

Australian/New Zealand Standard™

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



AS/NZS IEC 60601.2.1:2015

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.

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Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
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Australian/New Zealand Standard™

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

Originated as AS/NZS 3200.2.1:1999.
Jointly revised and redesignated as AS/NZS IEC 60601.2.1:2015.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.1 *Medical electrical equipment, Part 2.1: Particular requirements for safety—Electron accelerators in the range 1 MeV to 50 MeV*.

The objective of this Standard is to specify particular basic safety and essential performance requirements for electron accelerators in the range 1 MeV to 50 MeV and to specify tests to check compliance to those requirements.

The particular requirements of this Standard make reference to IEC 60601-1, which has been adopted as AS/NZS IEC 60601.1, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. Reference to the general requirements is essential for the application of this Standard.

This Standard is identical with, and has been reproduced from IEC 60601-2-1, Ed.3.1 (2014), *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*. This edition 3.1 incorporates Amendment 1 (2014). The text affected by Amendment 1 is indicated in the source document by marginal bars, redline and strikeout.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

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IEC FOREWORD

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 seventeen 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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

INTRODUCTION

The use of ELECTRON ACCELERATORS 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 and/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 ELECTRON ACCELERATORS 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 ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and end user.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, 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.

This International Standard was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. This third edition is prompted by the need to align this particular standard with the third edition of the general standard, IEC 60601-1:2005.

IEC 60976 and IEC/TR 60977 are closely related to this standard. The former specifies test methods and reporting formats for performance tests of ELECTRON ACCELERATORS for use in RADIOTHERAPY, with the aim of providing uniform methods for conducting such tests. The latter is not a standard per se, but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with present technology.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

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

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 ELECTRON ACCELERATORS, hereafter referred to as ME EQUIPMENT, in the range 1 MeV to 50 MeV, used for treatment of PATIENTS.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of ELECTRON ACCELERATORS

- 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, under NORMAL CONDITIONS and in NORMAL USE, deliver a RADIATION BEAM of X-RADIATION and/or ELECTRON RADIATION having
 - NOMINAL ENERGY in the range 1 MeV to 50 MeV,
 - maximum ABSORBED DOSE RATES between $0,001 \text{ Gy} \times \text{s}^{-1}$ and $1 \text{ Gy} \times \text{s}^{-1}$ at 1 m from the RADIATION SOURCE,
 - NORMAL TREATMENT DISTANCES (NTDs) between 0,5 m and 2 m from the RADIATION SOURCE,

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, e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
 - 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.

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

IEC 61271 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).

IEC 60676 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS. The standard is intended to facilitate comparisons of accelerator-based ME EQUIPMENTS of different manufacture. IEC 60676 contains no safety requirements, and is therefore not required for compliance with this particular standard. It should also be noted (as stated in the Introduction to IEC 60976:2007) that tests specified in IEC 60976 are not necessarily appropriate for ensuring that any individual medical ELECTRON ACCELERATOR conforms to the declared functional performance during the course of its working lifetime.

NOTE 3 IEC/TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*, is a related technical report that provides performance guidelines. It shall not be construed as a standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTRON ACCELERATORS in the range 1 MeV to 50 MeV 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, NOMINAL ENERGY, and ABSORBED DOSE,
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, by utilizing STATIONARY RADIOTHERAPY, MOVING BEAM RADIOTHERAPY, RADIATION 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 apply as modified in Clauses 206. IEC 60601-1-3, IEC 60601-1-8 and 60601-1-10² do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

² 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

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 sections, 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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.

"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:

NOTE Informative references are listed in the bibliography on page 60.

Addition:

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available in English only)

IEC 61217:1996, *Radiotherapy equipment – Coordinates, movements and scales*

201.3 Terms and definitions

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

NOTE An index of defined terms is to be found at the end of the document.

Addition:

201.3.201

AMBIENT DOSE EQUIVALENT

$H^*(10)$

DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT which would be generated in the associated oriented and expanded RADIATION FIELD at a depth of 10 mm on the radius of the ICRU sphere which is oriented opposite to the direction of incident RADIATION

NOTE 1 An oriented and expanded RADIATION FIELD is an idealized RADIATION FIELD which is expanded and in which the radiation is additionally oriented in one direction.

NOTE 2 See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

201.3.202

CONTROLLING TIMER

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

201.3.203

ELECTRON BEAM APPLICATOR

BEAM LIMITING DEVICE for ELECTRON RADIATION beams

201.3.204

ELECTRONIC IMAGING DEVICE

EID

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

[IEC 60976:2007, definition 3.5]

201.3.205

ELECTRONIC PORTAL IMAGING DEVICE

EPID

device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed substantially normal to the RADIATION BEAM AXIS, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen, using the medical ELECTRON ACCELERATOR'S RADIATION BEAM as the RADIATION SOURCE

NOTE 1 The primary function of an EPID is in verification of PATIENT set-up, and so replaces the need for port films for this same purpose.

[IEC 60976:2007, definition 3.6]

NOTE 2 This definition is not included in IEC/TR 60788.

201.3.206

GANTRY

part of the ME EQUIPMENT supporting the RADIATION HEAD

201.3.207**GEOMETRICAL RADIATION FIELD**

geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window; the GEOMETRICAL RADIATION FIELD may be defined at any distance from the front surface of the TARGET for X-RADIATION, or from the ELECTRON RADIATION window for ELECTRON RADIATION

201.3.208**HARD-WIRED**

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

201.3.209**INTENSITY MODULATION RADIATION THERAPY****IMRT**

treatment procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the PATIENT, and beam size of the external beam, either in a continuous or a discrete manner, and as pre-determined by a treatment plan

NOTE The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned TARGET VOLUME, while minimizing dose to surrounding healthy tissue.

201.3.210**INTERRUPTION OF IRRADIATION/TO INTERRUPT IRRADIATION**

stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

201.3.211**MOVING BEAM RADIOTHERAPY**

RADIOTHERAPY with any planned displacement of the RADIATION FIELD or PATIENT relative to each other or with any planned change of ABSORBED DOSE distribution

201.3.212**NOMINAL ENERGY****ENERGY**

<ELECTRON RADIATION> ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

<X-RADIATION> ENERGY stated by the MANUFACTURER to characterize the radiation BEAM

201.3.213**NORMAL TREATMENT DISTANCE****NTD**

<ELECTRON RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane

<X-RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for ME EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

201.3.214**PASSWORD**

<RADIOTHERAPY> sequence of keystrokes that permits OPERATOR access for NORMAL USE or to reset INTERLOCKS and, with a different sequence of keystrokes, permits access for adjustment and maintenance

201.3.215**PATIENT SUPPORT**

<RADIOTHERAPY> assembly of ME EQUIPMENT that supports the PATIENT

201.3.216**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

201.3.217**QUALIFIED PERSON**

person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

201.3.218**RADIATION TYPE**

nature of the waves or corpuscles comprising the RADIATION

NOTE E.g. whether the RADIATION is X-RADIATION or ELECTRON RADIATION.

201.3.219**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

201.3.220**RELATIVE SURFACE DOSE**

ratio of the ABSORBED DOSE on the REFERENCE AXIS, at the depth of 0,5 mm, to the maximum ABSORBED DOSE on the REFERENCE AXIS, both measured in a PHANTOM with its surface at a SPECIFIED distance

201.3.221**SITE TEST**

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

201.3.222**STEREOTACTIC RADIOTHERAPY****SRT**

treatment procedure in which RADIATION BEAMS of generally small size are oriented from various angles, and precisely positioned relative to a TARGET VOLUME within the PATIENT

NOTE Precise location of the TARGET VOLUME is enabled by use of a three-dimensional frame of reference, which may include anatomical registration points or markers, and immobilisation methods, or imaging techniques.

201.3.223**STEREOTACTIC RADIOSURGERY****SRS**

SPECIFIC version of STEREOTACTIC RADIOTHERAPY, in which a single high dose of RADIATION is delivered to the TARGET VOLUME, using a STEREOTACTIC FRAME OF REFERENCE in conjunction with anatomical registration points

201.3.224**STEREOTACTIC FRAME OF REFERENCE**

three-dimensional coordinate system for numerical specification of the position of those parts of a PATIENT anatomy intended for SRS/SRT treatment

201.3.225**TERMINATION OF IRRADIATION**

TERMINATE IRRADIATION

stopping of/to stop IRRADIATION and movements, with no possibility of restarting without the reselection of all operating conditions

NOTE 1 I.e. returning/to return to the PREPARATORY STATE.

NOTE 2 Events that TERMINATE IRRADIATION and stop movements include the following:

- when the pre-selected value of DOSE MONITOR UNITS is reached,
- when the pre-selected value of elapsed time is reached,
- a deliberate manual act,
- the operation of an INTERLOCK,
- in MOVING BEAM RADIOTHERAPY, when the pre-selected value of an angular or linear dimension is exceeded.

201.3.226**TRANSMISSION DETECTOR**

RADIATION DETECTOR through which the RADIATION BEAM passes

201.3.227**TYPE TEST**

~~ME EQUIPMENT test by the MANUFACTURER to establish compliance with SPECIFIED criteria for a particular design of device or ME EQUIPMENT~~

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Requirements of 201.10 are identified as ESSENTIAL PERFORMANCE requirements.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.1 TYPE TESTS

Additional subclause:

201.5.1.101 Test grades

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in 201.10 of 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.

201.5.4 Other conditions

Item 5.4 a) of the general standard does not apply.

Replacement of item 5.4 d):

d) Where cooling water is required, water as required in the technical description is used.

Addition:

The ~~MANUFACTURER~~ manufacturer shall state in the ACCOMPANYING DOCUMENTS any additional requirement 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:

201.7.2.4 ACCESSORIES

Addition:

The dimensions of the GEOMETRICAL RADIATION FIELD at NTD and the distance from the distal end to NTD shall be clearly legible on the outside of all interchangeable and non-adjustable BEAM LIMITING DEVICES (BLDs) and ELECTRON BEAM APPLICATORS.

Each manually interchangeable WEDGE FILTER shall be clearly marked to establish its identity.

201.7.2.20 Removable protective means

Addition:

Where the requirements of the subclause of the general standard 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 ~~symbol 11~~ safety sign 10 of Table D.4.2 of the general standard, indicating "~~Attention, consult ACCOMPANYING DOCUMENTS~~ 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

The following shall be provided:

- a) a mechanical scale or a numerical indication for each available movement;
- b) a means to align the PATIENT with respect to the REFERENCE AXIS (e.g. LIGHT FIELD, lasers etc.);
- c) a means to determine RADIATION SOURCE TO SKIN DISTANCE (e.g. scale, numerical indication, or lasers).

The designation, direction of increasing value and zero position of all movements shall comply with IEC 61217 (see Figure 201.108).

Compliance is checked by inspection.

201.7.8 Indicator lights and controls

201.7.8.1 Colours of indicator lights

Replacement:

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

RADIATION BEAM "on"	yellow
READY STATE	green

NOTE In the TREATMENT ROOM or at other locations, these states may require urgent action or caution; different colours, in accordance with the Table 201.101 below, may therefore be used in such locations.

**Table 101.101 – Colours of indicator lights and their meaning
for ME EQUIPMENT**

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

Urgent action required in response to an unintended state of operation red

PREPARATORY STATE

other colour

201.7.9 ACCOMPANYING DOCUMENTS

Addition:

Data required in the technical description to support Clause 201.10 SITE TEST compliance is given in Table 201.102.

**Table 201.102 – 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
201.10.1.2.101.1.2	b) d) e)		d)		a) b) c)
201.10.1.2.101.1.3	a) b)		b) c)		b)
201.10.1.2.101.1.4	d) e) f)			a) b) c) d) e) f)	
201.10.1.2.101.1.5				a) b)	
201.10.1.2.101.1.6	a) b) c) d)				b) c) d)
201.10.1.2.101.1.7	a)				b)
201.10.1.2.101.2	a) b) c)			a) d)	b) c)
201.10.1.2.101.3	b) c) d) e)			a)	b) c) d) e)
201.10.1.2.101.4	a) b) c) d) e)			a) b) c) d) e)	
201.10.1.2.101.5	c)		c)	a) b)	
201.10.1.2.101.6	c) f)		d) e)	a) b)	c) d) e) f)
201.10.1.2.101.7.1				a)	b)
201.10.1.2.101.7.2				a) c)	b)
201.10.1.2.101.7.3.1	†				†
201.10.1.2.101.7.3.2				a) c) d)	b)
201.10.1.2.101.8				a) b) c) d) e) f) g)	
201.10.1.2.101.9	a)			a)	
201.10.1.2.101.10	e)			a) b) c) d) e)	
201.10.1.2.101.11	†				
201.10.1.2.101.12	a) c)			a) b) c) d)	
201.10.1.2.101.13	a)			a) b)	
201.10.1.2.101.14	a) b)				a) b)
201.10.1.2.102.1	†			†	
201.10.1.2.102.2		†		†	

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
201.10.1.2.102.3			†		
201.10.1.2.103.2.1		a) b) c) d)		a) b) c) d)	
201.10.1.2.103.2.2	c)	a) 1), a) 2), b)		a) b)	c)
201.10.1.2.103.3		†			
201.10.1.2.103.4		†			
201.10.1.2.103.5	†	← grade A or grade C test →	†		†
201.10.1.2.104.1		a) b)		a) b)	
201.10.1.2.104.2			†		
201.10.1.2.104.3	b)	a)			
201.10.1.2.104.4	†			†	
201.10.1.2.104.5		†			
201.14.101	†				†
201.101.1	†				
201.101.2	†				
201.101.3	†				
201.101.5	†				
NOTE † denotes requirement of subclause having no other SPECIFIC identification.					