# IEC 60601-2-64

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# INTERNATIONAL STANDARD

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

## FOREWORD

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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. It is an International Standard.

This second edition cancels and replaces the first edition published in 2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) harmonization with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2011 and IEC 60601-1:2005/AMD2:2020;
b) harmonization with IEC 62667:2017 for defined terms and definitions;
c) address revision to neutrons outside the field of irradiation.

The text of this International Standard is based on the following documents:

| Draft | Report on voting |
|---|---|
| 62C/954/FDIS | 62C/964/RVD |

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,
– withdrawn, or
– revised.

# INTRODUCTION

The use of LIGHT ION BEAM ME EQUIPMENT for RADIOTHERAPY purposes can 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 can 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 IRRADIATION, cause INTERRUPTION OF IRRADIATION or cause TERMINATION OF 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 DOCUMENTATION, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

Closely related to this document is IEC 62667. 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. Annex A of IEC 62667:2017 provides forms for presenting performance values, measured per the methods SPECIFIED.

## 201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

### 201.1.1 Scope

*Replacement:*

This document 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 document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and SPECIFIED 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 document, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 2 In this document, 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.

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:*

The object of this document 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 document 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:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 applies as modified in Clause 206. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-9 [1][1] and IEC 60601-1-10 [2] 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 document will only apply subject to further amendment to this document.

### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.



The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text in this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

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1 Numbers in square brackets refer to the Bibliography.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document 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.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

## 201.2 Normative references

NOTE Informative references are listed in the bibliography.

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 2 applies, except as follows:

*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 60601-1:2005/AMD2:2020



IEC 60601-2-1:2020, *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 60601-2-68:2014, *Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of x-ray-based image guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*[2]

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

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

CISPR 11, *Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-2-1:2020, and IEC TR 60788:2004 apply, except as follows:

NOTE An index of defined terms is given after the Bibliography.

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2 A newer edition of IEC 60601-2-68 was published in 2025.

*Additional terms and definitions:*

**201.3.201**
**APPLICATOR CARRIAGE**
most distal part of the RADIATION HEAD that cannot be removed without using tools to which interchangeable LIGHT ION BEAM APPLICATORS are attached and which may extend toward and retract away from the ISOCENTRE or ERP

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

**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 ABSORBED 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 cause TERMINATION OF IRRADIATION

[SOURCE: IEC 60601-2-1:2020, 201.3.210]

**201.3.207**
**DOSE MONITOR UNIT**
parameter, reported by the DOSE MONITORING SYSTEM, from which, through a calibration procedure and with additional information, the ABSORBED DOSE delivered can be calculated

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

$$\Phi = dN/dA$$

Note 1 to entry: Definition from ICRU 85a:2011, 3.1.3.



**201.3.214**
**FLUX**
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:2011, 3.1.2.

**201.3.215**
**HARD-WIRED**
condition of a system where its features of a system can be modified only by physically removing and re-routing linked wires

[SOURCE: IEC 60601-2-1:2020, 201.3.224]

**201.3.216**
**INTERRUPTION OF IRRADIATION**
stopping of stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

[SOURCE: IEC 60601-2-1:2020, 201.3.227]

**201.3.217**
**LATERAL SPREADING DEVICE**
**LSD**
device used to increase the lateral ($Xg$, $Yg$) dimensions of a small diameter LIGHT ION BEAM produced by an accelerator

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

Note 1 to entry: $Xg$ and $Yg$ 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 LIGHT ION BEAM APPLICATORS may be available to reduce the weight of APERTURES lifted by the OPERATOR, decrease the distance from the skin to ACCESSORIES 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**
depth in a PHANTOM most distant from its surface at which the ABSORBED DOSE is a SPECIFIED value, given in the ACCOMPANYING DOCUMENTATION, 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**
**PATIENT POSITIONER**
<RADIOTHERAPY> assembly of equipment upon which the PATIENT is placed and positioned for RADIOTHERAPY ME EQUIPMENT

[SOURCE: IEC 60601-2-1:2020, 201.3.235, modified – Addition of "ME EQUIPMENT".]

**201.3.226**
**PATIENT POSITIONER TOP**
component of the PATIENT POSITIONER to which registration and immobilization devices are attached and upon which PATIENT is placed

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

[SOURCE: IEC 60601-2-1:2020, 201.3.254, modified – Main term "table top" replaced with "patient positioner top"; beginning of the definition "device attached to the table top support" replaced with "component of the PATIENT POSITIONER"; Note 1 replaced.]

**201.3.227**
**PORTAL**
collection of one or more pre-programmed TREATMENT segments treated automatically with a single PATIENT set-up

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

**201.3.228**
**PRE-PROGRAMMED MOVEMENT**
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



**201.3.229**
**PRIMARY/SECONDARY DOSE MONITORING COMBINATION**
utilization of two DOSE MONITORING SYSTEMS where one is arranged to be the PRIMARY DOSE MONITORING SYSTEM and the other the SECONDARY DOSE MONITORING SYSTEM

**201.3.230**
**PROGRAMMABLE RANGE MODULATED PORTAL**
**PRMP**
LIGHT ION PORTAL in which a program is used, with or without a RANGE MODULATION DEVICE (RMD), to tailor the DEPTH DOSE distribution by varying the penetration and weighting factors of several component segments

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

**201.3.231**
**QUALITY FACTOR**
***Q***
QUALITY FACTOR at a point in tissue given by:

$$Q = \frac{1}{D}\int_{L=0}^{\infty} Q(L)\, D_L\, dL$$

where $D$ is the ABSORBED DOSE at that point, $D_L$ 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 $L$

Note 1 to entry: The integration is to be performed over $D_L$, due to all charged particles, excluding their secondary electrons.

Note 2 to entry: The QUALITY FACTOR $Q$ at a point in tissue relates the DOSE EQUIVALENT $H$ at that point to the ABSORBED DOSE $D$ at that point, using the formula: $H = Q \times D$.

[SOURCE: ICRP Publication 116:2010]

**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 RADIATION BEAM into a PATIENT to tailor the DEPTH DOSE distribution during the delivery of one PORTAL



Note 1 to entry: The device may consist of a propellor shaped material that spins in the beam, a filter containing a repeating pattern of 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.

**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 cause TERMINATION OF IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

**201.3.236**
**SCANNING MODE**
method of delivering a scanned RADIATION BEAM to generate a laterally broad field

Note 1 to entry: Types of SCANNING MODES include: none, UNIFORM SCANNING 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 60601-2-1:2020, 201.3.253, modified – In Note 1 to entry, replacement of “responsible organization” with “end user”.]