

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



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

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



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IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –****Particular requirements for the basic safety  
and essential performance of LIGHT ION BEAM ME EQUIPMENT**

## FOREWORD

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

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

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

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

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## INTRODUCTION

The use of LIGHT ION BEAM ME EQUIPMENT for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose to the PATIENT, or if the ME EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIATION adequately or if there are inadequacies in the design of the TREATMENT ROOM.

This particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of LIGHT ION BEAM ME EQUIPMENT for use in RADIOTHERAPY; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such ME EQUIPMENT; it places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure that ESSENTIAL PERFORMANCE is maintained and to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It should be understood that, before installation, a MANUFACTURER can provide a compliance certificate relating only to TYPE TESTS. Data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

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

## MEDICAL ELECTRICAL EQUIPMENT –

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

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

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

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

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of LIGHT ION BEAM ME EQUIPMENT

- intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),
- that, in NORMAL USE, deliver a RADIATION BEAM of LIGHT IONS having ENERGY PER NUCLEON in the range 10 MeV/n to 500 MeV/n,

and

- intended to be
  - for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular SPECIFIED clinical purposes maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
  - subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises.

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

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

NOTE 4 IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

##### 201.1.2 Object

*Replacement:*

<sup>1</sup> The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LIGHT ION BEAM ME EQUIPMENT in the range 10 MeV/n to 500 MeV/n and to SPECIFY tests to check compliance to those requirements.

NOTE The adoption of this standard helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS;
- delivers the pre-selected RADIATION TYPE, ENERGY PER NUCLEON, LIGHT ION species, and ABSORBED DOSE;
- delivers pre-selected LIGHT ION BEAMS to the PATIENT, by utilizing LIGHT ION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

### 201.1.3 Collateral standards

*Addition:*

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-6 applies as modified in Clause 206. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-9<sup>2</sup> and IEC 60601-1-10<sup>3</sup> do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard or collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

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

<sup>3</sup> IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed loop controllers*

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

## 201.2 Normative references

Clause 2 of the general standard applies, except as follows:

### *Replacement:*

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*

### *Addition:*

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

IEC 60601-2-1:2009, *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 60601-2-11:2013, *Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*

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

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

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

NOTE Informative references are listed in the bibliography.

### 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-2-1: 2009, and IEC TR 60788:2004 apply, except as follows:

*Additional definitions:*

#### 201.3.201

##### **APPLICATOR CARRIAGE**

the most distal part of the RADIATION HEAD that can not 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.

#### 201.3.202

##### **BEAM FLUENCE DISTRIBUTION MONITOR**

system to monitor directly or indirectly the FLUENCE distribution of the beam to provide beam steering or lateral spreading information

Note 1 to entry: This monitor may be used as a surrogate monitor for the DOSE distribution delivered to the patient.

Note 2 to entry: Examples of BEAM FLUENCE DISTRIBUTION MONITORS include quadrant foil ionization chambers, concentric ring ionization chambers, multi-strip ionization chambers, scintillator plates, and scanning magnet field probes.

#### 201.3.203

##### **BEAM FLUX MONITOR**

system to monitor the FLUX of the beam

Note 1 to entry: This monitor may be used as a surrogate monitor for the DOSE rate delivered to the patient.

#### 201.3.204

##### **BEAM GATING**

allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

#### 201.3.205

##### **BEAM GATING SIGNAL**

signal generated for the purpose of BEAM GATING

EXAMPLE Examples include a respiratory spirometer, electrocardiogram, optical sensor, etc.

#### 201.3.206

##### **CONTROLLING TIMER**

device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, to TERMINATE IRRADIATION

[SOURCE: IEC 60601-2-1: 2009, 201.3.202]

#### 201.3.207

##### **DOSE MONITOR UNIT**

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

#### 201.3.208

##### **DOSE MONITOR UNIT RATE**

DOSE MONITOR UNIT per unit time

### **201.3.209**

#### **DOSE MONITOR UNIT RATE MONITORING SYSTEM**

system of devices for the measurement and DISPLAY of a radiation quantity related to DOSE MONITOR UNIT RATE

### **201.3.210**

#### **DOSE MONITORING SYSTEM**

system of devices for the measurement and DISPLAY of a radiation quantity related to the ABSORBED DOSE

### **201.3.211**

#### **ENERGY PER NUCLEON**

the 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

### **201.3.212**

#### **EQUIPMENT REFERENCE POINT**

##### **ERP**

point in space used for referencing dimensions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the reference point is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment systems 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.

### **201.3.213**

#### **FLUENCE**

particles per unit area

Note 1 to entry: See ICRU 33, ICRU 85a.

### **201.3.214**

#### **FLUX**

particles per unit time

Note 1 to entry: See ICRU 33, ICRU 85a.

### **201.3.215**

#### **HARD-WIRED**

term used where the features of a system can be modified only by physically removing and re-routing wires

[SOURCE: IEC 60601-2-1: 2009, 201.3.208]

### **201.3.216**

#### **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]

### **201.3.217**

#### **LATERAL SPREADING DEVICE**

##### **LSD**

device used to increase the lateral ( $x_b$ ,  $y_b$ ) 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.

Note 1 to entry:  $X_b$  and  $y_b$  are defined in IEC 61217:2011.

### **201.3.218**

#### **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

### **201.3.219**

#### **LIGHT ION BEAM**

collection of LIGHT IONS travelling in the same general direction

### **201.3.220**

#### **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 BEAM APPLICATORS may be available to reduce the weight of apertures lifted by therapists, decrease the aperture/bolus to skin distance and reduce leakage radiation.

### **201.3.221**

#### **LIGHT ION BEAM DISTRIBUTION SYSTEM**

system of components and a control system used to transport the RADIATION from a RADIATION SOURCE to several TREATMENT stations, experimental stations or beam dumps

EXAMPLE Examples of components include vacuum pipes, magnets, and steering coils.

### **201.3.222**

#### **LIGHT ION RANGE**

the depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is a SPECIFIED value, given in the ACCOMPANYING DOCUMENTS, of the dose at the nominal centre-of-modulation depth or of the dose maximum for a non-range-modulated beam, which is measured on the RADIATION BEAM 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

### **201.3.223**

#### **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 is different at different lateral locations

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

### **201.3.224**

#### **NON-PRIMARY RADIATION**

RADIATION emitted from the LIGHT ION BEAM ME EQUIPMENT that is not intended to treat the PATIENT

### **201.3.225**

#### **NORMAL USE**

operation, including routine inspection and adjustments by the OPERATOR, and STAND-BY, according to the instructions for use

Note 1 to entry: NORMAL USE includes PATIENT TREATMENT, equipment calibration, quality assurance procedures, maintenance, and other procedures performed by the OPERATOR required in preparation for PATIENT TREATMENTS.

[SOURCE: IEC TR 60788:2004, NG, 10.08, modified – A note to entry has been added.]

### **201.3.226**

#### **OPERATOR**

person utilizing an EQUIPMENT individually with or without the aid of an assistant, who controls some or all functions of the EQUIPMENT in his presence

[SOURCE: IEC TR 60788:2004, rm-85-02]

### **201.3.227**

#### **PATIENT SUPPORT**

<RADIOTHERAPY> assembly of ME EQUIPMENT that supports the PATIENT

[SOURCE: IEC TR 60601-2-1:2009, 201.3.215]

### **201.3.228**

#### **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 treatment beam IRRADIATION, motion of devices, or imaging.

### **201.3.229**

#### **PRE-PROGRAMMED MOVEMENTS**

movement of ME EQUIPMENT parts that takes place according to a previously planned programme without intervention by the OPERATOR during a PATIENT treatment or imaging

### **201.3.230**

#### **PRIMARY/SECONDARY DOSE MONITORING COMBINATION**

utilization of two DOSE MONITORING SYSTEMS where one is arranged to be the PRIMARY and the other the SECONDARY DOSE MONITORING SYSTEM

### **201.3.231**

#### **PROGRAMMABLE RANGE MODULATED PORTAL**

##### **PRMP**

a LIGHT ION PORTAL in which a RANGE MODULATION DEVICE or program is used 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 (tumour) resides.

Note 2 to entry: The corresponding note to entry in the French text indicates that the abbreviation "PRMP" stands for "PROGRAMMABLE RANGE MODULATED PORTAL" in English.

### **201.3.232**

#### **RADIATION HEAD**

structure from which the RADIATION BEAM emerges

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

### **201.3.233**

#### **RANGE MODULATION DEVICE**

##### **RMD**

device used to modulate the penetration of a 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.

Note 2 to entry: The corresponding note to entry in the French text indicates that the abbreviation "RMD" stands for "RANGE MODULATION DEVICE" in English.

**201.3.234****RANGE SHIFTER**

range modifying device that has a constant thickness at all positions lateral to the central axis of the beam

**201.3.235****REDUNDANT DOSE MONITORING COMBINATION**

utilization of two DOSE MONITORING SYSTEMS where both systems are arranged to TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

**201.3.236****SCANNING MODE**

method of delivering a scanned beam to generate a laterally broad field

Note 1 to entry: Types of SCANNING MODES include: UNIFORM SCANNING and MODULATED SCANNING.

**201.3.237****SITE TEST**

after installation, test of an individual device or ME EQUIPMENT to establish compliance with SPECIFIED criteria

Note 1 to entry: It is understood that SITE TESTS shall be performed but may or may not be performed by the MANUFACTURER, per the agreement between the MANUFACTURER and the end USER.

[SOURCE: IEC 60601-2-1:2009, 201.3.221, modified – The note to entry has been added.]

**201.3.238****TABLE TOP**

an exchangeable device attached to the patient positioner to which registration and immobilization devices are attached and upon which the patient is placed.

**201.3.239****TECHNICAL DOCUMENTATION**

documentation that enables the conformity of the product with the requirements of the standard(s) to be assessed

Note 1 to entry: This may include schedule drawings when a certification body is involved.

Note 2 to entry: It covers the design, manufacture and operation of the product and may contain:

- a general description;
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of drawings and layouts and the operation of the product;
- a list of the standards referred to in the Ex certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the standards;
- results of design calculations made, examinations carried out, etc.;
- test reports

Note 3 to entry: The technical description includes information derived from the TECHNICAL DOCUMENTATION.

[SOURCE: ISO/IEC 80079-34:2011, 3.12, modified – A third note to entry has been added.]

**201.3.240****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: Examples of events that may TERMINATE IRRADIATION and stop movements include:

- 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, or
- in MODULATED SCANNING, when pre-programmed scanning pattern is completed

[SOURCE: IEC 60601-2-11:2013, 201.3.225, modified – The wording of both the definition and the note to entry is slightly different.]

#### **201.3.241**

##### **TRANSMISSION DETECTOR**

RADIATION DETECTOR through which the LIGHT ION BEAM passes

[SOURCE: IEC 60601-2-1:2009, 201.3.226, modified – The term "RADIATION BEAM" has been replaced by "LIGHT ION BEAM".]

#### **201.3.242**

##### **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 standard

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

#### **201.3.243**

##### **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 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 beam passes or permanent magnets mechanically rotated or translated.

#### **201.3.244**

##### **USER**

when used in an IEC standard on eletromedical EQUIPMENT, organization or individual responsible for the use and maintenance of the EQUIPMENT

[SOURCE: IEC TR 60788:2004, rm-85-01]

### **201.4 General requirements**

Clause 4 of the general standard applies.

### **201.5 General requirements for testing of ME EQUIPMENT**

Clause 5 of the general standard applies except as follows:

#### **201.5.1 TYPE TESTS**

*Replacement of the title:*

#### **201.5.1 TYPE TESTS and SITE TESTS**

*Additional subclause:*

### 201.5.1.101 Test grades

Three grades of TYPE TEST and two grades of SITE TEST procedures are SPECIFIED in this particular standard. Their requirements are as follows:

- *TYPE TEST grade A: An analysis of ME EQUIPMENT design, as related to the SPECIFIED RADIATION safety provisions, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled.*
- *TYPE TEST/SITE TEST grade B: Visual inspection or functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the procedure SPECIFIED in this particular standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the ME EQUIPMENT.*
- *TYPE TEST/SITE TEST grade C: Functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this particular standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with circuitry or the construction of the ME EQUIPMENT, the test should be performed by, or under the direct supervision of, the MANUFACTURER or his agent.*

It is understood that SITE TESTS shall be performed but may or may not be performed by the MANUFACTURER, per the agreement between the MANUFACTURER and end USER.

### 201.5.4 Other conditions

*Replacement:*

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTS any additional requirements for testing.

### 201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

#### 201.5.9.2.1 Test finger

*Addition:*

Where the nature of the installation renders parts inaccessible per the test with the standard test finger and they can only be made accessible by use of a TOOL, those parts will not be considered ACCESSIBLE PARTS. The ACCOMPANYING DOCUMENTS shall describe such situations.

### 201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

### 201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

#### 201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

##### 201.7.2.4 ACCESSORIES

*Addition:*

The maximum aperture opening supported by non-PATIENT SPECIFIC BEAM LIMITING DEVICES (BLD) shall be clearly legible on the outside of all interchangeable and non-adjustable BLDs and BEAM APPLICATORS.

Each manually interchangeable BLD, LIGHT ION BEAM APPLICATOR, RANGE MODULATION DEVICE (RMD), and RANGE SHIFTER shall be clearly marked so that the OPERATOR can establish its identity.

#### **201.7.2.20 Removable protective means**

*Addition:*

Where the requirements of this item are wholly or partly met by the nature of the installation, compliance at installation should be checked by inspection; the results should be included in the SITE TEST report.

#### **201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**

*Additional subclause:*

##### **201.7.3.101 RADIATION HEAD**

Removal of the covers of the RADIATION HEAD shall expose safety sign 10 of Table D.2 of the general standard, indicating "Follow instructions for use".

#### **201.7.4 Marking of controls and instruments**

*Additional subclause:*

##### **201.7.4.101 Provision of scales and indications for moving parts**

For any LIGHT ION BEAM ME EQUIPMENT parameter adjustable by the OPERATOR in the TREATMENT ROOM that has a range of motions that influences the delivery of a PATIENT-SPECIFIC treatment, the following shall be provided:

- a) a mechanical scale or a numerical indication for each available movement;
- b) means to align PATIENT with respect to the ERP (e.g. LIGHT FIELD, lasers etc.);

The designation, direction of increasing value and zero position of all movements shall comply with IEC 61217.

*Compliance is checked by inspection.*

#### **201.7.8 Indicator lights and controls**

##### **201.7.8.1 Colours of indicator lights**

*Replacement:*

Where indicators (lights or DISPLAYS) are used on the TREATMENT CONTROL PANEL (TCP) or other control panels, the colours of the indicators shall accord with the following:

|                                                                        |              |
|------------------------------------------------------------------------|--------------|
| RADIATION BEAM "on"                                                    | yellow       |
| READY STATE                                                            | green        |
| Urgent action required in response to an unintended state of operation | red          |
| PREPARATORY STATE                                                      | other colour |

NOTE In the TREATMENT ROOM or at other locations, these states may require urgent action or caution; different colours, such as given in Table 2 of IEC 60601-1 may be used.

**201.7.9 ACCOMPANYING DOCUMENTS**

*Addition:*

Data required in the technical description to support SITE TEST compliance in Clause 201.10 is given in Table 201.101.

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

| Compliance subclause | Statement regarding data from TYPE TESTS grade A | Details of, and results from, TYPE TESTS grade B | Details of, and results from, TYPE TESTS grade C | SPECIFIC procedures and test conditions for SITE TESTS grade B | SPECIFIC procedures and test conditions for SITE TESTS grade C |
|----------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
| 201.10.2.101.1.1     | b)                                               | a)                                               |                                                  | c)                                                             |                                                                |
| 201.10.2.101.1.2     | c)                                               | a) b)                                            |                                                  | a) b)                                                          | c)                                                             |
| 201.10.2.101.1.3     | b) c)                                            | a) e)                                            | c)                                               | d)                                                             | a) b)                                                          |
| 201.10.2.101.1.4     | a) b) c)                                         | a)                                               | c)                                               |                                                                | b)                                                             |
| 201.10.2.101.1.5     | †                                                |                                                  |                                                  |                                                                | †                                                              |
| 201.10.2.101.1.6     |                                                  | †                                                |                                                  |                                                                |                                                                |
| 201.10.2.101.2.1     | a) b)                                            |                                                  | d)                                               | a) c)                                                          |                                                                |
| 201.10.2.101.2.2     | a) e)                                            |                                                  | c)                                               | a) b) c) d) e)                                                 |                                                                |
| 201.10.2.101.2.3     | b)                                               |                                                  |                                                  | a) c) d)                                                       | b)                                                             |
| 201.10.2.101.2.4     | b) c)                                            | a)                                               |                                                  |                                                                | b)                                                             |
| 201.10.2.101.2.5     | a) b) c) d) e)                                   | d)                                               | a) b)                                            |                                                                | c)                                                             |
| 201.10.2.101.2.6     | a) b) c) d)                                      | a)                                               | d)                                               | b) c)                                                          |                                                                |
| 201.10.2.101.2.7     | c) d)                                            |                                                  | e)                                               | a) b)                                                          | d)                                                             |
| 201.10.2.101.2.8     | †                                                |                                                  |                                                  |                                                                |                                                                |
| 201.10.2.101.2.9     | c) e)                                            |                                                  | a)                                               |                                                                | b) d)                                                          |
| 201.10.2.101.2.10    | a) b) c) d) f)                                   | a) b) e)                                         |                                                  | d)                                                             |                                                                |
| 201.10.2.101.3.1.1   | †                                                |                                                  |                                                  |                                                                |                                                                |
| 201.10.2.101.3.1.2   | †                                                |                                                  |                                                  |                                                                |                                                                |
| 201.10.2.101.3.1.3   | b) d) e)                                         |                                                  | d)                                               |                                                                | a) b) c)                                                       |
| 201.10.2.101.3.1.4   | a) b)                                            | b)                                               | b)                                               |                                                                | b)                                                             |
| 201.10.2.101.3.1.5   | a) b)                                            | b)                                               | b)                                               |                                                                | b)                                                             |
| 201.10.2.101.3.1.6   | †                                                |                                                  |                                                  |                                                                | †                                                              |
| 201.10.2.101.3.1.7   | a) d) e)                                         |                                                  |                                                  |                                                                | b) c) d) e) f)                                                 |
| 201.10.2.101.3.1.8   | a) b) c) d)                                      |                                                  |                                                  |                                                                | b) c) d)                                                       |
| 201.10.2.101.3.1.9   | a) b) c)                                         | b)                                               |                                                  |                                                                | b)                                                             |
| 201.10.2.101.3.1.10  | a) b) c) d) e)                                   |                                                  |                                                  | b)                                                             | c) d) e)                                                       |
| 201.10.2.101.3.2     | c)                                               |                                                  |                                                  | a) b) c) d) e) f)                                              |                                                                |
| 201.10.2.101.3.3     | †                                                |                                                  |                                                  |                                                                |                                                                |
| 201.10.2.101.3.4     | a) c) d)                                         |                                                  |                                                  | a) b) c) d)                                                    |                                                                |
| 201.10.2.101.3.5     | a)                                               |                                                  |                                                  | a) b)                                                          | c)                                                             |
| 201.10.2.101.3.6     | a) b)                                            |                                                  |                                                  |                                                                | a) b)                                                          |
| 201.10.2.101.3.7     | c)                                               | c)                                               |                                                  | a) b)                                                          |                                                                |
| 201.10.2.101.4.2     | a) b) d)                                         | a) b)                                            |                                                  |                                                                |                                                                |

| Compliance subclause                                                             | Statement regarding data from TYPE TESTS grade A | Details of, and results from, TYPE TESTS grade B | Details of, and results from, TYPE TESTS grade C | SPECIFIC procedures and test conditions for SITE TESTS grade B | SPECIFIC procedures and test conditions for SITE TESTS grade C |
|----------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
| 201.10.2.101.4.3                                                                 | a) b) e)                                         | a)                                               |                                                  |                                                                |                                                                |
| 201.10.2.101.4.4                                                                 | a) b) c) d)                                      | a)                                               |                                                  |                                                                |                                                                |
| 201.10.2.101.4.5                                                                 | b)                                               | a)                                               |                                                  |                                                                |                                                                |
| 201.10.2.101.4.6                                                                 | †                                                |                                                  | †                                                |                                                                | †                                                              |
| 201.10.2.101.5.1                                                                 | a) b) c)                                         |                                                  |                                                  |                                                                |                                                                |
| 201.10.2.101.5.2                                                                 | b)                                               | a)                                               |                                                  |                                                                |                                                                |
| 201.10.2.101.5.3                                                                 |                                                  | †                                                |                                                  |                                                                |                                                                |
| NOTE † denotes requirement of subclause having no other SPECIFIC identification. |                                                  |                                                  |                                                  |                                                                |                                                                |

### 201.7.9.2.10 Messages

*Addition:*

All system messages, error messages, and fault messages intended for the OPERATOR responsible for the PATIENT required in the general standard and presented at the TREATMENT CONTROL PANEL (TCP) shall provide sufficient information to identify the reason for the message and possible actions for the OPERATOR to decide quickly the disposition of the PATIENT under treatment.

### 201.7.9.2.15 Environmental protection

*Addition:*

NOTE The USER's radiological protection adviser is, generally, the person responsible for the identification and disposal of material that may exhibit RADIOACTIVITY.

To assist the RESPONSIBLE ORGANIZATION's radiological protection adviser, the following data shall be provided by the MANUFACTURER:

- LIGHT ION species available under conditions of NORMAL USE.
- ENERGY PER NUCLEON and corresponding maximum ABSORBED DOSE RATES at the ERP under conditions of NORMAL USE for LIGHT ION RADIATION;
- dimensioned shape of the maximum RADIATION FIELD at the ISOCENTRE or ERP on an orthogonal plane with respect to the beam direction for LIGHT ION RADIATION;
- available directions of the RADIATION BEAM;
- a list of ME EQUIPMENT or ME EQUIPMENT parts that may exhibit RADIOACTIVITY.

## 201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

### 201.8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

*Addition:*

The requirements of this clause do not apply where the installation prevents the test with the test rod. The ACCOMPANYING DOCUMENTS shall state when these conditions apply.

### **201.8.11 MAINS PARTS, components and layout**

#### **201.8.11.1 Isolation from the SUPPLY MAINS**

*Replacement of item b):*

- b) Means for isolation, except for those circuits that have to remain connected for safety reasons, e.g. vacuum pumps, room lights and certain safety INTERLOCKS, shall be incorporated either in the ME EQUIPMENT or externally in as many locations as may be considered necessary. Where such means are to be wholly or partly met by installation, the requirements shall be included in the technical description.

### **201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**

Clause 9 of the general standard applies, except as follows:

#### **201.9.2 MECHANICAL HAZARDS associated with moving parts**

##### **201.9.2.1 General**

*Addition:*

NOTE 101 The phrase 'to set-up automatically' or 'automatic set-up' is used to denote the moving of ME EQUIPMENT parts to a pre-programmed position required for the start of a PATIENT treatment or imaging.

##### **201.9.2.4 Emergency stopping devices**

*Additional subclause:*

###### **201.9.2.4.101 Motion emergency stop**

- a) Readily identifiable and accessible means for stopping all movements within the limits given in 201.9.2.101 a) 4) or established according to 201.9.2.101 a) 5) shall be provided in HARD-WIRED circuits or have a switching function with an equivalent level of safety. These means shall be near to, or on the PATIENT SUPPORT system and the TCP. The means provided near to, or on, the TCP shall also INTERRUPT IRRADIATION. When any of the means are to be incorporated on site by the RESPONSIBLE ORGANIZATION, the requirements and SITE TEST procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTS, the results should be incorporated in the SITE TEST report.
- b) If a PESS is involved, then the switching function technology must be shown to provide an equivalent level of safety through RISK MANAGEMENT.

*Compliance is checked as follows:*

- a) *TYPE TEST grade A – Checking by inspection of the ACCOMPANYING DOCUMENTS.*
- a) *TYPE TEST grade C – Measurement of stopping distances and disconnection times using suitable measuring instruments; in order to eliminate the effects of variable personal reaction times, measurements shall start at the instant the manually actuated switch contacts open or close. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance.*
- b) *TYPE TEST grade A – If a PESS is involved, verification that an analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*

*Additional subclauses:*

###### **201.9.2.101 GANTRY, RADIATION HEAD and PATIENT SUPPORT system**

- a) General

NOTE A 'failure of powered movements' is to be interpreted as the failure only of the SUPPLY MAINS associated with the powered movements.

- 1) When the RADIATION HEAD or any other part is provided with a control designed to reduce, in NORMAL USE, the risk of collision, including with the PATIENT, the operation and limitations of each control shall be described in the INSTRUCTIONS FOR USE.
- 2) When the RADIATION HEAD or any other part (including ACCESSORY items) is not designed with a control to reduce, in NORMAL USE, the risk of collisions, the collision risks shall be stated in the ACCOMPANYING DOCUMENTS.
- 3) For automatic set-up and for the checks of pre-programmed movements before treatment, the overshoot shall not exceed 2° for rotational displacements and 5 mm for linear displacements.
- 4) For an emergency interruption or failure of powered movements or of the SUPPLY MAINS for the ME EQUIPMENT, any parts in motion shall not exceed 5° for rotational displacements and 10 mm for linear displacements.
- 5) As an alternative to 3) - 4), additional means shall be provided for avoiding collisions and the ACCOMPANYING DOCUMENTS shall include a statement to evoke cautions if the angles or distances required for stopping movement exceed the SPECIFIED values. The MANUFACTURER must demonstrate through RISK MANAGEMENT that the angles and distances achieved do not pose an unacceptable risk to the equipment, PATIENT, or OPERATOR.
- 6) Where the possibility exists that failure of a powered movement during NORMAL USE might result in the PATIENT becoming trapped, means shall be provided to permit release of the PATIENT; these means shall be described in the INSTRUCTIONS FOR USE.
- 7) Equipment contained within the RADIATION HEAD and behind protective covers where collisions are not possible are exempt from the speed limits in sections b) and c).
- 8) For the PATIENT SUPPORT system, these requirements shall apply when the system is unloaded and when it is loaded with a distributed mass of the maximum load of the PATIENT SUPPORT system as SPECIFIED by the MANUFACTURER.

b) Rotational movements

- 1) The minimum speed available for each movement shall not exceed  $1^\circ \cdot s^{-1}$ .
- 2) No speed shall exceed  $7^\circ \cdot s^{-1}$  unless pre-programmed and identified as an acceptable risk through the MANUFACTURER'S RISK MANAGEMENT.
- 3) When rotating at the speed nearest to, but not exceeding,  $1^\circ \cdot s^{-1}$ , the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 0,5°, for speeds faster than  $1^\circ \cdot s^{-1}$ , it shall not exceed 3° unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable risk to the equipment, PATIENT, or OPERATOR.

Exception – Requirement 2) above does not apply to the BEAM LIMITING SYSTEM (BLS).

c) Linear movements

- 1) The minimum speed available for displacements 20, 21, 22 and 23 as SPECIFIED in IEC 61217, Figure 13c of the RADIATION FIELD edges, and displacements 9, 10 and 11 as SPECIFIED in Figure 201.101 of the PATIENT SUPPORT system shall not exceed  $10 \text{ mm} \cdot s^{-1}$ .
- 2) No speed shall exceed  $100 \text{ mm} \cdot s^{-1}$  unless pre-programmed and identified as an acceptable risk through the MANUFACTURER'S RISK MANAGEMENT.
- 3) The distance between the position of the moving part, at the instant of operating any control to stop the movement, and its final position shall not exceed 10 mm for any speed greater than  $25 \text{ mm} \cdot s^{-1}$ , and 3 mm for speeds not exceeding  $25 \text{ mm} \cdot s^{-1}$  unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable risk to the equipment, PATIENT, or OPERATOR.

Exception – Requirements 1) and 2) above do not apply to the BEAM LIMITING SYSTEM (BLS).

*Compliance is checked as follows:*

- a) 1) TYPE TEST grade A - Review that the INSTRUCTIONS FOR USE contain descriptions of the operation and limitations of each implemented control;

- a) 2) TYPE TEST grade A - Review that the INSTRUCTIONS FOR USE contain descriptions of the collision risks;
- a) 3), 4) and 8) TYPE TEST grade B - Verify by inspection and measurement that the limits are not exceeded;
- a) 5 TYPE TEST grade B - Verification that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.
- a) 6) TYPE TEST grade A - Review that the INSTRUCTIONS FOR USE contain descriptions of the means to be provided to permit release of the PATIENT;
- b) 1) TYPE TEST GRADE B – Verify by inspection and measurement that the limits are not exceeded.
- b) 2) and 3) TYPE TEST grade B - Verification that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.
- c) 1) TYPE TEST GRADE B – Verify by inspection and measurement that the limits are not exceeded.
- c) 2) and 3) TYPE TEST grade B - Verification that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.

#### **201.9.2.102      Operation of movements of ME EQUIPMENT parts from inside the TREATMENT ROOM**

- a) It shall not be possible to operate motorized movements of ME EQUIPMENT parts which may cause physical injury to the PATIENT, without continuous personal action by the OPERATOR on two switches simultaneously. Each switch, when released, shall be capable of interrupting movement; one switch may be common to all movements.
- b) For ME EQUIPMENT intended to be set-up automatically, it shall not be possible to initiate or maintain movements associated with this condition without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements.
- c) The switches required in a) and b) above shall be operable sufficiently close to the PATIENT SUPPORT system, so that, by careful observation, the OPERATOR can avoid possible injury to the PATIENT. At least one of the switches required in a) and b) shall be HARD-WIRED or have a switching function with an equivalent level of safety.
- d) The INSTRUCTIONS FOR USE shall contain advice that, when either an intended remotely controlled movement from the TCP or a pre-programmed movement is included in the treatment prescription, with the PATIENT positioned, a check of all intended or planned movements should be made by the OPERATOR.

*Compliance is checked as follows:*

- a) TYPE TEST grade B – Test that motorized movements of ME EQUIPMENT parts cannot be operated without continuous personal action by the OPERATOR on two switches simultaneously. Each switch, when released, shall be capable of interrupting movement; one switch may be common to all movements.
- b) TYPE TEST grade B – Test that for ME EQUIPMENT intended to be set up automatically, it shall not be possible to initiate or maintain movements associated with this condition without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements.
- c) TYPE TEST grade A – Demonstrate through analysis that the switches shall be operable sufficiently close to the PATIENT SUPPORT system and that one of the switches is HARD-WIRED or has a switching function with an equivalent level of safety.
- d) TYPE TEST grade A – Review that the INSTRUCTIONS FOR USE contain advice that a check of all intended or planned movements should be made by the OPERATOR before leaving the TREATMENT ROOM.

### **201.9.2.103      Operation of movements of ME EQUIPMENT parts from outside the TREATMENT ROOM**

- a) It shall be impossible to initiate or maintain movements associated with automatic set-up without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements. Each switch, when released, shall be capable of stopping movement; at least one of the switches shall be HARD-WIRED or have a switching function with an equivalent level of safety.
- b) After ME EQUIPMENT parts have been set up automatically or pre-programmed, it shall be impossible for the OPERATOR to adjust any movement parameter before the pre-programmed TREATMENT has been completed, without causing TERMINATION OF IRRADIATION unless that movement is restricted to motion of the PATIENT SUPPORT to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system. In that case, movement may cause INTERRUPTION OF IRRADIATION.
- c) For ME EQUIPMENT that has not been pre-programmed, it shall be impossible for the OPERATOR to adjust any movement parameter during IRRADIATION without causing TERMINATION OF IRRADIATION unless that movement is restricted to motion of the PATIENT SUPPORT to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system. In that case, movement may cause INTERRUPTION OF IRRADIATION.
- d) For ME EQUIPMENT that has not been pre-programmed, it shall be possible to adjust movement parameters before IRRADIATION, or after TERMINATION OF IRRADIATION, but only when there is continuous personal action by the OPERATOR on two switches simultaneously. Each switch, when released, shall be capable of stopping movement; one switch shall be HARD-WIRED or have a switching function with an equivalent level of safety and common to all movements. If the movement is restricted to motion of the PATIENT SUPPORT to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system, then in that case, movement may be possible during INTERRUPTION OF IRRADIATION.
- e) The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR should have an unobstructed view of the PATIENT before and during IRRADIATION.
- f) Any INTERRUPTION OF IRRADIATION or TERMINATION OF IRRADIATION, shall cause all ME EQUIPMENT parts in motion within the TREATMENT ROOM to be stopped within the limits given in 201.9.2.101.

*Compliance is checked as follows:*

*TYPE TEST grade C for a), b), c), d) and for f) with respect to the tolerances required in 201.9.2.101.*

*TYPE TEST grade A for e) Review the INSTRUCTIONS FOR USE.*

### **201.9.2.104      Operation of ME EQUIPMENT parts from outside the facility**

The ME equipment may be provided with the capability for electronic access (e.g. via the Internet) to the control system for the purpose of diagnostic evaluation of the equipment. Such evaluation may necessitate operation of equipment capabilities. For example, the TCP may be controlled by a remote site for such purposes. When functions and controls are accessed remotely from outside the facility:

- a) a means shall be provided at the TCP to enable control by a remote OPERATOR;
- b) the equipment shall require an action at the TCP at the time a connection is established and before any functions or movements are controlled remotely;
- c) the TCP shall indicate whenever a remote connection is established; and
- d) any movements shall comply with the provisions of subclause 201.9.2.101.

In addition, it shall be impossible, through remote access, to:

- e) violate or override of any of the provisions of subclauses 201.9.2.102 and 201.9.2.103;  
or
- f) allow the remote OPERATOR to bypass INTERLOCKS that could result in injury to any person;  
or
- g) allow the remote OPERATOR to turn on any RADIATION SOURCES.

*Compliance is checked by the following:*

- a) TYPE TEST Grade A - Inspection of ACCOMPANYING DOCUMENTS.
- b) SITE TEST Grade B - Attempt to connect from a remote site without first providing action at the TCP and verify that control cannot be established.
- c) SITE TEST Grade B - Demonstrate that the display indicates remote operation under remote control.
- d) TYPE TEST Grade A - Inspection of ACCOMPANYING DOCUMENTS
- e), f), and g) SITE TEST Grade B - demonstrate function of remote diagnostic capability

### **201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure**

*Additional subclause:*

#### **201.9.7.101 Change of pressure**

If a hazardous situation can arise from a change in the pressure of a system used to provide power for movements, all movement shall stop from any speed within the limits SPECIFIED in 201.9.2.101.

*Compliance is checked by the following:*

*TYPE TEST grade C – Test by simulation of a fault condition, operation of protective devices and measurement of stopping distances.*

### **201.9.8 MECHANICAL HAZARDS associated with support systems**

*Additional subclause:*

#### **201.9.8.101 Attachment of MANUFACTURER supplied ACCESSORIES**

- a) Where means are provided to permit the attachment of ACCESSORIES supplied by the MANUFACTURER, in particular those for shaping the RADIATION BEAM or influencing the ABSORBED DOSE distribution, such means shall be designed to retain those ACCESSORIES securely under all conditions of NORMAL USE.

*Compliance is checked by inspection, and by consideration of design data and applied safety factors.*

- b) The ACCOMPANYING DOCUMENTS shall contain maintenance requirements, and define the conditions and limits of use for the ACCESSORIES supplied; they should include guidance regarding design limits for other ACCESSORIES manufactured or commissioned by the RESPONSIBLE ORGANIZATION.

*Compliance is checked by the following:*

*TYPE TEST grade A – Analysis that demonstrates that the means provided to retain the ACCESSORIES functions under all conditions of NORMAL USE and that the risk of hurting a patient with a falling ACCESSORY is correctly mitigated.*

*SITE TEST grade C – Demonstrate that the mitigations identified in TYPE TEST grade A are correctly implemented.*

*Additional subclause:*

#### **201.9.101      Relative movement between immobilisation devices and PATIENT SUPPORT system**

The MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS requirements for the interface of immobilisation devices (e.g. head-frame) and the PATIENT SUPPORT system. The MANUFACTURER of the LIGHT ION BEAM ME EQUIPMENT shall state in the ACCOMPANYING DOCUMENTS that the RESPONSIBLE ORGANIZATION that integrates the immobilisation devices should perform an analysis of potential collisions and other hazards associated with their use.

*Compliance is checked by the following:*

*TYPE TEST grade A – Verify that the ACCOMPANYING DOCUMENTS contain the requirements for the interface of the immobilisation devices (e.g. head-frame) and the PATIENT SUPPORT system. Verify that the ACCOMPANYING DOCUMENTS contain that the manufacturer of the LIGHT ION BEAM ME EQUIPMENT states that the RESPONSIBLE ORGANIZATION that integrates the immobilisation devices should perform analysis of potential collisions and other hazards associated with their use.*

### **201.10 Protection against unwanted and excessive radiation HAZARDS**

Clause 10 of the general standard applies, except as follows:

#### **201.10.1      X-RADIATION**

##### **201.10.1.1      ME EQUIPMENT not intended to produce diagnostic or therapeutic X-RADIATION**

*Replacement (of title and text):*

##### **201.10.1.1      Adventitious IONIZING RADIATION**

For ME EQUIPMENT or ME EQUIPMENT parts not intended to produce IONIZING RADIATION for RADIOTHERAPY or for IMAGE GUIDED RADIOTHERAPY and which form part of LIGHT ION BEAM ME EQUIPMENT, IONIZING RADIATION caused by high voltages shall not produce an ambient dose equivalent,  $H^*(d)$ , exceeding 5  $\mu\text{Sv}$  in 1 h at a distance of 5 cm from any ACCESSIBLE SURFACE during normal operation.

*Compliance is checked as follows:*

*TYPE TEST grade B – Procedure: perform and record method, positions and results of measurements, averaged over an area not exceeding 10 cm<sup>2</sup>, in order to assess the dose due to small angle beams; use a RADIATION DETECTOR suitable for the ENERGY of the emitted RADIATION.*

*Controls and adjustments are set at the position resulting in the maximum emission of X-RADIATION. Single failures of components causing the least favourable situation are provoked in turn.*

##### **201.10.1.2      ME EQUIPMENT intended to produce diagnostic or therapeutic X-RADIATION**

Subclause 10.1.2 of the general standard does not apply.

#### **201.10.2      Alpha, beta, gamma, neutron, and other particle radiation**

*Addition:*

**201.10.2.101 ME EQUIPMENT intended to produce diagnostic or therapeutic light ions****201.10.2.101.1 Protection against incorrect RADIATION DISTRIBUTION****201.10.2.101.1.1 Selection, verification, and DISPLAY of RADIATION HEAD**

- a) LIGHT ION BEAM IRRADIATION shall only be enabled to the selected RADIATION HEAD after all relevant devices and parameters in the RADIATION HEAD have been verified.

NOTE Verification of relevant devices and parameters includes verifying that insertable devices that should not be in the RADIATION HEAD during LIGHT ION BEAM IRRADIATION (such as x-ray tubes and light sources) are not inserted.

- b) For ME EQUIPMENT capable of delivering multiple LIGHT ION species, means shall be provided to ensure that only the selected LIGHT ION species can be delivered to the selected RADIATION HEAD.
- c) the selected RADIATION HEAD shall be displayed at the TCP.

*Compliance is checked as follows:*

- a) *TYPE TEST grade B - For each type of relevant device and parameter of the LIGHT ION BEAM DISTRIBUTION SYSTEM and RADIATION HEAD, demonstrate that if the device or parameter is not correctly set, IRRADIATION is not enabled.*
- b) *TYPE TEST grade A – Verify that the ACCOMPANYING DOCUMENTS describe the means that are in place to prevent IRRADIATION if the relevant devices or parameters are not correctly set.*
- c) *SITE TEST grade B – Verify correct functioning of DISPLAYS for all possible selections.*

**201.10.2.101.1.2 Selection, verification, and DISPLAY of LIGHT ION species**

For ME EQUIPMENT capable of delivering multiple LIGHT ION species

- a) after TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of a LIGHT ION species has been made afresh at the TCP;
- b) the LIGHT ION species selected shall be displayed at the TCP before and during IRRADIATION;
- c) Means shall be provided to ensure that only the selected LIGHT ION species can be delivered to the PATIENT;

*Compliance is checked as follows:*

- a) *TYPE TEST grade B – At the end of an IRRADIATION, show that it is impossible to proceed with an IRRADIATION if the LIGHT ION species is not selected.*
- a) *SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selecting the LIGHT ION species.*
- b) *TYPE TEST grade B – Verify that the LIGHT ION species is displayed before and during IRRADIATION.*
- b) *SITE TEST grade B – Procedure: verify functioning of DISPLAYS for all possible selections.*
- c) *TYPE TEST grade A – Compliance is checked by the inspection of the RISK MANAGEMENT file.*
- c) *SITE TEST grade C – Demonstrate that the means described in the RISK MANAGEMENT file are correctly implemented.*

**201.10.2.101.1.3 Selection, verification, and DISPLAY of LIGHT ION RANGE or ENERGY PER NUCLEON**

- a) A means shall be provided to ensure that only the selected LIGHT ION RANGE or ENERGY PER NUCLEON is delivered during IRRADIATION such that the DEPTH DOSE differs by less than 10 % or 0,25 Gy, whichever is greater, from the intended DEPTH DOSE or 1 mm from the intended RANGE. If these conditions are not met, IRRADIATION shall be TERMINATED before an additional ABSORBED DOSE of 0,25 Gy is delivered.

NOTE Examples of the means include measurements of LIGHT ION energy in the accelerator, magnetic field or excitation current of bending magnets in the LIGHT ION BEAM DISTRIBUTION SYSTEM, etc.

- b) At least two independent systems shall prevent start of IRRADIATION if the set LIGHT ION RANGE or ENERGY PER NUCLEON of the LIGHT ION BEAM is not within the tolerance described in a).
- c) At least two independent systems and INTERLOCKS shall TERMINATE IRRADIATION if the LIGHT ION RANGE or ENERGY PER NUCLEON is not within the tolerance described in a).
- d) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of the LIGHT ION RANGE or ENERGY PER NUCLEON has been made afresh at the TCP.
- e) The TCP shall display before and during IRRADIATION the LIGHT ION RANGE or ENERGY PER NUCLEON selected and being delivered. For segmented treatments with multiple energies, an indication of the LIGHT ION RANGE or ENERGY PER NUCLEON shall be displayed during each segment.

*Compliance is checked as follows:*

- a) *b) SITE TEST grade C – Test each INTERLOCK individually. Operate the ME EQUIPMENT under simulated conditions at a SPECIFIED LIGHT ION RANGE or ENERGY PER NUCLEON in which the LIGHT ION RANGE or ENERGY PER NUCLEON is set to SPECIFIED incorrect values and verify that the INTERLOCK performs as intended.*
- a) *TYPE TEST grade B – Demonstrate through measurements or analysis that the system would TERMINATE IRRADIATION whenever a failure would lead to an incorrect selection of LIGHT ION RANGE or ENERGY PER NUCLEON causing an error of 10 %, 0,25 Gy, or 1 mm displacement in penetration depth in the intended ABSORBED DOSE. Demonstrate through measurement or analysis that TERMINATION of IRRADIATION would occur before an additional ABSORBED DOSE of 0,25 Gy is delivered.*
- b) *TYPE TEST grade A – Demonstrate through analysis that two independent systems prevent start of IRRADIATION if the ENERGY PER NUCLEON or LIGHT ION RANGE is not within tolerance.*
- c) *TYPE TEST grade A – Demonstrate through analysis that two independent systems terminate IRRADIATION if the ENERGY PER NUCLEON or delivered LIGHT ION RANGE is not within tolerance.*
- c) *TYPE TEST grade C – While delivering beam, verify that when the LIGHT ION RANGE or ENERGY PER NUCLEON exceeds the TOLERANCE, the IRRADIATION is TERMINATED.*
- d) *SITE TEST grade B – Verify that after TERMINATION of IRRADIATION, an IRRADIATION cannot be resumed until the LIGHT ION RANGE or ENERGY PER NUCLEON is selected afresh.*
- e) *TYPE TEST grade B – Procedure: verify functioning of DISPLAYS for SPECIFIED selections.*

#### **201.10.2.101.1.4 Selection, verification, and DISPLAY of GANTRY angle**

- a) The GANTRY angle shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION;
- b) Initiation of LIGHT ION BEAM IRRADIATION shall be prevented if the GANTRY position does not match the prescribed position within 0,5°.
- c) If the GANTRY position does not match the prescribed position within 0,5° during LIGHT ION BEAM IRRADIATION, then the IRRADIATION shall be INTERRUPTED.

*Compliance is checked as follows:*

- a) *b) c) TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- a) *TYPE TEST grade B – Test that the GANTRY angle is displayed at the TCP before and during LIGHT ION BEAM IRRADIATION.*
- b) *SITE TEST grade C – Test that the initiation of LIGHT ION BEAM IRRADIATION shall be prevented when the GANTRY position differs from the prescribed position by 0,5° or more.*
- c) *TYPE TEST grade C – Test that IRRADIATION is INTERRUPTED when the GANTRY position does not match the prescribed position within 0,5° during LIGHT ION BEAM IRRADIATION.*

**201.10.2.101.1.5 Obstruction monitoring**

An INTERLOCK shall prevent initiation of IRRADIATION if temporary devices that are part of the LIGHT ION BEAM ME EQUIPMENT that are partially transmissive to the beam and not prescribed for the PATIENT treatment are in the BEAM path and shall TERMINATE IRRADIATION when inserted into the BEAM path within the LIGHT ION BEAM DISTRIBUTION SYSTEM or RADIATION HEAD.

NOTE Examples of temporary devices include multi-wire or multi-strip ion chambers and scintillators inserted into the LIGHT ION BEAM DISTRIBUTION SYSTEM or RADIATION HEAD to tune the path of the beam between the accelerator and the RADIATION HEAD.

*Compliance is checked as follows:*

*TYPE TEST grade A – Statement regarding the means used to ensure compliance. Demonstrate through analysis that the interlock performs as intended.*

*SITE TEST grade C – Procedure: verify that the INTERLOCK is functioning properly.*

**201.10.2.101.1.6 DISPLAY of PATIENT SUPPORT coordinates**

If the PATIENT SUPPORT coordinates are a part of the IRRADIATION TREATMENT PRESCRIPTION, the PATIENT SUPPORT coordinates shall be displayed in the TREATMENT ROOM.

*Compliance is checked as follows:*

*TYPE TEST grade B – Verify that the PATIENT SUPPORT coordinates are displayed in the TREATMENT ROOM.*

**201.10.2.101.2 Protection against incorrect beam shaping****201.10.2.101.2.1 Selection and DISPLAY of LATERAL SPREADING DEVICES (LSD)**

For ME EQUIPMENT incorporating movable LATERAL SPREADING DEVICES:

- a) if a LATERAL SPREADING DEVICE can be selected by the USER
  - 1) initiation of IRRADIATION shall be prevented until a selection of the LSD(S) has been made at the TCP and
  - 2) the identity of the USER selectable LSD(S) in use is displayed at the TCP;
- b) two independent systems shall prevent or TERMINATE IRRADIATION if the selected LSD(S) is (are) not correctly positioned.
- c) any LSD which is removable by hand shall be clearly marked to establish its identity. Means shall be provided to prevent start of LIGHT ION BEAM IRRADIATION if the LSD which is removable by hand does not match the selected LSD.
- d) if an LSD is capable of applying more than one thickness of a scatterer or more than one scan pattern and is selectable by the USER;
  - 1) IRRADIATION shall be prevented until a selection of scatterer thickness or scan pattern has been made at the TCP, and
  - 2) the scatterer thickness or scan pattern in use is displayed at the TCP.

NOTE When applying the energy stacking technique, the LSD thickness or LSD scan pattern may be automatically loaded from the PATIENT prescription by the TCP for each energy layer.

*Compliance is checked as follows:*

- a) *TYPE TEST grade A – Statement regarding the means used to ensure compliance. Demonstrate through analysis that the INTERLOCK performs as intended.*
- a) *SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selecting LSD(s); verify functioning of DISPLAYS for SPECIFIED selections.*

- b) *TYPE TEST grade A – Demonstrate through analysis that IRRADIATION is prevented or TERMINATED if the combination of requested LSDs is not correct*
- c) *SITE TEST grade B – Procedure: visually inspect all LSDs for identity markings and compare them with the DISPLAYS in a) 2) above.*
- d) *TYPE TEST grade C – If the LSD(s) is(are) capable of providing multiple thicknesses or multiple scan patterns, verify that selection of the LSD thickness or scan pattern is required and that the SPECIFIED LSD thickness or scan pattern is displayed at the TCP.*

#### **201.10.2.101.2.2 Selection and DISPLAY of RANGE MODULATION DEVICES (RMD) and PROGRAMMABLE RANGE MODULATED PORTALS (PRMP)**

- a) If a RANGE MODULATION DEVICE can be selected by the USER:
  - 1) IRRADIATION shall be prevented until a selection of a RMD has been made at the TCP,
  - 2) the identity of the RMD(s) in use shall be displayed at the TCP;
- b) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until a SPECIFIC RMD, PRMP, or "no RMD" has been selected afresh at the TCP.
- c) When a PATIENT prescription specifies that multiple RMDs are to be used simultaneously, such as a "propellor" type RMD in combination with a "ripple filter" type RMD, all RMDs must be verified.
- d) ME EQUIPMENT supplied with a system of RMDs or PRMPs shall be provided with a DISPLAY at the TCP showing which RMD or PRMP (or "no RMD") is in use; each RMD shall be clearly marked to establish its identity (see 201.7.2.4)
- e) IRRADIATION shall be prevented or TERMINATED if the selected RMD(s) or PRMPs is(are) not correctly positioned. If two or more independent systems to monitor the position are not used, the MANUFACTURER shall demonstrate how a single monitoring system provides an acceptable level of safety through RISK MANAGEMENT.

*Compliance is checked as follows:*

- a) *TYPE TEST grade A – Demonstrate through analysis that IRRADIATION is prevented or TERMINATED if the requested RMD is not correct.*
- a) *SITE TEST grade B – Attempt to initiate IRRADIATION without selecting RMD(s). Verify functioning of DISPLAYS for SPECIFIED selections.*
- b), c) *SITE TEST grade B – Attempt to initiate IRRADIATION without selecting RMD(s).*
- c) *TYPE TEST grade C – For user selected RMD(s), verify that IRRADIATION is prevented if the RMD has not been selected and that the identity of the selected RMD is displayed at the TCP. When multiple RMDs are required, verify that all RMDs necessary are DISPLAYED. For systems with automatic RMD or PRMPs, verify that the selected combination is DISPLAYED at the TCP.*
- d) *SITE TEST grade B – Verify functioning of DISPLAYS for SPECIFIED selections. Visually inspect all RMDs for identity markings and compare them with the DISPLAYS. For RMD(s) selected by hand, verify that all possible RMD(s) are correctly identifiable.*
- e) *TYPE TEST grade A – If two or more independent systems to monitor the position are not used, verify that an analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*
- e) *SITE TEST grade B – Attempt to initiate IRRADIATION with the RMD(s) in an incorrect position for SPECIFIED RMD(s).*

#### **201.10.2.101.2.3 Selection and DISPLAY of RANGE SHIFTERS**

For ME EQUIPMENT incorporating RANGE SHIFTERS:

- a) if a RANGE SHIFTER can be selected by the USER
  - 1) IRRADIATION shall be prevented until a selection of the RANGE SHIFTER(s) has been made at the TCP,

- 2) the identity of the USER selectable RANGE SHIFTER(S) in use shall be displayed at the TCP;
- b) Initiation of IRRADIATION shall be prevented or IRRADIATION shall be TERMINATED if the selected RANGE SHIFTER(S) is(are) not correctly positioned. If two or more independent systems to monitor the position are not used, the MANUFACTURER shall demonstrate how a single monitoring system provides an acceptable level of safety through RISK MANAGEMENT.
- c) any RANGE SHIFTER which is removable by hand shall be clearly marked to establish its identity.
- d) if a RANGE SHIFTER device is capable of applying more than one thickness and is selectable by the USER;
  - 1) IRRADIATION shall be prevented until a new selection of RANGE SHIFTER(S) has been made at the TCP,
  - 2) the identity of the RANGE SHIFTER(S) and operating parameters in use shall be displayed at the TCP.

NOTE When applying the energy stacking technique, the RANGE SHIFTER thickness may be automatically loaded from the PATIENT prescription by the TCP for each energy layer.

*Compliance is checked as follows:*

- a) *SITE TEST grade B – Attempt to initiate IRRADIATION without selecting RANGE SHIFTER(S); verify functioning of DISPLAYS for SPECIFIED selections.*
- b) *TYPE TEST grade A – Demonstrate through analysis that IRRADIATION is prevented or terminated if the combination of requested RANGE SHIFTERS is not correct. If two independent systems to monitor the position are not used, verify that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*
- b) *SITE TEST grade C – Verify that the monitoring system(s) is functioning properly.*
- c) *SITE TEST grade B – Procedure: visually inspect all RANGE SHIFTERS for identity markings and compare them with the DISPLAYS in a) 2) above.*
- d) *SITE TEST grade B – For a multiple thickness RANGE SHIFTER, verify that a selection of the thickness is required and that the thickness is displayed at the TCP.*

#### **201.10.2.101.2.4 Selection and DISPLAY of APPLICATOR CARRIAGE position**

- a) the configured position of the APPLICATOR CARRIAGE shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION;
- b) IRRADIATION shall be prevented or TERMINATED if the APPLICATOR CARRIAGE is(are) not correctly positioned. If two or more independent systems to monitor the position are not used, the MANUFACTURER shall demonstrate how a single monitoring system provides an acceptable level of safety through RISK MANAGEMENT.
- c) For a) and b), the tolerance for agreement between the configured and intended positions shall be given in the ACCOMPANYING DOCUMENTS.

*Compliance is checked as follows:*

- a) *TYPE TEST grade B – Verify that the position of the APPLICATOR CARRIAGE is displayed before and during IRRADIATION.*
- b) *TYPE TEST grade A – Demonstrate through analysis that a verification of the APPLICATOR CARRIAGE position is performed during IRRADIATION and that the IRRADIATION would be TERMINATED in case it does not match the prescribed position. If two independent systems to monitor the position are not used, verify that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*
- b) *SITE TEST grade C – Verify that the IRRADIATION cannot be started if the position of the APPLICATOR CARRIAGE is not at the prescribed position*
- b) *SITE TEST grade C – Verify that the monitoring system(s) is functioning properly.*
- c) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*

#### **201.10.2.101.2.5 Verification and DISPLAY of multi-element BEAM LIMITING DEVICE shapes**

- a) If a multi-element BLD is used to provide configured shapes, the shape of the multi-element BLD shall be displayed before LIGHT ION BEAM IRRADIATION is initiated;
- b) For multi-segment PORTAL delivery using a multi-element BLD providing configured shapes, the DISPLAY of the configured shape shall be updated for each segment during IRRADIATION.
- c) Initiation of LIGHT ION BEAM IRRADIATION shall be prevented if the multi-element BLD configuration does not match the intended configuration.
- d) If the configuration of the multi-element BLD does not match the intended configuration during LIGHT ION BEAM IRRADIATION, then the IRRADIATION shall be TERMINATED.
- e) For a) through d), the tolerance for agreement between the actual configuration and intended configuration shall be given in the ACCOMPANYING DOCUMENTS.

*Compliance is checked as follows:*

- a) to d) *TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- a) b) *TYPE TEST grade C – Verify that the shape of the multi-element BLD is displayed before IRRADIATION or for segmented IRRADIATION, before each segment.*
- c) *SITE TEST grade C – Verify that IRRADIATION cannot be started if the configuration of the multi-element BLD is not correct.*
- d) *TYPE TEST grade B – Demonstrate through operation that a verification of the multi-element BLD configuration is performed during IRRADIATION that would TERMINATE the IRRADIATION in case of mismatch.*
- e) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*

#### **201.10.2.101.2.6 Selection, verification, and DISPLAY of LIGHT ION BEAM APPLICATOR**

- a) The USER installed LIGHT ION BEAM APPLICATOR shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION;
- b) Initiation of LIGHT ION BEAM IRRADIATION shall be prevented if the installed LIGHT ION BEAM APPLICATOR does not match the intended LIGHT ION BEAM APPLICATOR.
- c) Initiation of LIGHT ION BEAM IRRADIATION shall be prevented if the installed LIGHT ION BEAM APPLICATOR is not properly affixed.
- d) If the installed LIGHT ION BEAM APPLICATOR is not properly affixed during LIGHT ION BEAM IRRADIATION, then the IRRADIATION shall be terminated. If two or more independent systems to monitor correct installation are not used, the MANUFACTURER shall demonstrate how the single monitoring system provides an acceptable level of safety through RISK MANAGEMENT.

*Compliance is checked as follows:*

- a) to c) *TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- a) *TYPE TEST grade B – Verify that the LIGHT ION BEAM APPLICATOR is displayed before and during IRRADIATION.*
- b) *SITE TEST grade B – Verify that the IRRADIATION cannot be started if the installed LIGHT ION BEAM APPLICATOR does not match the intended LIGHT ION BEAM APPLICATOR.*
- c) *SITE TEST grade B – Demonstrate through operation that a verification of the LIGHT ION BEAM APPLICATOR position is performed before IRRADIATION and that the IRRADIATION cannot be started if the LIGHT ION BEAM APPLICATOR is not properly affixed.*
- d) *TYPE TEST grade A – If two or more independent systems to monitor the correct attachment of the applicator are not used, verify that an analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*

- d) *TYPE TEST grade C – Demonstrate through operation that a verification of the LIGHT ION BEAM APPLICATOR position is performed during IRRADIATION and that the IRRADIATION would be INTERRUPTED if the LIGHT ION BEAM APPLICATOR is not properly affixed.*

#### **201.10.2.101.2.7 Selection, verification, and DISPLAY of BEAM LIMITING DEVICE**

- a) The identity of the USER selected BEAM LIMITING DEVICE shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION.
- b) Means shall be provided to prevent initiation of IRRADIATION with a LIGHT ION BEAM if the installed BEAM LIMITING DEVICE does not match the selected BEAM LIMITING DEVICE.
- c) The INSTRUCTIONS FOR USE in the ACCOMPANYING DOCUMENTS shall warn the USER of the risk of incorrect selection of BEAM LIMITING DEVICES if the BEAM LIMITING DEVICES are not codified.
- d) If the installed USER selected BEAM LIMITING DEVICE, or its components, is incorrectly affixed, initiation of LIGHT ION BEAM IRRADIATION shall be prevented. For a BLD consisting of several components (e.g. layers), all components must be correctly installed before IRRADIATION with a LIGHT ION BEAM can be initiated. If two independent systems to monitor correct fixation are not used, the MANUFACTURER shall demonstrate how the single method provides an acceptable level of safety through RISK MANAGEMENT.
- e) If the installed USER selected BEAM LIMITING DEVICE (including multiple layers) becomes incorrectly affixed during LIGHT ION BEAM IRRADIATION, then IRRADIATION shall be TERMINATED.

NOTE This section does not apply to multi-element BLDs.

*Compliance is checked as follows:*

- a) *SITE TEST grade B – Verify that the USER selected BLD is displayed before and during IRRADIATION.*
- b) *SITE TEST grade B – Verify that the IRRADIATION cannot be started if the BLD is incorrectly affixed or is not the selected BLD.*
- c) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*
- d) *TYPE TEST grade A – If two independent systems to monitor the correct fixation are not used, verify that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*
- d) *SITE TEST grade C – Verify that the IRRADIATION cannot be started if the BLD is incorrectly affixed or is not the selected BLD.*
- e) *TYPE TEST grade C – Demonstrate that a verification of the BLD position is performed during IRRADIATION and that the IRRADIATION would be stopped in case the BLD becomes improperly affixed.*

#### **201.10.2.101.2.8 Manufacturing of PATIENT specific interchangeable BEAM LIMITING DEVICES**

The MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS information regarding requirements for compatibility of PATIENT SPECIFIC interchangeable BLDS.

*Compliance is checked as follows:*

*TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*

#### **201.10.2.101.2.9 Selection, verification, and DISPLAY of USER supplied ACCESSORIES**

- a) USER supplied and installed ACCESSORIES, if they affect the dose distribution, shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION.
- b) Means shall be provided to prevent initiation of LIGHT ION BEAM IRRADIATION if the installed ACCESSORIES do not match the ACCESSORIES selected at the TCP.

- c) The INSTRUCTIONS FOR USE in the ACCOMPANYING DOCUMENTS shall warn the USER of the risk of incorrect selection of ACCESSORIES if the ACCESSORIES are not codified.
- d) If the installed USER selected ACCESSORIES are incorrectly affixed, initiation of LIGHT ION IRRADIATION shall be prevented.
- e) If the installed USER selected ACCESSORIES were to become incorrectly affixed during LIGHT ION IRRADIATION, then the IRRADIATION shall be TERMINATED.

*Compliance is checked as follows:*

- a) *TYPE TEST grade C – Verify that the USER selected ACCESSORIES are displayed before and during IRRADIATION.*
- b) d) *SITE TEST grade C – Verify that the IRRADIATION cannot be initiated unless the USER installed ACCESSORIES are correctly affixed and are the selected ACCESSORIES.*
- c) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*
- e) *TYPE TEST grade A – Demonstrate through analysis that verification of each ACCESSORY position is performed during IRRADIATION and that the IRRADIATION would be stopped in case any ACCESSORY were to become improperly affixed.*

#### **201.10.2.101.2.10 Selection, verification, and DISPLAY of TABLE TOP**

If more than one type of TABLE TOP can be selected by the USER, or if the TABLE TOP can be removed by the USER and the beam passes through the TABLE TOP, the following requirements shall be satisfied;

- a) If TABLE TOPS are coded, the USER selected TABLE TOP type shall be displayed at the TCP before and during LIGHT ION BEAM IRRADIATION;
- b) If TABLE TOPS are coded, initiation of LIGHT ION BEAM IRRADIATION shall be prevented if the installed TABLE TOP type does not match the selected TABLE TOP type.
- c) If TABLE TOPS are not coded, these TABLE TOPS shall be easily identifiable by the OPERATOR and the INSTRUCTIONS FOR USE shall warn the USER about the risks of incorrect selection of these devices.
- d) If the installed TABLE TOP is incorrectly affixed, initiation of LIGHT ION BEAM IRRADIATION shall be prevented.
- e) If the installed TABLE TOP becomes incorrectly affixed during LIGHT ION BEAM IRRADIATION, then IRRADIATION shall be TERMINATED.
- f) As an alternative to d) and e), additional means shall be provided for ensuring that the TABLE TOP remains affixed. The MANUFACTURER must demonstrate an acceptable level of safety through RISK MANAGEMENT.

NOTE A TABLE TOP with a different water equivalent thickness would be considered a different TABLE TOP type.

*Compliance is checked as follows:*

- a) to d) *TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- a) *TYPE TEST grade B – Procedure: verify correct DISPLAY of USER installed selections.*
- b) *TYPE TEST grade B – Procedure: verify that LIGHT ION BEAM IRRADIATION cannot start with an incorrect TABLE TOP type installed.*
- c) *TYPE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTS.*
- d) *SITE TEST grade B – Procedure: verify that LIGHT ION BEAM IRRADIATION cannot start with a incorrectly affixed TABLE TOP.*
- e) *TYPE TEST grade B – Demonstrate through operation that IRRADIATION is terminated when the TABLE TOP becomes incorrectly affixed.*
- f) *TYPE TEST grade A – Verify that the analysis of the implemented mitigation(s) is included in the TECHNICAL DOCUMENTATION.*

**201.10.2.101.3 Protection against incorrect ABSORBED DOSE to TREATMENT volume****201.10.2.101.3.1 Monitoring and control of ABSORBED DOSE****201.10.2.101.3.1.1 General**

To maintain correct delivery of the ABSORBED DOSE distribution, the LIGHT ION FLUX and the LIGHT ION FLUENCE distribution in a plane perpendicular to the central axis of the LIGHT ION BEAM shall be monitored continuously throughout each treatment.

*Compliance is checked as follows:*

*TYPE TEST grade A – Demonstrate that the system includes monitoring of the FLUX and FLUENCE in a plane perpendicular to the central axis of the LIGHT ION BEAM.*

**201.10.2.101.3.1.2 Types of DOSE MONITORING SYSTEMS**

Two independent DOSE MONITORING SYSTEMS shall be provided.

*Compliance is checked as follows:*

*TYPE TEST grade A – Statement regarding the means used to ensure compliance.*

**201.10.2.101.3.1.3 DOSE MONITORING SYSTEMS**

The beam monitors SPECIFIED in 201.10.2.101.3.1.4 and 201.10.2.101.3.1.5 shall form part of two DOSE MONITORING SYSTEMS. A calibration procedure shall be used to convert the signals from these DOSE MONITORING SYSTEMS to values indicative of the ABSORBED DOSE delivered. The DOSE MONITORING SYSTEMS shall satisfy the following requirements:

- a) malfunctioning of one DOSE MONITORING SYSTEM shall not affect the correct functioning of the other;
- b) failure of any common element that could change the radiation response of either DOSE MONITORING SYSTEM by more than 5 % shall TERMINATE IRRADIATION;
- c) when separate power supplies are used, failure of either supply shall TERMINATE IRRADIATION and prevent further IRRADIATIONS;

NOTE Failure of a power supply includes failure to supply a voltage or current within the range necessary for correct functioning of the DOSE MONITORING SYSTEM as SPECIFIED in the ACCOMPANYING DOCUMENTS.

- d) the DOSE MONITORING SYSTEMS shall be arranged either as a REDUNDANT DOSE MONITORING COMBINATION or as a PRIMARY/SECONDARY DOSE MONITORING COMBINATION. In the case of a REDUNDANT DOSE MONITORING COMBINATION, both systems shall be capable of the performance stated in the technical description. In the case of a PRIMARY/SECONDARY DOSE MONITORING COMBINATION, at least the PRIMARY DOSE MONITORING SYSTEM shall be capable of the stated performance. Whichever combination is provided, its performance for ABSORBED DOSE RATES up to the SPECIFIED maximum shall be included in the technical description;
- e) if selected circuit parameters in the DOSE MONITORING SYSTEMS are changed automatically with changes of RADIATION TYPE or ENERGY, the changes in one DOSE MONITORING SYSTEM shall be independent of those in the other system.

*Compliance is checked as follows:*

- a) *SITE TEST grade C – Principle: Demonstrate that a malfunction of either of the two independent DOSE MONITORING SYSTEMS with generated or simulated malfunctions does not affect the other system.*
- b) *TYPE TEST grade A – Statement regarding which elements are common to both systems, and how failure of each of these elements will TERMINATE IRRADIATION.*

- b) *SITE TEST grade C – Principle: verification of the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION by simulation of failure of each common element.*
- c) *SITE TEST grade C – Principle: verification of the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION, by generation or simulation of power failure.*
- d) *TYPE TEST grade C – Principle: verification of the functioning of the DOSE MONITORING SYSTEMS at up to the maximum SPECIFIED ABSORBED DOSE RATES for the ME EQUIPMENT in which they are used; functioning may also be verified with the systems removed from the ME EQUIPMENT and tested by other means.*
- d) *TYPE TEST grade A – Statement regarding the performance of the chosen combination of DOSE MONITORING SYSTEMS.*
- e) *TYPE TEST grade A – Statement regarding the independence of systems with change of circuit parameters.*

#### **201.10.2.101.3.1.4 BEAM FLUX MONITORS (BFM)**

- a) At least two independent BEAM FLUX MONITORS shall be provided; at least one of these shall be a TRANSMISSION DETECTOR mounted on the PATIENT side of all LATERAL SPREADING DEVICES (LSDS).
- b) The BEAM FLUX MONITORS may be of fixed or movable type. Fixed BEAM FLUX MONITORS shall be moved or removed only by using tools. Movable BEAM FLUX MONITORS shall be INTERLOCKED to prevent IRRADIATION if they are incorrectly positioned; means shall be provided to ensure that operation of these INTERLOCKS for the BFMS are tested before initiation of each PORTAL or designed to an adequate safety level. The adequacy of the safety level shall be shown by RISK MANAGEMENT.

*Compliance is checked as follows:*

- a) *TYPE TEST grade A - Demonstrate that the two BFMS operate independently. Demonstrate that at least one of the BFDMS is located on the patient side of all LSDs and that it is a transmission type.*
- b) *TYPE TEST grade A – Statement regarding the operation of the INTERLOCKS and how to ensure that their operation is tested before each IRRADIATION.*
- b) *TYPE TEST grade C – Principle: verification that the displacement of each BEAM FLUX MONITOR, in turn, from the calibrated position, prevents IRRADIATION, with the BEAM FLUX MONITORS incorrectly positioned.*
- b) *SITE TEST grade C – Principle: verification of the functioning of the INTERLOCKS by generation or simulation of a condition to generate the INTERLOCK.*
- b) *TYPE TEST grade B – Demonstrate that means are in place to verify the operation of the movable BFMS before each IRRADIATION.*

#### **201.10.2.101.3.1.5 BEAM FLUENCE DISTRIBUTION MONITORS (BFDM)**

- a) At least two independent BEAM FLUENCE DISTRIBUTION MONITORS shall be provided; at least one of these shall be a TRANSMISSION DETECTOR located on the PATIENT side of all LATERAL SPREADING DEVICES (LSDS).
- b) The BEAM FLUENCE DISTRIBUTION MONITORS may be of fixed or movable type. Fixed BEAM FLUENCE DISTRIBUTION MONITORS shall be moved or removed only by using tools. Movable BEAM FLUENCE DISTRIBUTION MONITORS shall be INTERLOCKED to prevent IRRADIATION if they are incorrectly positioned; means shall be provided to ensure that operation of these INTERLOCKS for the BFDMS are tested before initiation of each PORTAL or designed to an adequate safety level. The adequacy of the safety level shall be shown by RISK MANAGEMENT.
- c) If a BEAM FLUENCE DISTRIBUTION MONITOR serves also as a BEAM FLUX MONITOR, it shall also fulfill all requirements of 201.10.2.101.3.1.4.

NOTE One of the BFDMS may employ indirect monitoring of the beam FLUENCE distribution to provide beam steering or lateral spreading information.

*Compliance is checked as follows:*