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE of the PORTAL need be stated.						

7.4 Proportionality of MU delivery

7.4.1 Requirement

For a change of MU with all other beam delivery conditions identical, the relationship between the measured RADIATION DETECTOR response and the delivered number of DOSE MONITOR UNITS shall be linear and of the form

$$D = S \times U$$

where

D is the RADIATION DETECTOR response,

S is the proportionality factor,

U is the value of the DOSE MONITOR UNIT.

7.4.2 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the maximum deviation between the measured RADIATION DETECTOR response, D , and the calculated product of the DOSE MONITOR UNITS, U , and the proportionality factor, S .

The maximum deviation shall be expressed as a percentage and absolute variation of the value calculated from the equation in 7.4.1.

The maximum deviation at the maximum, minimum, and $(\max + \min)/2$ available ENERGY PER NUCLEON levels shall be given.

The maximum deviation shall apply over the ranges of available DOSE MONITOR UNITS and ranges of available DOSE MONITOR UNIT RATES at the ERP, for each combination of SCANNING MODE and LSD, (including large and small values of DOSE MONITOR UNITS) provided.

7.4.3 Test

The proportionality of MU delivery shall be tested for:

- a) standard test conditions according to 7.2 and Table 2 for each combination of SCANNING MODE and LSD that use scatterers or UNIFORM SCANNING;
- b) each combination of SCANNING MODE and LSD if the system has a plurality of combinations of SCANNING MODES and LSDS;
- c) highest and lowest available DOSE MONITOR UNIT RATES if the system has the capability of multiple USER selectable DOSE MONITOR UNIT RATES.

Five series of IRRADIATIONS are made for each set of test conditions given in Table 2, each delivering a different number of DOSE MONITOR UNITS at approximately equal intervals within the SPECIFIED range of DOSE MONITOR UNITS at the ERP.

The location of the RADIATION DETECTOR shall coincide with the plane passing through the ISOCENTRE or ERP and normal to the LIGHT ION REFERENCE AXIS. These measurement conditions shall apply for all measurements of R_i .

Table 2 – Conditions for testing proportionality of the DOSE MONITORING SYSTEM

Angular position of		Combination of SCANNING MODE and LSD	RADIATION FIELD mm × mm ^b	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
GANTRY Axis ① ^{a,c}	BEAM LIMITING SYSTEM ^d Axis ④ ^a					
0°	0°	Each combination if selectable	Standard test condition for scatterers or UNIFORM SCANNING or single ENERGY PER NUCLEON and SPOT map for MODULATED SCANNING	Highest and lowest, if selectable	Each LIGHT ION species	Maximum, minimum, and (max + min)/2 ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE ^e
^a See Figure 3. ^b MANUFACTURER'S reference IRRADIATION FIELD SIZE described in ACCOMPANYING DOCUMENTATION. ^c For stationary GANTRY type, test shall be performed at available stationary angle. ^d For systems with a BEAM LIMITING SYSTEM. ^e Either NON-RANGE MODULATED OR RANGE MODULATED PORTAL is acceptable.						

7.5 Off-axis response of beam FLUX monitor for MODULATED SCANNING

7.5.1 Information to the USER

For RADIATION HEADS used for MODULATED SCANNING, the ACCOMPANYING DOCUMENTATION shall state the maximum differences between the maximum value and the minimum value of the ratio $\bar{R}$ for LIGHT ION RADIATION when the scanned SPOT is transmitted through different off-axis positions of the beam FLUX monitor.

The maximum differences shall be expressed as percentages of the mean value of $\bar{R}$ for LIGHT ION RADIATION.

7.5.2 Test

$\bar{R}$ is determined from five measurements for each set of standard test conditions given in 7.2 and Table 3. The test shall be performed for each LIGHT ION species. The ratio shall be measured at various off-axis locations to sample the entire active beam FLUX monitor area. During the measurements for each set of test conditions the equipment is stationary. The ratio between the response of the test detector and the beam FLUX monitor response is determined for a series of off-axis positions.

Table 3 – Conditions for testing off-axis response of the beam FLUX monitor for MODULATED SCANNING

Angular position of		Combination of SCANNING MODE and LSD	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
GANTRY	BEAM LIMITING SYSTEM ^c				
Axis ① ^{a,b}	Axis ④ ^a				
0°, 180°	0°	Each combination if selectable	Highest and lowest, if selectable	Each LIGHT ION species	One ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
^a See Figure 3. ^b For stationary GANTRY type, test shall be performed at available stationary angle. ^c For systems with a rotating BEAM LIMITING SYSTEM.					

7.6 Dependence of MU delivery on angular position

7.6.1 Information to the USER

For rotating and multiple-discrete angles GANTRIES, the ACCOMPANYING DOCUMENTATION shall state the maximum differences between the maximum value and the minimum value of the ratio $\bar{R}$ for LIGHT ION RADIATION when the RADIATION HEAD is placed in different orientations through the full range of directions.

The maximum differences shall be expressed as percentages of the mean value of $\bar{R}$ for LIGHT ION RADIATION as defined in 7.3.2.

The values shall be stated for each RADIATION HEAD available.

7.6.2 Test

$\bar{R}$ is determined from five measurements for each set of test conditions given in 7.2 and Table 4. The tests shall be performed for the LIGHT ION species with the highest atomic number. The same ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE shall be used for all GANTRY angles. During the measurements for each set of test conditions the equipment is stationary.

Table 4 – Conditions for testing dependence of the DOSE MONITORING SYSTEM on angular position

Angular position of GANTRY Axis ① ^{a,c,d}	RADIATION FIELD mm × mm ^b	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE
0°	Reference size ^b	One fixed	LIGHT ION species with the highest atomic number	One ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^e
90°	Reference size ^b	One fixed	LIGHT ION species with the highest atomic number	One ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^e
180°	Reference size ^b	One fixed	LIGHT ION species with the highest atomic number	One ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^e
270°	Reference size ^b	One fixed	LIGHT ION species with the highest atomic number	One ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^e
^a See Figure 3. ^b MANUFACTURER'S reference IRRADIATION FIELD SIZE described in ACCOMPANYING DOCUMENTATION. ^c For a multiple-discrete angles GANTRY type, test shall be performed at the available angles. ^d For a rotational GANTRY with a limited range of angles, test shall be performed at all available quadrantal (even multiple of 90°) angles. ^e Either NON-RANGE MODULATED OR RANGE MODULATED PORTAL is acceptable.				

7.7 Stability of MU DELIVERY

7.7.1 Stability of MU DELIVERY throughout the day

7.7.1.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state for LIGHT ION RADIATION the maximum difference between the ratios $\bar{R}$ of the measured RADIATION DETECTOR response and the DOSE MONITOR UNITS made:

- immediately following the LIGHT ION BEAM ME EQUIPMENT having reached the READY STATE after an extended period in the stand-by state as defined by the MANUFACTURER, and
- throughout a simulated PATIENT TREATMENT period of 8 h of successive IRRADIATION cycles, each cycle consisting of an IRRADIATION at a typical ABSORBED DOSE RATE and resulting in an ABSORBED DOSE of approximately 3 Gy for typical ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE followed by about 15 min without IRRADIATION.

The maximum difference shall be expressed as a percentage of the value of $\bar{R}$ determined at the beginning of the test.

7.7.1.2 Test

The dose per monitor unit measurements shall be made before, in the middle, and at the end of an 8 h period.

$\bar{R}$ is determined for five measurements for each set of test conditions given in 7.2 and Table 5, each IRRADIATION resulting in an ABSORBED DOSE of approximately 3 Gy at the ISOCENTRE OR ERP.

During the test, corrections for changes of temperature, pressure and humidity are applied according to the ACCOMPANYING DOCUMENTATION.

NOTE The approximate IRRADIATION ABSORBED DOSES of 3 Gy to simulate PATIENT TREATMENTS during the measurement period can often be satisfied by IRRADIATIONS performed for other tests.

Table 5 – Conditions for testing stability throughout the day of the DOSE MONITORING SYSTEM

Angular position of		RADIATION FIELD mm × mm ^b	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE
GANTRY Axis ① ^{a,c}	BEAM LIMITING SYSTEM ^d Axis ④ ^a				
0°	0°	Reference size ^b	One fixed	LIGHT ION species with highest available atomic number	One ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^e
^a See Figure 3. ^b MANUFACTURER'S reference IRRADIATION FIELD SIZE described in ACCOMPANYING DOCUMENTATION. ^c For stationary GANTRY type, test shall be performed at available stationary angle. ^d For systems with a BEAM LIMITING SYSTEM. ^e Either a NON-RANGE MODULATED PORTAL OR RANGE MODULATED PORTAL is acceptable.					

7.7.2 Stability of MU DELIVERY throughout the week

7.7.2.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state for LIGHT ION RADIATION the maximum difference between the highest and lowest ratios $\bar{R}$ of the measured values of RADIATION DETECTOR response and DOSE MONITOR UNITS determined from measurements made on five days. The maximum difference shall be expressed as a percentage of the mean value of all measured values of $\bar{R}$.

7.7.2.2 Test

$\bar{R}$ is to be determined from at least five measurements for each set of test conditions given in 7.2 and Table 6, each IRRADIATION resulting in an ABSORBED DOSE of approximately 2 Gy at the ISOCENTRE OR ERP.

During the test, corrections for changes of temperature, pressure and humidity to the DOSE MONITORING SYSTEM of LIGHT ION BEAM ME EQUIPMENT are applied according to the ACCOMPANYING DOCUMENTATION.

Table 6 – Conditions for testing stability throughout the week of the DOSE MONITORING SYSTEM

Angular position of		RADIATION FIELD mm × mm ^b	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
GANTRY Axis ① ^{a,c}	BEAM LIMITING SYSTEM ^d Axis ④ ^a				
0°		Reference size ^b	Any ^e	LIGHT ION species with highest available atomic number	One ENERGY PER NUCLEON OR LIGHT ION BEAM RANGE
^a See Figure 3. ^b MANUFACTURER'S reference IRRADIATION FIELD SIZE described in ACCOMPANYING DOCUMENTATION. ^c For stationary GANTRY type, test shall be performed at available stationary angle. ^d For systems with a BEAM LIMITING SYSTEM. ^e The MU rate shall not change during the test throughout the week.					

8 DEPTH DOSE characteristics

8.1 DEPTH DOSE distributions for NON-RANGE MODULATED PORTALS

8.1.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall present datasets of DEPTH DOSE measured at multiple depths on the LIGHT ION REFERENCE AXIS for the maximum, minimum, and (max + min)/2 available ENERGY PER NUCLEON levels for each LIGHT ION species for NON-RANGE MODULATED PORTALS (i.e. single ENERGY PER NUCLEON field).

- a) for the largest IRRADIATION FIELD SIZE supported for each LIGHT ION BEAM APPLICATOR for each GANTRY type for IRRADIATION methods that use scatterers or UNIFORM SCANNING, or
- b) for a single SPOT for MODULATED SCANNING.

The following information shall be provided with each distribution:

- a) LIGHT ION BEAM RANGE;
- b) depth of ISOCENTRE OR ERP.

8.1.2 Test

DEPTH DOSE distributions should be measured for NON-RANGE MODULATED PORTALS. In the entrance region the depth interval between measurement points shall not exceed 10 mm. In the peak region the depth interval between measurement points should be no greater than 0,3 mm of water equivalent material. A parallel plate ionization chamber should be used.

If a ripple filter is required to achieve the MANUFACTURER specifications, it shall be used for the test and its presence and beam modifying characteristics shall be reported in the ACCOMPANYING DOCUMENTATION.

NOTE 1 If a ripple filter is a necessary device for PATIENT TREATMENT, for this test a ripple filter is not considered a USER selectable RANGE MODULATION DEVICE and the PORTAL is considered to be a NON-RANGE MODULATED PORTAL.

If an APERTURE is used to shape the RADIATION FIELD, its presence and the APERTURE-to-PHANTOM distance used for the measurement shall be reported in the ACCOMPANYING DOCUMENTATION.

The diameter of the active area, the thickness of the front wall, and the gas gap of the ionization chamber used for the measurement shall be reported in the ACCOMPANYING DOCUMENTATION.

NOTE 2 For the entrance dose measurement, a thin window parallel plate ionization chamber can be used in a solid PHANTOM.

NOTE 3 As an alternative to supplying the ion chamber characteristics, the MANUFACTURER can provide the name of the MANUFACTURER of the ion chamber and model of the ion chamber.

- a) The ENTRANCE-TO-PEAK DOSE RATIO shall be extracted from each NON-RANGE MODULATED PORTAL DEPTH DOSE distribution defined in 8.1.1 and provided in the ACCOMPANYING DOCUMENTATION (see Figure 1.)
- b) The TAIL-TO-PEAK DOSE RATIO shall be extracted from each NON-RANGE MODULATED PORTAL DEPTH DOSE distribution defined in 8.1.1 and provided in the ACCOMPANYING DOCUMENTATION (see Figure 1.)
- c) The difference between depths in water of the point distal from the peak where the ABSORBED DOSE is 80 % of the ABSORBED DOSE of the peak and the point distal from the peak where the ABSORBED DOSE is 20 % of the ABSORBED DOSE of the peak, measured on the LIGHT ION REFERENCE AXIS in the RADIATION FIELD SPECIFIED in 8.3.1.
- d) The difference between depths in water of the point distal from the peak where the ABSORBED DOSE is 90 % of the ABSORBED DOSE of the peak and the point distal from the peak where the ABSORBED DOSE is 50 % of the ABSORBED DOSE of the peak, measured on the LIGHT ION REFERENCE AXIS in the RADIATION FIELD SPECIFIED in 8.3.1.

8.2 Range modulating techniques

8.2.1 Type and sequence of range MODULATION DEVICES in RADIATION HEAD

If the RMDs are selectable by the USER for IRRADIATION, the ACCOMPANYING DOCUMENTATION shall provide the following information for each RANGE MODULATION DEVICE in each available GANTRY type:

- a) distance from the RMD to the ISOCENTRE or ERP;
- b) type;
- c) subtype;
- d) insertion method.

NOTE 1 Examples of RANGE MODULATION DEVICE types include: propellor, ridge filter, mini-ridge filter, ripple filter, cone.

NOTE 2 RANGE MODULATION DEVICES can be of subtype: discrete, programmable.

NOTE 3 Discrete RANGE MODULATION DEVICES can have an insertion method of: manual, automatic.

8.2.2 Discrete RANGE MODULATION DEVICE

For each discrete RMD available, the ACCOMPANYING DOCUMENTATION shall provide the following information:

- a) designation;
- b) NOMINAL RANGE MODULATION WIDTH;
- c) ENERGY PER NUCLEON levels and maximum IRRADIATION FIELD SIZES for which the discrete RMD is applicable.

8.2.3 Programmable RANGE MODULATION DEVICE

For each programmable RMD available, the ACCOMPANYING DOCUMENTATION shall provide the following information:

- a) description of the process to deliver the PROGRAMMABLE RANGE MODULATED PORTAL using the programmable RMD;
- b) designation of the programmable RMD that can be programmed;
- c) range of NOMINAL RANGE MODULATION WIDTHS available;
- d) ENERGY PER NUCLEON levels and maximum IRRADIATION FIELD SIZES over which the programmable RMD is applicable.

8.3 RANGE MODULATED PORTAL DEPTH DOSE distributions

8.3.1 Information to the USER

This clause does not apply to MODULATED SCANNING beam delivery techniques.

The ACCOMPANYING DOCUMENTATION shall contain relative DEPTH DOSE distribution plots along the LIGHT ION REFERENCE AXIS for RANGE MODULATED PORTALS. The relative DEPTH DOSE distribution plots shall be normalized to the depth corresponding to the centre of the NRMW.

NOTE Due to measurement noise and ripple in the DEPTH DOSE distribution, the ABSORBED DOSE to which to normalize the distribution are averaged over measurements at several depths close to and surrounding the centre of the NRMW.

DEPTH DOSE distributions shall be provided for each beam delivery technique provided by the MANUFACTURER for each intended combination of RMD, PRMP, LSD AS SPECIFIED by the MANUFACTURER.

The data shall be acquired for each LIGHT ION BEAM APPLICATOR, LIGHT ION species, and beam delivery technique using the maximum IRRADIATION FIELD SIZE available for each intended combination.

Data shall be acquired for the largest available NRMW and a NRMW of 60 mm for a LIGHT ION BEAM RANGE of approximately 200 mm. If the maximum range is shorter than 200 mm, the maximum available range shall be selected. For LIGHT ION BEAM RANGES less than 200 mm, data shall be acquired for the maximum NRMW and a NRMW approximately one-half of the maximum NRMW. If the maximum NRMW is smaller than 60 mm, then the maximum available NRMW shall be used.

All DEPTH DOSE distributions shall be measured with the depth corresponding to the nominal centre of modulation placed at the ISOCENTRE or ERP.

DEPTH DOSE distribution measurements are not required for combinations of equipment not available to the USER.

The following information shall be provided with each distribution:

- a) LIGHT ION BEAM RANGE for highest ENERGY PER NUCLEON component;
- b) depth of ISOCENTRE OR ERP;
- c) NRMW.

8.3.2 Test

DEPTH DOSE distributions should be measured for RANGE-MODULATED PORTALS. The depth interval between measurement points shall not exceed 10 mm. Within minus 3 mm of the LIGHT ION BEAM RANGE and plus 3 mm of the distal 10 % dose the depth interval between measurement points should be no greater than 1,0 mm of water equivalent material. A parallel plate ionization chamber should be used. Together with each DEPTH DOSE distribution, a warning shall be given that the values shown are only typical values and shall not be used for the planning of the TREATMENT of the PATIENT unless they have been verified by measurements on the individual LIGHT ION BEAM ME EQUIPMENT. Distributions shall be measured for all available RADIATION HEADS.

NOTE For the entrance dose measurement, a thin window parallel plate ionization chamber can be used in a solid PHANTOM.

8.4 Stability of LIGHT ION BEAM RANGE

8.4.1 Stability of LIGHT ION BEAM RANGE throughout an IRRADIATION

8.4.1.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the maximum deviation of LIGHT ION BEAM RANGE in water with time during an IRRADIATION of 2 min.

The LIGHT ION BEAM RANGE shall be sampled at an interval SPECIFIED by the MANUFACTURER not to exceed 3 s during the IRRADIATION.

The maximum deviation shall be given in millimetres of water.

The test shall be performed at the maximum, minimum, and (maximum + minimum)/2 ENERGY PER NUCLEON levels for each LIGHT ION species (Table 7).

8.4.1.2 Test

Measurements shall be made in a PHANTOM. The PHANTOM shall be suitable for measurement of the ratio between the ABSORBED DOSE at approximately the depth of 50 % of peak dose and a simultaneous entrance ABSORBED DOSE measurement.

The variation of this ratio is converted to a change in LIGHT ION BEAM RANGE using the DEPTH DOSE gradient derived from the DEPTH DOSE distributions required in 8.1.

Table 7 – Conditions for testing stability of LIGHT ION BEAM RANGE during an IRRADIATION

RADIATION TYPE	ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE
Each LIGHT ION species	Low, medium, and high ENERGY PER NUCLEON levels or LIGHT ION BEAM RANGES

8.4.1.3 Inspection of the information

The ACCOMPANYING DOCUMENTATION shall be inspected for inclusion of the values.

8.4.2 Dependence of LIGHT ION BEAM RANGE on GANTRY rotation

8.4.2.1 Information to the USER

For rotating type GANTRIES, the ACCOMPANYING DOCUMENTATION shall state the maximum deviation of LIGHT ION BEAM RANGE at two GANTRY angles separated by 90°.

The maximum deviation shall be given in millimetres of water.

The test shall be performed at the maximum, minimum, and (maximum + minimum)/2 ENERGY PER NUCLEON levels for each LIGHT ION species (Table 8).

The data shall be acquired for all LIGHT ION BEAM APPLICATORS, LIGHT ION species, and beam delivery techniques using the maximum IRRADIATION FIELD SIZE available for each LIGHT ION BEAM APPLICATOR.

8.4.2.2 Test

Measurements shall be made in a PHANTOM. The PHANTOM shall be suitable for measurement of the ratio between the ABSORBED DOSE at approximately the depth of 50 % of peak dose and a simultaneous entrance ABSORBED DOSE measurement.

The variation of this ratio of ABSORBED DOSE at the two depths is converted to a change in LIGHT ION BEAM RANGE using the DEPTH DOSE gradient derived from the DEPTH DOSE distributions required in 8.1.

**Table 8 – Conditions for testing dependence of the
LIGHT ION BEAM RANGE on GANTRY angle**

Angular position of GANTRY	RADIATION FIELD mm × mm ^b	DOSE MONITOR UNIT RATE	RADIATION TYPE	ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE
Axis ① ^{a,b,c}				
Angle 1	Max IRRADIATION FIELD SIZE for each LIGHT ION BEAM APPLICATOR	One fixed	Each LIGHT ION species	Maximum, minimum, and (max + min)/2 ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^d
Angle 2	Max IRRADIATION FIELD SIZE for each LIGHT ION BEAM APPLICATOR	One fixed	Each LIGHT ION species	Maximum, minimum, and (max + min)/2 ENERGY PER NUCLEON OF LIGHT ION BEAM RANGE ^d
^a See Figure 3. ^b For a multiple-discrete angles GANTRY type, test shall be performed at two available angles separated by the maximum angle. ^c For a rotational GANTRY with a limited range of angles, test shall be performed at two angles separated by 90°. ^d Either a NON-RANGE MODULATED PORTAL OR RANGE MODULATED PORTAL is acceptable.				

9 Lateral profiles of LIGHT ION PORTALS

9.1 Lateral profiles of LIGHT ION PORTALS for systems that use scatterers or UNIFORM SCANNING

9.1.1 General

For testing of lateral profiles, the maximum IRRADIATION FIELD SIZE supported for each LIGHT ION BEAM APPLICATOR shall be used with a constant LIGHT ION BEAM RANGE across the field. Lateral profiles shall be measured at depths corresponding to the surface, proximal 90 % depth plus 10 % of the NRMW, the centre of the range modulated region, and the distal 90 % dose depth minus 10 % of the NRMW (see Figure 4). An example profile of ABSORBED DOSE for a LIGHT ION PORTAL is shown in Figure 5. If a GANTRY has more than one delivery technique, then measurements shall be made and reported for each delivery technique.

Data shall be acquired for the largest available NRMW and a NRMW of 60 mm for the maximum, minimum, and (maximum + minimum)/2 selectable ENERGY PER NUCLEON levels of each LIGHT ION species under standard test conditions (see Clause 7). For ENERGY PER NUCLEON levels with LIGHT ION BEAM RANGE less than 100 mm, data shall be acquired for the largest available NRMW and a NRMW approximately one-half of the maximum NRMW. If the largest NRMW is less than 60 mm, data may be acquired only for the largest available NRMW. The distance from the

downstream surface of the BLD to the upstream surface of the PHANTOM shall be larger or equal to 50 mm and shall be SPECIFIED by the MANUFACTURER. The exposure shall be made using the MU stated by the MANUFACTURER or the time required to produce a uniform dose distribution (see 11.1).

9.1.2 Flatness of LIGHT ION PORTALS

9.1.2.1 Information to the USER

Flatness shall be evaluated for all lateral profiles described in 9.1 except the surface profile. The ACCOMPANYING DOCUMENTATION shall state the flatness by providing both the maximum and minimum values of the ratio of ABSORBED DOSE anywhere in the flattened area to the ABSORBED DOSE at the LIGHT ION REFERENCE AXIS. The dose along the lateral profile shall be averaged over not more than 1 cm² for determining the maximum and minimum doses.

The flattened area is defined along straight lines joining points on the major axes and diagonals of square fields as shown in Figure 6a or straight lines crossing through the beam axes of circular fields as shown in Figure 6b. The flattened area extends from the LIGHT ION REFERENCE AXIS to within d_m of the field edge along major axes and, for rectangular fields, to within d_d along diagonal axes. A typical profile is given in Figure 5. d_m and d_d are calculated by multiplying the lateral PENUMBRA width (measured in 9.1.4) along each line by a factor of 2.

The maximum and minimum ratios shall be expressed as a percentage of the ABSORBED DOSE on the LIGHT ION REFERENCE AXIS.

The maximum and minimum values shall be given for the maximum, minimum, and (maximum + minimum)/2 ENERGY PER NUCLEON levels available for the maximum IRRADIATION FIELD SIZE possible for each LIGHT ION BEAM APPLICATOR for each LIGHT ION species for angular positions of the GANTRY of 0°, 90°, 180°, and 270°. For rotational GANTRIES with less than 360° rotation, values shall be provided for the minimum and maximum GANTRY angles and available GANTRY angles of 0°, 90°, 180°, and 270°.

The maximum and minimum values shall be given for all profiles measured in 9.1 except the surface profile.

9.1.2.2 Test

For each lateral profile within the set of test conditions given in 9.1, the ABSORBED DOSE distribution at each depth should be measured and the profiles along the major axes and the diagonals of the LIGHT ION PORTAL extracted and analysed using the parameters from Figures 6a and 6b.

9.1.3 Symmetry of LIGHT ION PORTALS

9.1.3.1 Information to the USER

Symmetry shall be evaluated for all lateral profiles described in 9.1 except the surface profile. For LIGHT ION PORTALS the ACCOMPANYING DOCUMENTATION shall state the maximum value of the ratio of the highest to the lowest ABSORBED DOSE (averaged over not more than 1 cm²) at any two positions symmetrical to the LIGHT ION REFERENCE AXIS and inside the flattened area.

This ratio shall be expressed as a percentage.

The maximum value shall be given for all profiles measured in 9.1.

9.1.3.2 Test

The information may be extracted from the profiles measured for 9.1 except the surface profile.

9.1.4 Lateral PENUMBRA

9.1.4.1 Information to the USER

The lateral PENUMBRA shall be evaluated for all lateral profiles described in 9.1 except the surface profile. The ACCOMPANYING DOCUMENTATION shall state the width of the lateral PENUMBRA as the maximum distance along the major axes between the 80 % and 20 % points of the ABSORBED DOSE distribution of each profile measured in 9.1.

The 80 % and 20 % points are with reference to the ABSORBED DOSE on the LIGHT ION REFERENCE AXIS.

The width of the lateral PENUMBRA shall be given in millimetres.

9.1.4.2 Test

The information may be extracted from the profiles measured for 9.1.

9.2 Lateral profiles of LIGHT ION PORTALS for systems that use MODULATED SCANNING

9.2.1 Information to the USER

For systems that use MODULATED SCANNING, the ACCOMPANYING DOCUMENTATION shall provide the following information for the scanning SPOT for each GANTRY for each nominal SPOT size, at the maximum, minimum and (maximum + minimum)/2 ENERGY PER NUCLEON or LIGHT ION BEAM RANGE, and for each LIGHT ION species:

- a) GANTRY angle of measurement;
- b) maximum difference between measured and selected X and Y SPOT positions in (Xg,Yg) coordinates;
- c) average and its standard deviation of the non-signed differences between measured and selected X and Y SPOT positions in (Xg,Yg) coordinates;
- d) maximum difference between measured and SPECIFIED full-width-half-maximum for major axis and minor axis at the ISOCENTRE or ERP;
- e) 2-D plots of lateral FLUENCE profiles in air for single LIGHT ION BEAM SPOTS;
- f) all measurements shall be reported in millimetres.

9.2.2 Test

All measurements are to be made in air in a plane located at the ISOCENTRE or ERP.

Expose a SPOT pattern with at least 17 SPOTS separated on the whole scanning amplitude range with one SPOT located on the LIGHT ION REFERENCE AXIS.

Expose the SPOT pattern at GANTRY angles of 0°, 90°, 180°, 270°, and an available overlap angle or for stationary or multiple-discrete angles GANTRIES at all available angles. For rotational GANTRIES with less than 360° rotation, exposures shall be made for the minimum and maximum GANTRY angles and available GANTRY angles of 0°, 90°, 180°, and 270°.

Expose the SPOT pattern for each nominal SPOT size for the maximum, minimum, and (maximum + minimum)/2 ENERGY PER NUCLEON levels for each LIGHT ION species.

10 LIGHT ION PORTAL with energy and FLUENCE modulation (EFM)

10.1 Information to the USER

If EFM capability has been provided, the ACCOMPANYING DOCUMENTATION shall provide details of any routine quality assurance tests designed to verify the capabilities of the multi-element BLD or MODULATED SCANNING beam to produce EFM LIGHT ION PORTALS.

NOTE Energy and FLUENCE modulation may be provided by several beam delivery methods. One example is energy stacking using range shifters combined with a multi-element BEAM LIMITING DEVICE. Another example is energy stacking using accelerator energy extraction combined with lateral MODULATED SCANNING.

In addition to any quality assurance test procedures SPECIFIED by the equipment MANUFACTURER, the following TYPE TESTS shall also be performed, and typical results made available to the USER.

10.2 Beam characteristics and dosimetry system performance for small delivered doses

- a) For scattered and UNIFORM SCANNING beam delivery techniques, where applicable, the tests in 7.3 to 7.7 and 9.1 shall include measurements made for the smallest number of DOSE MONITOR UNITS SPECIFIED by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION.
- b) For MODULATED SCANNING beam delivery techniques, the ACCOMPANYING DOCUMENTATION shall specify the smallest and the largest numbers of DOSE MONITOR UNITS for which the specifications in Clause 7 and 9.2.1 are met.

NOTE The MANUFACTURER can provide additional performance values outside the DOSE MONITOR UNITS range SPECIFIED in a).

11 Time to irradiate SPECIFIED volumes

11.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the minimum time in seconds required to deliver an ABSORBED DOSE of 2 Gy to the following SPECIFIED volumes with a uniform ABSORBED DOSE within the volume of $\pm 5\%$ of the dose at the centre of the volume:

- a) 100 mm wide $\times$ 100 mm long $\times$ 100 mm deep centred at a water equivalent depth of 205 mm in a PHANTOM.
- b) 200 mm wide $\times$ 200 mm long $\times$ 50 mm deep centred at a water equivalent depth of 100 mm in a PHANTOM.

The uniformity of ABSORBED DOSE across the SPECIFIED volume shall be measured and reported. Two-dimensional plots shall be obtained in planes perpendicular to the LIGHT ION REFERENCE AXIS at depths corresponding to the proximal 90 % depth plus 10 % of the NRMW, the centre of the range modulated region, and the distal 90 % dose depth minus 10 % of the NRMW.

If the maximum LIGHT ION BEAM RANGE is shorter than 300 mm, the maximum available LIGHT ION BEAM RANGE shall be used.

If the maximum NRMW is not large enough to cover the SPECIFIED volume with uniform dose, the maximum available NRMW shall be used.

If the maximum IRRADIATION FIELD SIZE is not large enough to cover the SPECIFIED volume with uniform dose, the maximum available IRRADIATION FIELD SIZE shall be used.

For LIGHT ION BEAM ME EQUIPMENT that do not deliver uniform DEPTH DOSE distributions across a SPECIFIED volume, the test conditions shall be SPECIFIED by the MANUFACTURER and shall be provided in the ACCOMPANYING DOCUMENTATION.

NOTE For beam delivery systems for LIGHT IONS heavier than hydrogen that use clinical RANGE MODULATOR DEVICES such as ridge filters, uniform DEPTH DOSE distributions are not delivered.

The test shall be performed using only the allowed combinations of beam parameters for TREATMENT described in 5.2.

The available times shall be provided for:

- a) each LIGHT ION species if the system has the capability to deliver more than one LIGHT ION species;
- b) each combination of SCANNING MODE and LSD if the system has a plurality of combinations.

11.2 Test

Start a timer when IRRADIATION commences for the SPECIFIED PORTALS and stop the timer when the IRRADIATION TERMINATES completely. Report the times and uniformity for each PORTAL.

NOTE The measurements for this clause can use either a water or solid PHANTOM.

12 Indication of RADIATION FIELDS

12.1 APPLICATOR CARRIAGE extension indicator

12.1.1 Information to the USER

If the GANTRY has a retractable/extendable APPLICATOR CARRIAGE, there shall be a numerical indication of the extension. The ACCOMPANYING DOCUMENTATION shall state the maximum difference between the numerical indication and the measured distance.

The maximum difference shall be given in millimetres.

12.1.2 Test

Extend the APPLICATOR CARRIAGE to full extension. Measure the distance between the APPLICATOR CARRIAGE reference point and the numerical indication reference point. Repeat the measurement for several APPLICATOR CARRIAGE extensions.

12.2 Multi-element BLD element position indications

12.2.1 Information to the USER

For a multi-element BLD (excluding binary BLDS, which are either open or closed) there shall be numerical indications of the coordinates, as SPECIFIED by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION, of each element's mechanical edge position.

The ACCOMPANYING DOCUMENTATION shall state the maximum difference(s) between the numerical element-indications and the actual positions of the element edges.

The maximum difference shall be given in millimetres.

12.2.2 Test

The positions of each element edge in the coordinate system defined in the ACCOMPANYING DOCUMENTATION are mechanically measured and the differences from numerical indications are deduced. The maximum difference is obtained for tests performed with a 100 mm × 100 mm coordinate system and the maximum opening settings and position measurements, the number of repetitions being defined in the ACCOMPANYING DOCUMENTATION.

12.3 Indication of THE LIGHT ION REFERENCE AXIS

12.3.1 General

LIGHT ION BEAM ME EQUIPMENT may provide devices for indicating the LIGHT ION REFERENCE AXIS relative to the PATIENT, for example: lasers, FRONT POINTER, cross hairs, orthogonal x-rays.

NOTE Safety aspects of x-ray IMAGE-GUIDED RADIOTHERAPY (IGRT) equipment are covered in IEC 60601-2-68:2014.

12.3.2 Indication on entry to the PATIENT

12.3.2.1 Information to the USER

If a device for indicating the LIGHT ION REFERENCE AXIS is provided, the ACCOMPANYING DOCUMENTATION shall contain the maximum deviations of the indicated positions from the LIGHT ION REFERENCE AXIS for each of the conditions given in Table 9 for each RADIATION HEAD.

Table 9 – Conditions for testing the indication on entry to the PATIENT

Angular position of GANTRY	Angular position of BEAM LIMITING SYSTEM ^c	RADIATION FIELD	Position of RADIATION DETECTOR	RADIATION TYPE	ENERGY PER NUCLEON
Axis ① ^{a,b}	Axis ④ ^a				
0°	0°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
0°	45°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
180°	180°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
90°	90°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
0°	90°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
270°	90°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
Overlap angle	0°	Max IRRADIATION FIELD SIZE for each applicator	ISOCENTRE or ERP	LIGHT ION	One
^a See Figure 3. ^b For stationary and multiple-discrete angles GANTRY types, test shall be performed at the available angles. ^c For systems with a BEAM LIMITING SYSTEM.					

12.3.2.2 Test

The maximum deviation is determined by exposing a RADIATION DETECTOR with sufficient spatial resolution perpendicularly to the LIGHT ION REFERENCE AXIS at the ERP, 250 mm proximal of the ERP, and 250 mm distal of the ERP.

NOTE If RADIOGRAPHIC FILM is used as the RADIATION DETECTOR, the indicated LIGHT ION REFERENCE AXIS can be marked with several pin pricks. If an EID is used, the pin pricks can be replaced with a radio-opaque marker aligned with the indicated LIGHT ION REFERENCE AXIS.

The maximum deviation shall be provided for SPECIFIED LIGHT ION species.

The maximum deviation shall be reported for GANTRY angles of 0°, 90°, 180°, 270°, and an available overlap angle or for stationary or multiple-discrete angle GANTRIES at all available angles. For rotational GANTRIES with less than 360° rotation, values shall be reported for the minimum and maximum GANTRY angles and available GANTRY angles of 0°, 90°, 180°, and 270°.

If the working range of the indicating device is smaller than plus or minus 250 mm from the ERP, the indicating device is placed at the extremes of the working range.

12.3.3 Indication of the LIGHT ION REFERENCE AXIS on distal side of PATIENT

12.3.3.1 Information to the USER

If an exit indicator is provided, the ACCOMPANYING DOCUMENTATION shall contain the maximum deviation of the indication from the LIGHT ION REFERENCE AXIS for the range of 0 mm to 500 mm beyond the ERP or within the SPECIFIED working range of the device, whichever is smaller.

12.3.3.2 Test

One exposure of a RADIATION DETECTOR is made for each set of test conditions. The maximum deviation is determined by exposing a RADIATION DETECTOR oriented perpendicularly to the LIGHT ION REFERENCE AXIS at the ERP and 500 mm distal of the ERP.

NOTE If RADIOGRAPHIC FILM is used as the RADIATION DETECTOR, the indicated LIGHT ION REFERENCE AXIS can be marked with several pin pricks. If an EID is used, the pin pricks can be replaced with a radio-opaque marker aligned with the indicated LIGHT ION REFERENCE AXIS.

The maximum deviation shall be provided for a SPECIFIED LIGHT ION species.

The maximum deviation shall be reported for GANTRY angles of 0°, 90°, 180°, 270°, and an available overlap angle or for stationary or multiple-discrete angles GANTRIES at all available angles. For rotational GANTRIES with less than 360° rotation, values shall be reported for the minimum and maximum GANTRY angles and available GANTRY angles of 0°, 90°, 180°, and 270°.

If the working range of the indicating device is smaller than 500 mm beyond the ERP the RADIATION DETECTOR is placed at the extremes of the working range.

12.4 LIGHT FIELD-indicator

12.4.1 Information to USER

Some systems may incorporate a light source to indicate the area treated by the LIGHT ION RADIATION FIELD. For these systems, the ACCOMPANYING DOCUMENTATION shall contain the maximum position difference between the projected LIGHT FIELD edges and the LIGHT ION RADIATION FIELD edges.

12.4.2 Test

One exposure of a RADIATION DETECTOR is made for each set of test conditions. The maximum deviation between the LIGHT FIELD and the LIGHT ION RADIATION FIELD is determined by exposing the RADIATION DETECTOR oriented perpendicularly to the LIGHT ION REFERENCE AXIS at the ERP and the proximal and distal extremes of the working range of the LIGHT FIELD along the LIGHT ION REFERENCE AXIS.

NOTE If RADIOGRAPHIC FILM is used as the RADIATION DETECTOR, the indicated LIGHT FIELD can be marked with several pin pricks. If an EID is used, the pin pricks can be replaced with a radio-opaque marker aligned with the edges or corners of the indicated LIGHT FIELD.

The maximum deviation shall be provided for a SPECIFIED LIGHT ION species.

The proximal and distal extremes of the working range of the LIGHT FIELD indicator relative to the ERP shall be provided in the ACCOMPANYING DOCUMENTATION.

The maximum deviation shall be reported for GANTRY angles of 0°, 90°, 180°, 270°, and an available overlap angle or for stationary or multiple-discrete angles GANTRIES at all available angles. For rotational GANTRIES with less than 360° rotation, values shall be reported for the minimum and maximum GANTRY angles and available GANTRY angles of 0°, 90°, 180°, and 270°.

13 PATIENT SUPPORTS

13.1 General

PATIENT SUPPORTS may include permanently mounted TABLE TOPS or exchangeable TABLE TOPS or they may be of a dedicated chair type design.

Each PATIENT SUPPORT shall have a defined reference point that is described in the ACCOMPANYING DOCUMENTATION.

13.2 TABLE TOPS

13.2.1 General

13.2 and its subclauses do not apply to dedicated chair type PATIENT SUPPORTS.

13.2.2 Available TABLE TOPS

- a) If a PATIENT SUPPORT allows multiple TABLE TOPS, the ACCOMPANYING DOCUMENTATION shall list the available TABLE TOPS provided by the MANUFACTURER that can be accommodated by the PATIENT SUPPORT.

NOTE Example types of TABLE TOPS include: flat board, fork (single pillar on one end, double pillars on the other end), single pillar, double C-arm, water PHANTOM holder, whole body semi-circular pod, head and neck pod, chair, and halo adaptor.

- b) The ACCOMPANYING DOCUMENTATION shall state the approximate time (in minutes) to exchange each available TABLE TOP using the method described in the INSTRUCTIONS FOR USE.
- c) For GANTRIES that can, under conditions of NORMAL USE, project a LIGHT ION BEAM through a TABLE TOP, the ACCOMPANYING DOCUMENTATION shall state the area of each available TABLE TOP that can be placed at the ERP through which the LIGHT ION BEAM may pass unimpeded; e.g. lacking presence of metallic supports, sensors, or large gradients in thickness. For double C-arm and fork type TABLE TOPS, the length and width of the clear area shall be provided when the arms are at their most extended outward position.
- d) The ACCOMPANYING DOCUMENTATION shall state the maximum weight capacity (in kilograms) of each available TABLE TOP.
- e) For C-arm type TABLE TOPS, the ACCOMPANYING DOCUMENTATION shall state the maximum rotation angle of the C-arms in degrees.

13.2.3 Extent of movements of TABLE TOP relative to PATIENT SUPPORT

If the TABLE TOP moves relative to the PATIENT SUPPORT, the ACCOMPANYING DOCUMENTATION shall list the maximum extent of movements (translational and rotational) for each available movement of the TABLE TOP relative to the PATIENT SUPPORT.

13.2.4 Positional deviation of the TABLE TOP surface during longitudinal motion

13.2.4.1 Information to the USER

For each available TABLE TOP that moves longitudinally with respect to the PATIENT SUPPORT base, the ACCOMPANYING DOCUMENTATION shall contain:

- a) the maximum pitch angle of the TABLE TOP surface from the horizontal; and
- b) the maximum difference between the heights of the surface of the TABLE TOP next to the ISOCENTRE or ERP when the TABLE TOP is;
 - loaded with 30 kg distributed over a length of 1 m or, if the length of the TABLE TOP is less than 1 m, over the length of the TABLE TOP;
 - loaded with the MANUFACTURER SPECIFIED maximum load distributed over a length of 2 m or, if the length of the TABLE TOP is less than 2 m, over the length of the TABLE TOP;
 - acting through the ISOCENTRE or ERP.

The maximum difference shall be given in millimetres.

13.2.4.2 Test

See also Table 10.

The surface of the TABLE TOP is set approximately at the height of the ISOCENTRE or ERP.

The angular positions of the axes ⑤ and ⑥ (Figure 3) are set to zero.

The longitudinal displacement of the TABLE TOP, direction ⑪ (Figure 3), is set to the least extension which still includes the ERP. The TABLE TOP is then loaded with 30 kg distributed over the length of 1 m while the lateral displacement of the TABLE TOP is zero. Measure the height of the TABLE TOP surface immediately adjacent to the ISOCENTRE or ERP and measure the pitch angle of the surface.

Load the TABLE TOP with the MANUFACTURER SPECIFIED maximum load distributed over a length of 2 m acting through the ISOCENTRE or ERP. Then set the longitudinal displacement to its greatest extension re-measure the height of the TABLE TOP surface immediately adjacent to the ISOCENTRE or ERP and remeasure the pitch angle of the surface.

Calculate and report the maximum difference of the TABLE TOP heights and pitch angles.

If the LIGHT ION BEAM ME EQUIPMENT supports compensation for the TABLE TOP weight load, then the test may be performed using compensation for each test weight.

Table 10 – Conditions for testing positional and pitch deviation of the TABLE TOP surface during longitudinal motion relative to the PATIENT SUPPORT base

Angular position of		Height of TABLE TOP	Weight of Load	Longitudinal displacement of the TABLE TOP
ISOCENTRIC rotation of PATIENT SUPPORT	Rotation of TABLE TOP			
Axis ⑤ ^a	Axis ⑥ ^a	Direction ⑧ ^a		Direction ⑪ ^a
0°	0°	Coincident with the ISOCENTRE or ERP	30 kg	Least extension containing the ISOCENTRE or ERP
		Coincident with the ISOCENTRE or ERP	MANUFACTURER SPECIFIED maximum load	Greatest extension

^a See Figure 3.

13.2.5 Positional deviation of the TABLE TOP surface during lateral motion

13.2.5.1 Information to the USER

For each available TABLE TOP that moves laterally with respect to the PATIENT SUPPORT base, the ACCOMPANYING DOCUMENTATION shall contain:

- the maximum roll angle of the TABLE TOP surface from the horizontal; and
- the maximum difference between the heights of the surface of the TABLE TOP next to the ISOCENTRE or ERP and when the TABLE TOP is laterally displaced, direction ⑩ (Figure 3).

The maximum angle shall be given in degrees and the maximum variation of the height shall be given in millimetres.

The values shall apply over the full range of height of the PATIENT SUPPORT, Direction ⑨ (Figure 3), when the TABLE TOP is loaded with the MANUFACTURER SPECIFIED maximum load distributed over 2 m of the length of the TABLE TOP or, if the length of the TABLE TOP is less than 2 m, over the length of the TABLE TOP.

13.2.5.2 Test

The longitudinal displacement of the TABLE TOP, direction ⑪ (Figure 3), is set to the greatest extension and the TABLE TOP is loaded with the MANUFACTURER SPECIFIED maximum load distributed over a length of 2 m acting through the ISOCENTRE or ERP while the lateral displacement of the TABLE TOP is zero.

The TABLE TOP is put into the positions according to the set of test conditions in Table 11.

In each of these positions

- the angle of roll of the TABLE TOP next to the ISOCENTRE or ERP is measured with a clinometer and reported;
- the deviation of the height of the longitudinal midline of the TABLE TOP is measured and reported.

If the LIGHT ION BEAM ME EQUIPMENT supports compensation for the TABLE TOP weight load, then the test may be performed using compensation for each test weight.

Table 11 – Conditions for testing positional deviation of the TABLE TOP surface during lateral motion relative to PATIENT SUPPORT base

Angular position of		Height of TABLE TOP	Lateral displacement of the TABLE TOP
ISOCENTRIC rotation of PATIENT SUPPORT	Rotation of TABLE TOP		
Axis ⑤ ^a	Axis ⑥ ^a	Direction ⑧ ^a	Direction ⑩ ^a
0°	0°	Maximum	Max. to right
			Centred
			Max. to left
0°	0°	100 mm below ISOCENTRE OR ERP	Max. to right
			Centred
			Max. to left
^a See Figure 3.			

13.3 Coordinate system

The coordinate system and scales shall either comply with IEC 61217:2011 or if the equipment used is not IEC 61217:2011 compliant, the ACCOMPANYING DOCUMENTATION shall state the coordinate transformation to IEC 61217:2011 coordinates.

13.4 Extent of movements for PATIENT SUPPORT

13.4.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall list the maximum extent of movements for each available translational and rotational movement of the PATIENT SUPPORT.

NOTE These movements can include: longitudinal, lateral, vertical, yaw, pitch, roll, ISOCENTRIC, eccentric, etc.

For PATIENT SUPPORTS with TABLE TOPS, the reported movements shall be given for the reference point on the TABLE TOP adaptor with respect to the IEC fixed coordinate system. If there is only one TABLE TOP available for the PATIENT SUPPORT and it is not removable, then the reference point shall be located at the top surface of the TABLE TOP along the longitudinal midline.

For dedicated chair type PATIENT SUPPORTS, the reported movements shall be given for the reference point on the chair with respect to the IEC fixed coordinate system. The ACCOMPANYING DOCUMENTATION shall state the definition of the reference point.

13.4.2 ISOCENTRIC rotation of THE PATIENT SUPPORT

13.4.2.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the maximum displacement of the axis of ISOCENTRIC rotation of the PATIENT SUPPORT from the GANTRY ISOCENTRE when the TABLE TOP is loaded with 30 kg distributed over a length of 1 m and with the maximum MANUFACTURER SPECIFIED load distributed over a length of 2 m or, if the length of the TABLE TOP is less than 2 m, over the length of the TABLE TOP.

The maximum displacement shall be given in millimetres.

NOTE A PATIENT SUPPORT is considered an ISOCENTRIC PATIENT SUPPORT if it can be programmed such that a point on the TABLE TOP located at the GANTRY ISOCENTRE before a series of moves remains at the GANTRY ISOCENTRE point after the moves.

13.4.2.2 Test

A pointer is placed on the PATIENT SUPPORT at the previously determined ISOCENTRE location (6.8). The pointer is observed with two perpendicularly oriented optical theodolites, x-ray tubes and imagers, or equivalent devices. The PATIENT SUPPORT is rotated through its full range of angles around its axis of ISOCENTRIC or simulated ISOCENTRIC rotation. Triangulation between the two views is used to determine the displacement of the pointer at each intermediate angular position. The maximum deviation found for both clockwise and counter clockwise rotations is reported.

13.4.3 Accuracy of PATIENT SUPPORT translational motions

13.4.3.1 Information to the USER

The ACCOMPANYING DOCUMENTATION shall state the accuracy of moving a vector distance for a movement between two points. The points shall be at least 200 mm apart in each of the Xf, Yf, and Zf directions in the IEC fixed coordinate system or, if the maximum movement allowed is less than 200 mm, the maximum allowed movement.