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Interested committees:

Title: BS EN IEC 60601-2-64 AMD 1. Medical electrical equipment

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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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THIS DRAFT IS NOT CURRENT BEYOND 19 July 2023**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62C/878/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 60601-2-64/AMD1 ED1	
DATE OF CIRCULATION: 2023-06-23	CLOSING DATE FOR COMMENTS: 2023-08-18
SUPERSEDES DOCUMENTS: 62C/853/CD, 62C/861A/CC	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE: Amendment 1 - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
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NOTE FROM TC/SC OFFICERS: In the attached CD2, red characters represent changes from Ed1 to AMD1/CD1 and blue characters represent changes from AMD1/CD1 to AMD1/CD2 based on the NCs' comments and discussion in WG 1. As indicated in 62C/766/Q, the scope of AMD1 is as follows: 1) Harmonisation with IEC 60601-1 Ed1/AMD2 2) Harmonisation with IEC 62667 (light ion performance) for defined terms 3) Neutrons outside the field of irradiation.

In addition, a correction to the current edition has been prepared for CD2, while any other comments, such as the introduction of a new concept, are excluded and are expected to be discussed in a future amendment or edition.

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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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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: Medical equipment, software, and systems.

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

FDIS	Report on voting
62C/XXX/FDIS	62C/XXX/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.

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

INTRODUCTION

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 standard¹ 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:

¹ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012/[AMD2:2020](#), 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 60601-1-9² and IEC 60601-1-10³ 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.

² 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

³ 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/[AMD1:2020](#), *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~Disturbance – 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/[AMD2:2020](#)

~~IEC 60601-2-1:2009/2020, 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/[AMD1:2012/AMD2:2020+A1:2012](#), IEC 60601-2-1:[20092020](#), 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:[20092020](#), 201.3.[202210](#)]

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~~ the quotient of dN by dA , where dN is the number of particles incident on a sphere of cross-sectional area dA , thus

$$\dot{\phi} = dN/dA$$

Note 1 to entry: Definition from See ICRU 33 ICRU 85a.

201.3.214**FLUX**

~~particles per unit time~~

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

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

$$\dot{N} = dN/dt$$

Note 1 to entry: Definition from 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~~2020, 201.3. ~~208~~224]

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

364 [SOURCE: IEC 60601-2-1: ~~2009~~2020, 201.3. ~~210~~227]

365 201.3.217

366 LATERAL SPREADING DEVICE

367 LSD

368 device used to increase the lateral ~~(X_q , Y_q)~~ (x_p , y_p) dimensions of a small diameter LIGHT
369 ION BEAM produced by an accelerator

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

372 Note 1 to entry: ~~X_q and Y_q are defined in IEC 61217:2011. The definition was taken from IEC 60601-2-64:2014 but further~~
373 ~~review after publication of the standard showed that the GANTRY frame of reference would be more appropriate.~~

374 201.3.218

375 LIGHT ION

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

378 201.3.219

379 LIGHT ION BEAM

380 collection of LIGHT IONS travelling in the same general direction

381 201.3.220

382 LIGHT ION BEAM APPLICATOR

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

385 Note 1 to entry: Several LIGHT ION BEAM APPLICATORS may be available to reduce the weight of APERTURES lifted
386 by ~~the OPERATOR~~therapists, decrease the APERTURE/~~ACCESSORY~~bolus to skin distance and reduce leakage
387 radiation.

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

391 201.3.221

392 LIGHT ION BEAM DISTRIBUTION SYSTEM

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

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

396 201.3.222

397 LIGHT ION RANGE

398 the depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is a
399 SPECIFIED value, given in the ACCOMPANYING DOCUMENTS, of the dose at the nominal
400 centre-of-modulation depth or of the dose maximum for a non-range-modulated beam, which
401 is measured on the RADIATION BEAM AXIS in a SPECIFIED RADIATION FIELD and with the surface of
402 the PHANTOM at a SPECIFIED distance from the ERP without RANGE SHIFTERS or ACCESSORIES
403 installed in the RADIATION HEAD downstream of the ENERGY PER NUCLEON or range monitoring
404 system

405 201.3.223

406 MODULATED SCANNING

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

410 Note 1 to entry: Various spatial and temporal scanning patterns may be used to generate the modulated FLUENCE
411 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, ~~NC, 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 PATIENT POSITIONER**~~

<RADIOTHERAPY> assembly of equipment upon which the PATIENT is placed and positioned for RADIOTHERAPY~~assembly of ME EQUIPMENT that supports the PATIENT~~

Note 1 to entry: The PATIENT POSITIONER includes the TABLE TOP and TABLE TOP SUPPORT.

[SOURCE: IEC ~~TR~~ 60601-2-1:20092020, 201.3.215235]

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, with or without a RANGE MODULATION DEVICE (RMD) to tailor the DEPTH DOSE distribution by varying the penetration and weighting factors of several component segments

Note 1 to entry: Typically the DEPTH DOSE distribution is tailored to give a uniform dose distribution over the depths where the ~~TARGET VOLUME~~~~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
QUALITY FACTOR, Q

The quality factor at a point in tissue, is given by:

$$Q = \int_{L=0}^{\infty} Q(L) D_L dL$$

where D is the absorbed dose at that point, DL is the distribution of D in unrestricted linear energy transfer L at the point of interest, and Q(L) is the quality factor as a function of L. The integration is to be performed over DL, due to all charged particles, excluding their secondary electrons.

[SOURCE: ICRU Publication 116]

201.3.232233
RADIATION HEAD
 structure from which the RADIATION BEAM emerges

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

201.3.233
RANGE MODULATED PORTAL
RMP

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

201.3.234
RANGE MODULATION DEVICE
RMD

device used to modulate the penetration of a ~~RADIATION BEAM~~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.~~

201.3.235
RANGE SHIFTER

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

201.3.236
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

201.3.237
SCANNING MODE

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

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

201.3.238
SITE TEST

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

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

503 [SOURCE: IEC 60601-2-1:20092020, 201.3.221253, modified – The note to entry has been
504 added.]

505 **201.3.239**

506 **TABLE TOP**

507 ~~an exchangeable device attached to the patient positioner to which registration and immobilization~~
508 ~~devices are attached and upon which the patient is placed.~~
509 ~~device attached to the PATIENT SUPPORT PATIENT POSITIONER~~ TABLE TOP SUPPORT to which
510 registration and immobilization devices are attached and upon which the PATIENT is placed

511
512 Note 1 to entry: TABLE TOPS are often exchangeable to hold PATIENTS or equipment in different orientations, for instance a flat
513 board or a chair mounted on PATIENT POSITIONER.
514

515 [SOURCE: IEC 60601-2-1:2020, 201.3.254, modified – Words "an exchangeable device attached to
516 the patient positioner" have been replaced by "device attached to the TABLE TOP SUPPORT", and note
517 added.]
518

519 **201.3.240**

520 **TABLE TOP SUPPORT**

521 device used in conjunction with the TABLE TOP to support and position the PATIENT during
522 RADIOTHERAPY

523 [SOURCE: IEC 60601-2-1:2020, 201.3.255]

524 **201.3.240241**

525 **TECHNICAL DOCUMENTATION**

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

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

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

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

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

539 [SOURCE: ISO/IEC 80079-34:20112018, 3.12, modified – A third note to entry has been
540 added.]

541 **201.3.241242**

542 **TERMINATION OF IRRADIATION**

543 **TERMINATE IRRADIATION**

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

546 Note 1 to entry: Examples of events that may TERMINATE IRRADIATION and stop movements include:

- 547 – when the pre-selected value of DOSE MONITOR UNITS is reached,
- 548 – when the pre-selected value is reached in the termination system independent of the DOSE MONITORING
549 SYSTEM,
- 550 – 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.]

201.3.242243

TRANSMISSION DETECTOR

RADIATION DETECTOR through which the LIGHT ION BEAM passes

[SOURCE: IEC 60601-2-1:20092020, 201.3.226257, modified – The term "RADIATION BEAM" has been replaced by "LIGHT ION BEAM".]

201.3.243244

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 [documentstandard](#).

[SOURCE: IEC 60601-1:2005/[AMD1:2012/AMD2:2020](#), 3.135]

201.3.244245

UNIFORM SCANNING

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

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

201.3.245246

USER

when used in an IEC standard on electromedical 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~~~~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~~~~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~~~~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.

201.5.5 Supply voltages, type of current, nature of supply, frequency

Replacement of clause a):

- a) Where test results are influenced by deviations of the characteristics of the SUPPLY MAINS from their RATED values, the effect of such deviations is taken into account.

The values used during testing are according to 4.10.2 or according to that marked on the LIGHT ION BEAM ME EQUIPMENT (see 7.2.6), whichever is least favorable, unless it can be demonstrated by risk management that protective measure(s) are in place to avoid possible deviations of the characteristics of the SUPPLY MAINS from their RATED values that could have an impact on BASIC SAFETY or ESSENTIAL PERFORMANCE. The conditions for testing shall be disclosed in the ACCOMPANYING DOCUMENTS and the analysis of the implemented protective measure(s) shall be included in the TECHNICAL DOCUMENTATION

Note : protective measures that avoid deviations of the characteristics of the SUPPLY MAINS include: UNINTERRUPTIBLE POWER SYSTEMS, line monitoring devices, etc.

201.5.7 Humidity preconditioning treatment

Replacement:

Prior to the tests of 8.7.4 and 8.8.3, all light ion beam me equipment or its parts shall be subjected to a humidity preconditioning treatment with the exception of light ion beam me equipment or its parts that are to be used only in controlled environments, as specified in the accompanying documents.

If light ion beam me equipment or its parts are subjected to a humidity preconditioning treatment, the following applies:

light ion beam me equipment or its parts shall be set up complete (or where necessary partially).

Covers used during transport and storage are detached.

This treatment is applied only to those light ion beam me equipment parts which are influenced by the climatic conditions that are simulated by the test.

Parts that can be detached without the use of a TOOL are detached but are treated