BSI Standards Publication

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

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Full document details: BS EN IEC 60601-2-1:2021

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-1:2021. It is identical to IEC 60601-2-1:2020. It supersedes BS EN 60601-2-1:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2021

ISBN 978 0 580 95504 4

ICS 11.040.60

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2021.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-1

July 2021

ICS 11.040.60

Supersedes EN 60601-2-1:2015 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV (IEC 60601-2-1:2020)

Appareils électromédicaux - Partie 2-1: Exigences particulières pour la sécurité de base et les performances essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV
(IEC 60601-2-1:2020)

Medizinische elektrische Geräte - Teil 2-1: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV
(IEC 60601-2-1:2020)

This European Standard was approved by CENELEC on 2020-12-02. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 62C/770/FDIS, future edition 4 of IEC 60601-2-1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-1:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

This document supersedes EN 60601-2-1:2015 and all of its amendments and corrigenda (if any).

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Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

Endorsement notice

The text of the International Standard IEC 60601-2-1:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-3:2008	NOTE	Harmonized as EN 60601-1-3:2008 (not modified)
IEC 60601-1-3:2008/A1:2013	NOTE	Harmonized as EN 60601-1-3:2008/A1:2013 (not modified)
IEC 60601-1-9:2007	NOTE	Harmonized as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Harmonized as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-10:2007	NOTE	Harmonized as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Harmonized as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-2-11:2013	NOTE	Harmonized as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17:2013	NOTE	Harmonized as EN 60601-2-17:2015 (not modified)
IEC 60601-2-64:2014	NOTE	Harmonized as EN 60601-2-64:2015 (not modified)
IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified)
IEC 62083:2009	NOTE	Harmonized as EN 62083:2009 (not modified)
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
IEC 62680-2-1:2015	NOTE	Harmonized as EN 62680-2-1:2015 (not modified)

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following replacements:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-2-68	2014	Electrical medical 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	EN 60601-2-68	2015
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN IEC 61000-4-3	-

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Publication	Year	Title	EN/HD	Year
IEC 61217	2011	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	2012
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
CISPR 11	-	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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 60601-2-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition cancels and replaces the third edition published in 2009 and Amendment 1:2014. This edition constitutes a technical revision.

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

a) alignment with the new relevant collateral standards;
b) addition of computer interface and control;
c) addition of new technologies in RADIOTHERAPY, including
   - BEAM GATING, and
   - ADAPTIVE RADIOTHERAPY.

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

FDIS	Report on voting
62C/770/FDIS	62C/785/RVD

Full information on the voting for the approval of this document 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 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 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 standard conform to usage described in Clause 7 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 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.

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 AA.

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.

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

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

NOTE The attention of users of this document is drawn to the fact that equipment MANUFACTURERs and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose distribution to the PATIENT, or if the ME EQUIPMENT design fails to meet the requirements of BASIC SAFETY and ESSENTIAL PERFORMANCE. 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 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.

Clauses 201.10, 201.103, 201.104, 201.105 and 201.108 contain limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. In this document, the information in Clause 201.10 has either been reorganized or moved to other clauses in order to better reflect current usage and broaden the applicability of certain clauses to always apply to the ME EQUIPMENT when IRRADIATION is being produced and not just when a PATIENT is being treated. Annex AA provides a table showing the relationship between the clauses in IEC 60601-2-1:2009 and IEC 60601-2-1:2009/AMD1:2014 and the clauses in this document.

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 is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and RESPONSIBLE ORGANIZATION.

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

IEC 60601-2-1 was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. The third edition was prompted by the need to align IEC 60601-2-1 with the third edition of the general standard, IEC 60601-1:2005, and was amended in 2014. This fourth edition is prompted by the need to update IEC 60601-2-1 for the technology that is in current use as well as to bring it into alignment with IEC 60601-1:2005 and IEC 60601-2-1/AMD1:2012. This prompted the relabelling and organization of Clause 201.10 as well as the addition of Clauses 201.102 through 201.109.

IEC 60976:2007 and IEC TR 60977:2008 are closely related to the third edition of this document. 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 performance standard but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with technology available at the time of publication. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERs replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

When a stated requirement does not apply to a given piece of equipment because the function involved does not exist on that equipment, compliance with that requirement is not necessary. However, when that stated requirement addresses a RISK that could be caused by a substantially similar function of the equipment, the MANUFACTURER needs to address the RISK caused by that similar function in the RISK MANAGEMENT FILE.

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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 standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 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.

NOTE 1 While ELECTRON ACCELERATORS used for TREATMENT of PATIENTS are always ME EQUIPMENT, there are times in this document where they are referred to as EXTERNAL BEAM EQUIPMENT (EBE). Usage of EBE does not remove the requirements placed on the ME EQUIPMENT but is meant to clarify that the ME EQUIPMENT being discussed is the EBE and not some other ME EQUIPMENT that may be part of the system configuration.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies to the manufacture and some installation aspects of ELECTRON ACCELERATORS and their included equipment used to increase the precision, accuracy and volumetric targeting of the TREATMENT delivery

– intended for RADIOTHERAPY in medical practice, including those in which the selection and DISPLAY of TREATMENT 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 or ELECTRON RADIATION having
  - NOMINAL ENERGY in the range 1 MeV to 50 MeV,
  - maximum ABSORBED DOSE RATES between 0,001 Gy × s^{-1} and 1 Gy × s^{-1} at the ERP from the RADIATION SOURCE, and
  - REFERENCE TREATMENT DISTANCES (RTDs) between 0,5 m and 2 m from the RADIATION SOURCE;

and

– intended to be
  - for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS appropriately licensed or 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, and
  - subject to regular QUALITY ASSURANCE performance and calibration checks by a QUALIFIED PERSON.

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

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NOTE 2 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 3 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

NOTE 4 The limits on maximum ABSORBED DOSE RATES are included for two reasons. The first is due to requirements related to time in this document. This restriction limits the total dose that could be delivered during a SPECIFIED time (examples: timer, TIME TO INTERRUPT or TERMINATE, LATENCY). The second is to limit the amount of RADIATION damage that can occur during the time required to take action (often as a follow up to an INTERRUPTION or TERMINATION OF IRRADIATION). Wherever requirements were made to limit the amount of dose delivered before action is taken, the RADIATION damage was considered to be independent of the dose rate and only dependent on the dose. This would largely hold true if the dose rate stayed within the range stated above.

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).

IEC 60976:2007 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS and is intended to facilitate comparisons of accelerator-based ME EQUIPMENTs of different manufacture. IEC 60976:2007 contains no safety requirements, and is not required to show compliance with this document. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

IEC TR 62926 provides guidance for integration of ELECTRON ACCELERATORS with other equipment.

IEC TR 63183 provides guidance on the construction of error and warning messages.

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 document helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- maintains OPERATOR and general public safety during ME EQUIPMENT NORMAL USE and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE, and
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, 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 the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 applies. IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clause 206. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013, IEC 60601-1-11 and IEC 60601-1-12 do not apply, and all other collateral standards in the IEC 60601-1 series do not apply.

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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.

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

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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 3.147, 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, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" 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.

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201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Replacement:

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

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

Addition:

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

IEC 60601-2-68:2014*, Medical electrical equipment – 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*

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

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 and IEC 60601-1:2005/AMD1:2012, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 111.

Addition:

201.3.201
ADAPTIVE RADIOTHERAPY
RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

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Note 1 to entry: IMAGE-GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY.

201.3.202
AMBIENT DOSE EQUIVALENT
$H^*(10)$
DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT that would be produced by the corresponding aligned and expanded RADIATION FIELD at a depth of 10 mm in the ICRU sphere on the radius opposing the direction of the aligned RADIATION FIELD

Note 1 to entry: 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 to entry: See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

201.3.203
BEAM GATING
allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

[SOURCE: IEC 60601-2-64:2014, 201.3.204]

201.3.204
BEAM GATING SIGNAL
signal generated for the purpose of BEAM GATING

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

[SOURCE: IEC 60601-2-64:2014, 201.3.205]

201.3.205
BEAM GATING LATENCY
time between the assertion of the BEAM GATING SIGNAL and the inhibition or enabling of IRRADIATION

Note 1 to entry: The inhibition or enabling of IRRADIATION is measured at 90 % of dose rate change.

201.3.206
BEAM HOLD
condition, during IRRADIATION, in which the ME EQUIPMENT has minimized the TREATMENT IRRADIATION output

Note 1 to entry: BEAM HOLD is not the same as INTERRUPTION OF IRRADIATION where the ME EQUIPMENT is changed to the beam off state.

Note 2 to entry: BEAM HOLD is a subcondition of IRRADIATION for the purpose of rapid transition to intended TREATMENT IRRADIATION output.

Note 3 to entry: BEAM HOLD approximates the IRRADIATION off condition by inhibiting the IRRADIATION output.

Note 4 to entry: This is commonly used during gating, INTENSITY-MODULATED RADIATION THERAPY (IMRT), etc.

201.3.207
BEAM LIMITING DEVICE
BLD
<RADIOTHERAPY> structure, fixed or movable, intended to block or collimate IONIZING RADIATION, resulting in shielding the TREATMENT region from unintended X-RADIATION or ELECTRON RADIATION

Note 1 to entry: Examples are non-adjustable primary collimators, adjustable collimators, JAWS, MLCs, cones (non-adjustable BLD), etc.

[SOURCE: IEC 60976:2007, 3.2, modified – Note added.]

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201.3.208
BEAM LIMITING SYSTEM
BLS
entirety of parts and their geometrical configuration contributing to the limitation of the RADIATION BEAM

[SOURCE: IEC 60601-1-3:2008, 3.12, modified – Abbreviated term "BLS" added.]

201.3.209
CONTROL POINT
CP
point in TREATMENT delivery sequence representing the geometric or radiological parameters at a particular time or state of the delivery device

Note 1 to entry: The time separation between CONTROL POINTS can be determined by a trigger other than time (e.g. GANTRY position, DOSE MONITOR UNITS).

Note 2 to entry: CONTROL POINT 0 (CP_0) defines the initial setup where all applicable parameters are defined.

Note 3 to entry: For $n > 0$, CP_n defines the parameters that change relative to $CP_{(n-1)}$.

201.3.210
CONTROLLING TIMER
device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, to TERMINATE IRRADIATION

201.3.211
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

Note 1 to entry: The DOSE MONITOR UNIT reported by the DOSE MONITORING SYSTEM is related to the amount of IRRADIATION produced by the ME EQUIPMENT.

[SOURCE: IEC 60601-2-64:2014, 201.3.207, modified – Note added.]

201.3.212
DOSE MONITORING SYSTEM
system of devices for the measurement and DISPLAY of a RADIATION QUANTITY directly related to the ABSORBED DOSE

Note 1 to entry: It may include means for TERMINATION OF IRRADIATION when a pre-selected value is reached.

[SOURCE: IEC TR 60788:2004, rm-33-01]

201.3.213
ELECTRON BEAM APPLICATOR
device that, on its own or in combination with an interchangeable aperture, is a BEAM LIMITING DEVICE for ELECTRON RADIATION beams

201.3.214
ELECTRONIC IMAGING DEVICE
EID
device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

[SOURCE: IEC 60976:2007, 3.5, modified – Note deleted.]

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201.3.215
ELECTRONIC PORTAL IMAGING DEVICE
EPID
device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed 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 to entry: 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.

[SOURCE: IEC 60976:2007, 3.6]

201.3.216
EQUIPMENT REFERENCE AXES
coordinate axes defined in the EQUIPMENT REFERENCE COORDINATE SYSTEM

201.3.217
EQUIPMENT REFERENCE COORDINATE SYSTEM
cartesian right-handed coordinate system with its origin at the ERP and the Z axis vertically upward when all coordinate system angles are set to zero

Note 1 to entry: The EQUIPMENT REFERENCE COORDINATE SYSTEM is identical to the fixed reference system in IEC 61217.

201.3.218
EQUIPMENT REFERENCE POINT
ERP
point in space used for referencing dimensions and positions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the EQUIPMENT REFERENCE POINT is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment system may be used.

[SOURCE: IEC 60601-2-64:2014, 201.3.212, modified – Words "and positions" added in the definition, and Note 2 deleted.]

201.3.219
EXTERNAL BEAM EQUIPMENT
EBE
external RADIATION equipment utilizing ELECTRON ACCELERATORS, LIGHT ION BEAM equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

[SOURCE: IEC 60601-2-68:2014, 201.3.207, modified – Note deleted.]

201.3.220
EXTERNAL MONITORING DEVICE
device that can be connected to ME EQUIPMENT and monitors PATIENT anatomy or physiology

201.3.221
FLUENCE RATE
quotient of $d\Phi$ by dt, where $d\Phi$ is the increment of the fluence in the time interval dt

Note 1 to entry: The unit of FLUENCE RATE is $m^{-2}s^{-1}$.

[SOURCE: ICRU Report 60:1998, modified – Rephrased to follow IEC term format.]

201.3.222
GANTRY
part of the ME EQUIPMENT supporting the RADIATION HEAD

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Note 1 to entry: The GANTRY is any mechanical device that supports the RADIATION HEAD regardless of movement limitations.

201.3.223
GEOMETRICAL RADIATION FIELD
geometrical projection of the aperture formed at the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS at the EQUIPMENT REFERENCE POINT, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window

201.3.224
HARD-WIRED
condition of a system where its features can be modified only by physically removing and re-routing physically linked wires

201.3.225
IMAGE-GUIDED RADIOTHERAPY
IGRT
RADIOTHERAPY process by which the location of a RADIOTHERAPY beam relative to the intended TARGET VOLUME within a PATIENT's anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of the beam to the TARGET VOLUME

Note 1 to entry: The time period of "at the time of TREATMENT" is specified in the definitions of REAL-TIME IGRT, ONLINE IGRT and OFFLINE IGRT.

[SOURCE: IEC 60601-2-68:2014, 201.3.209 modified – Note 1 replaced.]

201.3.226
INTENSITY-MODULATED 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

[SOURCE: IEC 60976:2007, 3.9, modified – Words "of the external beam" added in the definition, and note deleted.]

201.3.227
INTERRUPTION OF IRRADIATION
stopping of IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

201.3.228
JAW
BLD used to collimate the primary RADIATION BEAM to form a single simple geometric shape of adjustable size

Note 1 to entry: Examples of shapes are rectangles and circles.

201.3.229
LATENCY
time interval between occurrence or initiation of an event and its detection or effect

201.3.230
MULTILEAF COLLIMATOR
MLC
multi-element BLD capable of defining RADIATION FIELDS of irregular shapes

Note 1 to entry: The positions of the individual elements can either be static or can be changed dynamically during IRRADIATION.

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201.3.231
NOMINAL ENERGY
numerical value stated by the MANUFACTURER to identify the RADIATION BEAM

201.3.232
OFFLINE ADAPTIVE RADIOTHERAPY
process wherein the PATIENT setup or TREATMENT PLAN is adjusted for application in subsequent TREATMENT delivery sessions

201.3.233
ONLINE ADAPTIVE RADIOTHERAPY
process wherein the PATIENT setup or TREATMENT PLAN is adjusted immediately prior to or during the therapeutic IRRADIATION session requiring OPERATOR initiated adjustments.

Note 1 to entry: The PATIENT stays on the PATIENT POSITIONER and is immobile during and in-between adaptive calculations and TREATMENT.

201.3.234
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

201.3.235
PATIENT POSITIONER
<RADIOTHERAPY> assembly of equipment upon which the PATIENT is placed and positioned for RADIOTHERAPY

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

201.3.236
PREPARATORY STATE
state of equipment for setting essential operating conditions, if in the STAND-BY STATE the setting of these conditions is not possible

[SOURCE: IEC TR 60788:2004, rm-84-04]

201.3.237
PRIMARY DOSE MONITORING SYSTEM
DOSE MONITORING SYSTEM which is intended to TERMINATE IRRADIATION when a pre-selected value is reached

[SOURCE: IEC TR 60788:2004, rm-33-03]

201.3.238
PROGRAMMABLE WEDGE FIELD
PWF
generation of a RADIATION FIELD with a wedge-shaped DOSE PROFILE, with or without the use of a fixed metal WEDGE FILTER placed in the X-ray beam, where the programmed wedge DOSE PROFILE may be generated by controlling the relationship between the beam intensity and a moveable BEAM LIMITING DEVICE

[SOURCE: IEC 60976:2007, 3.18, modified – Words "a RADIATION FIELD with" added in the definition.]

201.3.239
QUALIFIED PERSON
person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

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[SOURCE: IEC TR 60788:2004, rm-85-04, modified – Word "specified" replaced by "particular" in the definition.]

201.3.240
QUALITY ASSURANCE
QA
part of quality management focused on providing confidence that quality requirements will be fulfilled

Note 1 to entry: Unless given requirements fully reflect the needs of the RESPONSIBLE ORGANIZATION, QUALITY ASSURANCE will not be complete.

Note 2 to entry: For effectiveness, QUALITY ASSURANCE requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as VERIFICATIONS and audits of production, installation and inspection operations. Providing confidence can involve producing evidence.

Note 3 to entry: Within an organization, QUALITY ASSURANCE also serves to provide confidence in the supplier.

[SOURCE: IEC TR 61258:2008, 2.5]

201.3.241
RADIATION HEAD
structure from which the RADIATION BEAM emerges

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

201.3.242
RADIATION TYPE
nature of the waves or corpuscles comprising the RADIATION

EXAMPLE RADIATION is X-RADIATION or ELECTRON RADIATION

201.3.243
REAL-TIME ADAPTIVE RADIOTHERAPY
RADIOTHERAPY that, throughout therapeutic IRRADIATION, monitors PATIENT anatomy or physiology and based upon that information, allows autonomous adjustments of TREATMENT PARAMETERS throughout the therapeutic IRRADIATION without OPERATOR intervention

201.3.244
REDUNDANT DOSE MONITORING SYSTEM
utilization of two DOSE MONITORING SYSTEMS where both systems are arranged to TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

[SOURCE: IEC 60976:2007, 3.21, modified – The words "be the PRIMARY DOSE MONITORING SYSTEM" have been replaced by "TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS".]

201.3.245
REFERENCE ABSORBED DOSE
area-weighted averaged ABSORBED DOSE within the hatched area as shown in Figure 201.101 and measured at the REFERENCE TREATMENT DISTANCE at a depth containing the maximum ABSORBED DOSE measured on the REFERENCE AXIS, whose measurement area is defined by the dimensions in Table 201.101

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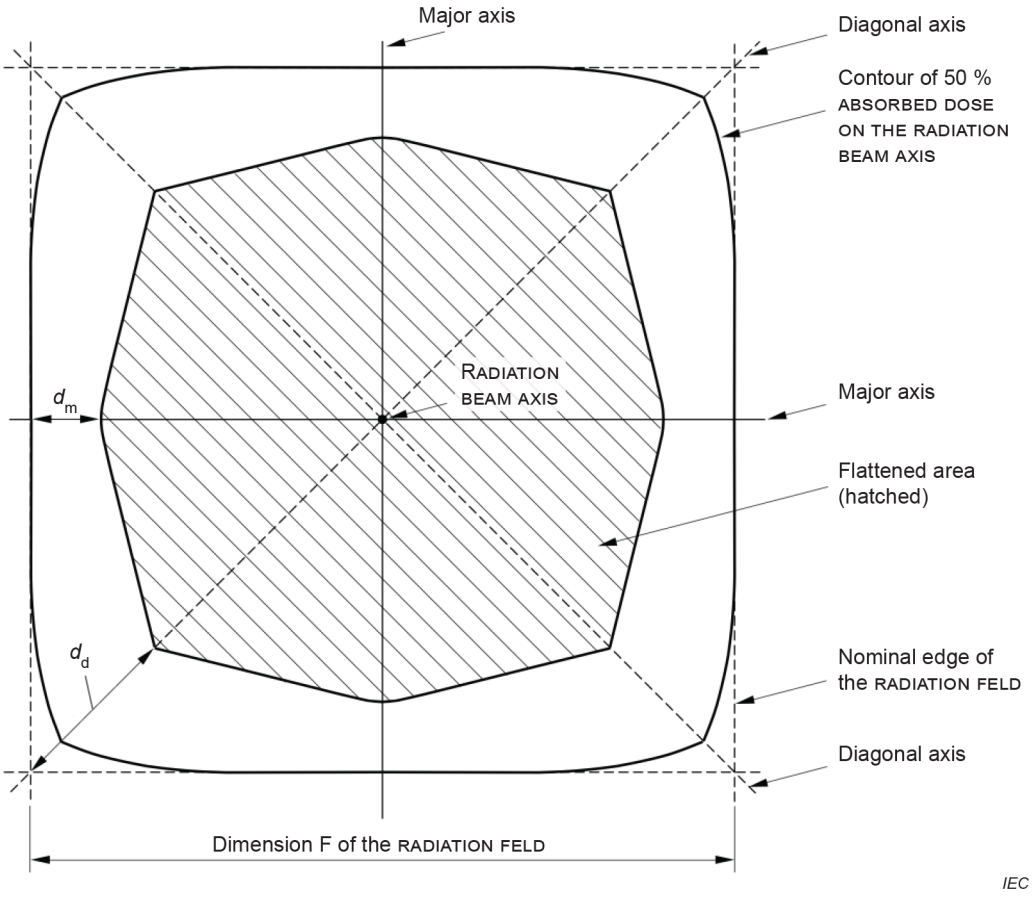

Figure 201.101 – Flattened area within the RADIATION FIELD

Table 201.101 – Dimensions defining the flattened area according to Figure 201.101

Square RADIATION FIELD F c_m	Dimensions defining the measurement area	
	d_m	d_d
$5 \leq F \leq 10$	1 cm	2 cm
$10 < F \leq 30$	0,1 F	0,2 F
$30 < F$	3 cm	6 cm

Note 1 to entry: As an alternative, measurement points arranged in an equidistant square pattern and with each point no more than 1 cm from any other point may be used.

Note 2 to entry: Area-weighted averages are defined as follows:

$$\overline{D}_{\text{area}} = \frac{1}{\text{area}} \int_{\text{area}} D(x,y)\,dx\,dy,\ \overline{D}_{\text{area}} = \frac{1}{\text{area}} \int_{\text{area}} D(r,\varphi)\,r\,dr\,d\varphi,\ \overline{D}_{\text{area}} = \sum_{i=1}^{n} D_i A_i \,/\, \sum_{i=1}^{n} A_i$$

201.3.246
REFERENCE AXIS
line through the centre of a RADIATION SOURCE in the direction perpendicular to the plane of either the front surface of the TARGET if X-RADIATION, or the ELECTRON RADIATION window if ELECTRON RADIATION

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201.3.247
REFERENCE CONDITIONS
conditions under which all influence quantities and instrument parameters have their reference values

[SOURCE: IEC TR 60788:2004, rm-70-12]

201.3.248
REFERENCE TREATMENT DISTANCE
RTD
SPECIFIED distance measured along the REFERENCE AXIS which is, for ELECTRON RADIATION, measured from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT, or for X-RADIATION, from the TARGET surface of the exiting beam to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT

Note 1 to entry: The REFERENCE TREATMENT DISTANCE replaces the use of NORMAL TREATMENT DISTANCE in previous editions of IEC 60601-2-1.

201.3.249
REFERENCE TREATMENT PLANE
RTP
plane containing the EQUIPMENT REFERENCE POINT and which is perpendicular to the therapeutic REFERENCE AXIS

201.3.250
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 water or a water-equivalent PHANTOM with its surface at a SPECIFIED distance

201.3.251
SECONDARY DOSE MONITORING SYSTEM
DOSE MONITORING SYSTEM which is intended to TERMINATE IRRADIATION in the event of failure of the PRIMARY DOSE MONITORING SYSTEM

[SOURCE: IEC TR 60788:2004, rm-33-04]

201.3.252
SEGMENT
span between two consecutive CONTROL POINTS

201.3.253
SITE TEST
test, after installation, 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 RESPONSIBLE ORGANIZATION.

201.3.254
TABLE TOP
device attached to the TABLE TOP SUPPORT to which registration or immobilization devices are attached and upon which the PATIENT is placed

Note 1 to entry: The TABLE TOP can be exchangeable.

[SOURCE: IEC 60601-2-64:2014, 201.3.238, modified – Words "an exchangeable device attached to the patient positioner" have been replaced by "device attached to the TABLE TOP SUPPORT", and note added.]

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201.3.255
TABLE TOP SUPPORT
device used in conjunction with the TABLE TOP to support and position the PATIENT during RADIOTHERAPY

201.3.256
TERMINATION OF IRRADIATION
stopping of IRRADIATION and movements, with no possibility of restarting without the reselection of all operating conditions

Note 1 to entry: I.e. returning to the PREPARATORY STATE.

Note 2 to entry: Events that TERMINATE IRRADIATION and stop movements include the following:

– normal TERMINATION OF IRRADIATION:
  - when the pre-selected value of DOSE MONITOR UNITS is reached;
  - when the pre-selected value of elapsed time is reached;
  - when the pre-selected value of an angular or linear dimension is reached;
– abnormal termination of IRRADIATION:
  - a deliberate manual act;
  - the operation of an INTERLOCK which is not due to a pre-selected value being reached;
  - when the pre-selected value of an angular or linear dimension is exceeded.

201.3.257
TRANSMISSION DETECTOR
RADIATION DETECTOR through which the RADIATION BEAM passes

201.3.258
TREATMENT PARAMETER
factor that describes one aspect of the IRRADIATION of a PATIENT during RADIOTHERAPY

Note 1 to entry: Examples of a TREATMENT PARAMETER include such values as RADIATION ENERGY, SOURCE STRENGTH and TREATMENT TIME.

[SOURCE: IEC 60601-2-17:2013, 201.3.214, modified – Information in the new note moved from the definition.]

201.3.259
TREATMENT VOLUME
<RADIOTHERAPY> region, in the PATIENT, to which the prescribed ABSORBED DOSE is delivered

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing ME EQUIPMENT

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

201.5.1 TYPE TESTS

Addition:

201.5.1.101 Test grades

Three grades of TYPE TEST and three of SITE TEST procedures are SPECIFIED as follows, and used throughout this document:

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– TYPE TEST/SITE 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 a) does not apply.

Replacement of item d):

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

Addition:

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION any additional requirement for testing.

201.5.9.2.1 Test finger

Addition:

Where the nature of the installation renders parts inaccessible to 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 DOCUMENTATION 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:

201.7.1.1 USABILITY of the identification, marking and documents

Addition:

All sub-assemblies, components and ACCESSORIES of ELECTRON ACCELERATORS that can be removed in NORMAL USE, and are relevant to compliance with this document, shall be marked to ensure

- that they can be identified readily and correlated with their ACCOMPANYING DOCUMENTATION;
- that interchangeable devices are individually distinguishable to the OPERATOR both in NORMAL USE and for the purpose of obtaining replacements.

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201.7.2.4 ACCESSORIES

Addition:

For all interchangeable and non-adjustable BEAM LIMITING DEVICES (BLDs) and ELECTRON BEAM APPLICATORS, the dimensions of the GEOMETRICAL RADIATION FIELD at the REFERENCE TREATMENT DISTANCE (RTD) and the distance from the distal end to RTD shall be clearly legible on the outside of the device.

The dimensions of the GEOMETRICAL RADIATION FIELD at the RTD shall be clearly stated in the ACCOMPANYING DOCUMENTATION for all non-adjustable BLDs.

For adjustable devices, the minimum and maximum size of the GEOMETRICAL RADIATION FIELD at the REFERENCE TREATMENT PLANE shall be SPECIFIED in the ACCOMPANYING DOCUMENTATION.

For any ACCESSORY supplied by the MANUFACTURER, the limitations of each device shall be SPECIFIED in the ACCOMPANYING DOCUMENTATION.

Each manually interchangeable RADIATION FILTER and BLD shall be clearly marked to establish its identity.

Any ACCESSORY that could present collision RISK when attached to the ME EQUIPMENT shall be clearly marked on its outside with the distance along the REFERENCE AXIS from its distal end to the REFERENCE TREATMENT DISTANCE.

Compliance is checked by inspection

201.7.2.20 Removable protective means

Addition:

Where the requirements of 7.2.20 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 safety sign 10 of Table D.2 of the general standard, indicating "Follow instructions for use".

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 PROVISION OF SCALES AND INDICATIONS FOR MOVING PARTS

The following non- X-ray based means shall be provided:

a) a means to align the PATIENT with respect to the EQUIPMENT REFERENCE POINT of the ME EQUIPMENT (e.g. LIGHT FIELD, lasers, imaging systems);

NOTE For ISOCENTRIC equipment, the EQUIPMENT REFERENCE POINT is the ISOCENTRE of the ME EQUIPMENT.

b) a means to determine RADIATION SOURCE TO SKIN DISTANCE (e.g. scale, numerical indication, lasers, imaging systems).

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For a) and b) above, if the ME EQUIPMENT only allows ON-LINE X-IGRT TREATMENTs, the use of an X-ray based imaging system may be the only means provided.

A statement indicating the accuracy of each scale or numerical indication of the TREATMENT geometry of the ME EQUIPMENT shall be provided in the ACCOMPANYING DOCUMENTATION.

The following shall be provided for all ACCESSORIES attached either mechanically or electrically to the ME EQUIPMENT that are provided by the MANUFACTURER:

c) a mechanical scale, numerical indication, or status indicator shall be presented to the OPERATOR if the MANUFACTURER's HAZARDS ANALYSIS determines that the information is required for safe operation;

d) when a mechanical scale, numerical read out or a status indicator aligns with an IEC 61217 axis, then the IEC 61217 axis shall be used for each available IEC 61217 movement;

e) when a mechanical scale, numerical read out or a status indicator does not align with an IEC 61217 axis, then the MANUFACTURER shall state in its ACCOMPANYING DOCUMENTATION a transformation method from these coordinates into IEC 61217 coordinates;

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

With all linear displacements along all coordinate axes and all IEC 61217 rotational angles set to zero, the RADIATION BEAM REFERENCE AXIS shall be directed vertically downward and pass through the ERP.

Compliance is checked as follows:

- *TYPE TEST grade A – Statement regarding accuracy of each scale or numerical indication of the TREATMENT geometry of the ME EQUIPMENT.*
- *SITE TEST grade A – Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.*

201.7.8.1 Colours of indicator lights

Replacement:

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

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

When the ME EQUIPMENT cannot automatically correct for misalignment during REAL-TIME ADAPTIVE RADIOTHERAPY, the colour red shall be used as this represents an urgent action required by the OPERATOR.

NOTE 1 In the TREATMENT ROOM or at other locations, these states can require urgent action or caution; different colours, as given in IEC 60601-1:2005, Table 2, can therefore be used in such locations.

NOTE 2 When computer generated, the hue of the colours stated above are determined to be correctly displayed through usability testing.

NOTE 3 Icons on a computer DISPLAY that change colours as a result of the ME EQUIPMENT states above are considered indicator lights regardless of any text that can exist with the icon.

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201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

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

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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
201.7.4.101	†				
201.7.9.2.5	†				
201.9.2.4.101		†			
201.9.2.5	†				
201.110	a) d) c)			a) b) e) f) g)	
201.10.1.1			†		
201.10.101.1.1.2	b) d) e)		d)		a) b) c)
201.10.101.1.1.3	a) b)		b) c)		b)
201.10.101.1.1.4	d) f) g)			a) b) c) d) e) f) g)	
201.10.101.1.1.5	a) b) c) d)				b) c) d)
201.10.101.1.1.6	a)				b)
201.10.101.1.7	d) e)			a)	b)
201.10.101.1.8				b) c) d) e)	
201.10.101.1.9	a) b) c) d) e)	d)	b)		c)
201.10.101.1.10	d) e)		f)	a) b) c) e) g)	
201.10.101.1.11	c) e)		a)		b) d)
201.10.101.1.12	a) b) c) d)				c) d)
201.10.101.1.13		†			
201.10.101.1.14	e)			a) b) c) d) e)	
201.10.101.1.15	†				
201.10.101.1.16	a)			a) b)	
201.10.101.1.17	a)		d)	a) b)	c) e)
201.10.101.1.18	a) c)			d)	a) c)
201.10.101.2.1	†			†	
201.10.101.2.2		†		†	
201.10.101.2.3			†		

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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
201.10.101.3.2.1		a) b) c) d)		a) b) d)	
201.10.101.3.2.2	c)	a) 1), a) 2), b)		a) b)	c)
201.10.101.3.3		†			†
201.10.101.3.4		†			
201.10.101.3.5	† ← *grade A or grade C test* →		†		†
201.10.101.4.1		a) b)		a) b)	
201.10.101.4.2			†		
201.10.101.4.3	b)	a)			
201.10.101.4.4	†			†	
201.10.101.4.5	c)	a)		a) b)	
201.10.101.5.1	†		†		†
201.10.101.5.2	b)	a) b)			
201.105.2	f)	a) b)		c) d) e)	
201.105.3		†		†	
201.106				†	
201.107	†			†	
201.108.2	†			†	
201.108.3	†			†	
201.14.101	†				†
NOTE † denotes requirement of subclause having no other specific identification.					

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Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description are given in Table 201.103.

Table 201.103 – Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description

Check reference	ACCOMPANYING DOCUMENTATION	INSTRUCTIONS FOR USE	Technical description
1			201.5.1.101
2	201.5.4		
3	201.5.9.2.1		
4	201.7.2.4		
5		201.7.3.101	
6	201.7.4.101, second paragraph after b), e)		
7			201.7.9
8	201.7.9.2.2		
9	201.7.9.2.2.101		
10	201.7.9.2.5		
11		201.7.9.2.15	
12	201.7.9.2.17		
13	201.8.4.2		
14			201.8.11.1
15	201.9.2.4.101		
16	201.9.2.5		
17		201.9.2.5	
18		201.9.2.101 a) 1)	
19	201.9.2.101	201.9.2.101	
20		201.9.2.102	
21		201.9.2.103 e)	
22	201.110 a) c) d)		
23	201.9.8.101 b)		
24	201.9.8.102	201.9.8.102	
25			201.10 (see Table 201.101)
26	201.10.101.1.1.2 c) Note		
27			201.10.101.1.1.2 d)
28			201.10.101.1.3 b), c), f)
29			201.10.101.1.4 e)
30		201.10.101.1.5 b)	
31	201.10.101.1.9 e)		
32			201.10.101.1.10 e)
33	201.10.101.1.11 c)		
34		201.10.101.1.11 c)	
35		201.10.101.1.14 e)	
36		201.10.101.1.16 a)	

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Check reference	ACCOMPANYING DOCUMENTATION	INSTRUCTIONS FOR USE	Technical description
37		201.10.101.1.17 a)	
38	201.10.101.1.17 f)		
39		201.10.101.1.18 a)	
40	201.10.101.4.5		
41		201.10.101.5.2 b)	
	201.10.101.5.2		
42	201.10.101.5.3		
43	201.10.101.5.4		
44	201.10.101.5.5		
45	201.103.2.3 a) b)		
46			201.10.101.4.1 b)
47			201.10.101.4.3 b)
48		201.14.101 e)	
49	201.16.2 Note, a), b)		
50	201.17		
51	201.17.101		
52	201.103.1		
53	201.103.2.3 a) b)		
54	201.104 a) b) d) e) f) g) h) i)		
55			201.105.1 a) b)
56	201.105.2 f)		
57	201.105.3	201.106	
58	201.108.2		
59	201.108.3		
NOTE The check reference is given as an aid for checking the availability of compliance documentation.			

201.7.9.2.2 Warning and safety notices

Addition:

The ACCOMPANYING DOCUMENTATION shall describe the devices or systems supplied or recognized by the ME EQUIPMENT MANUFACTURER for use with the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTATION shall warn that any devices or systems not described by the ME EQUIPMENT MANUFACTURER shall be evaluated for correct system operation and safety by the RESPONSIBLE ORGANIZATION.

201.7.9.2.2.101 Interaction of RADIATION with active medical devices

The ACCOMPANYING DOCUMENTATION shall contain a cautionary statement regarding the potential detrimental interaction of the imaging and therapeutic RADIATION on active implantable or body worn medical devices and indicate that:

- the MANUFACTURER of such devices should be contacted for more information,
- the device should be checked for correct operation after the IRRADIATION.

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201.7.9.2.5 ME EQUIPMENT description

Addition:

The MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTATION a method to locate the position of the ERP and EQUIPMENT REFERENCE AXES of the ME EQUIPMENT.

The accuracy of the relationship of all axes of the ME EQUIPMENT to the ERP shall be stated in the ACCOMPANYING DOCUMENTATION.

The accuracy of determining the relationships of the axes to the ERP and the technique of measurement establishing these values shall be stated in the ACCOMPANYING DOCUMENTATION.

The expected stability of the ERP and EQUIPMENT REFERENCE COORDINATE SYSTEM in relation to the ME EQUIPMENT at the time of the last calibration and the recommended frequency of QUALITY ASSURANCE (QA) shall be stated in the ACCOMPANYING DOCUMENTATION.

NOTE An example of items to consider:

- long term mechanical drift;
- short term drift during a fraction (e.g. rotation);
- changes related to OPERATOR activity, for example fitting accessories, removing/deploying hardware;
- changes related to machine position and configuration.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the TREATMENT geometry including accuracy, technique of measurement and importance of periodic reassessment.

201.7.9.2.10 Messages

Addition:

All system messages, error messages, and fault messages required by 7.9.2.10 of the general standard that are intended for the OPERATOR during clinical use and are displayed at the TCP shall identify the reason for the message and provide possible actions for the OPERATOR to respond promptly and appropriately to the message.

NOTE It is intended that the OPERATOR be shown all information needed to make an informed decision concerning the continuation or TERMINATION of the TREATMENT without the need to reference other information.

201.7.9.2.15 Environmental protection

Addition:

The INSTRUCTIONS FOR USE shall provide guidance and advice on precautions to be taken regarding the identification, handling and disposal of ME EQUIPMENT or ME EQUIPMENT parts that may exhibit RADIOACTIVITY.

201.7.9.2.17 ME EQUIPMENT emitting RADIATION

Replacement:

To assist the RESPONSIBLE ORGANIZATION's RADIOLOGICAL PROTECTION adviser, the following information shall be provided in the ACCOMPANYING DOCUMENTATION:

– For each NOMINAL ENERGY:

  - maximum electron energy striking the TARGET or ELECTRON WINDOW and corresponding maximum ABSORBED DOSE RATES at RTD under conditions of NORMAL USE for

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  - X-RADIATION, with and without any ADDED FILTER if NORMAL USE is possible in both these states, and
  - ELECTRON RADIATION;
- dimensioned shape of the maximum RADIATION FIELDS at RTD for X-RADIATION and ELECTRON RADIATION;
- location(s), referenced to accessible points on the RADIATION HEAD, of
  - the surface of the TARGET facing the PATIENT, and
  - the ELECTRON BEAM RADIATION window;
- available directions of the RADIATION BEAM.

– For each X-RADIATION NOMINAL ENERGY, if a primary RADIATION BEAM shield (a "beam stopper") is incorporated, its transmission factor shall be provided in the ACCOMPANYING DOCUMENTATION.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

Addition to item d):

These requirements do not apply where the installation prevents the test rod or the test pin from being inserted into the openings concerned. The ACCOMPANYING DOCUMENTATION shall state when these conditions apply.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Addition to item b):

– with the ME EQUIPMENT energised in the PREPARATORY STATE and with the worst possible combination of simultaneously powered movements.

201.8.7.3 Allowable values

Replacement of item d):

The EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 10 mA.

NOTE Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710.

The allowable values of the EARTH LEAKAGE CURRENT are permitted for each sub-assembly of the ELECTRON ACCELERATOR that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central PROTECTIVE EARTH TERMINAL may be provided inside the outer ENCLOSURE or cover of the ELECTRON ACCELERATOR. If other sub-assemblies or ASSOCIATED EQUIPMENT are connected to the PROTECTIVE EARTH TERMINAL, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

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