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INTERNATIONAL STANDARD

Medical electrical equipment – Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-68:2014. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 60601-2-68 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

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

a) alignment with the new editions of the relevant standards:
   – IEC 60601-2-1:2020;
   – IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016;
   – IEC 60601-2-64:2014;
b) clarification of the use of IEC 60601-2-68 for CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE);
c) introduction of updated requirements related to MECHANICAL HAZARDS, RADIATION HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

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

Draft	Report on voting
62C/927/FDIS	62C/941/RVD

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

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

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

In this document, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT 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 document are by number only.

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

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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.

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

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMES/critical structures may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy ~~may~~ can extend over many days, during which the TARGET VOLUME/PATIENT ~~may~~ can shrink or grow ~~and/~~or move. Hence, the exact location of the TARGET VOLUME/critical structures ~~may~~ can change between the time of TREATMENT PLANNING imaging and the actual administration of a TREATMENT.

IMAGE-GUIDED RADIOTHERAPY (IGRT) combines planar or volumetric imaging during the course of RADIOTHERAPY to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR ~~AND/~~or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs ~~and/~~or other reference features, to compensate for anatomical changes including internal organ motions ~~and/~~or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

This document establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with an EXTERNAL BEAM EQUIPMENT such as an ELECTRON ACCELERATOR, ~~medical~~ LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT, for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

~~This particular standard applies to X-ray based IGRT equipment used in-room for IGRT purposes. This particular standard does not apply to standard CT scanners, which are not used for IGRT. However if a CT scanner is used in-room with a linear (electron) accelerator (linac) for IGRT then this particular standard applies.~~

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, the IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1:2009). However, since IGRT usage ~~may or may~~ does not ~~require~~ necessarily have such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

This document deals with the safety aspect of image acquisitions, image analysis, data transfer and TREATMENT replanning or EBE/PATIENT repositioning.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT, and REAL-TIME X-IGRT.

X-IGRT EQUIPMENT is also related to the following current publications:

~~– IEC 60976, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*~~

~~– IEC TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics.*~~

– IEC 60601-2-1

– IEC 60601-2-44

– IEC 60601-2-64

– IEC 62083

– IEC 61217

– IEC 62274

~~This particular standard may give rise to amendments to some of the above standards.~~

This document will focus on the safety aspects of the primary function of X-IGRT. It will not focus on emerging technologies within the field so as to not hinder progress, yet it will define a safe way of achieving X-IGRT.

MEDICAL ELECTRICAL EQUIPMENT –

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201.1 Scope, object and related standards

Clause 1 of ~~the general standard[1]~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-ray based IMAGE-GUIDED RADIOTHERAPY equipment for use with EXTERNAL BEAM EQUIPMENT (EBE).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices integrated in a ~~known~~ specified geometrical relationship with EBE for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT ~~EXTERNAL BEAM~~ EBE SYSTEM ~~(X-IGRT EBS)~~. For example, in the case of ONLINE X-IGRT, the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

This document does not apply to CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY, that are not intended for use for IGRT.

Requirements that are being tested according to another standard can be identified by the manufacturer. If these requirements are equivalent, retesting is not required, but instead evidence can refer to the CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY for RADIOSCOPY manufacturer's compliance statements or test reports.

If the X-IGRT EQUIPMENT is combined with an MEE, any requirement that is the same for the X-IGRT EQUIPMENT and the MEE, such as a PATIENT POSITIONER, is not required to be tested twice, but can be accepted as tested by the MEE.

This document applies to X-RAY EQUIPMENT for RADIOGRAPHY, RADIOSCOPY, and COMPUTER TOMOGRAPHY used for IGRT.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE SYSTEMS, the content of that clause or subclause will say so. Where that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

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

This document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of ~~appropriately licensed or~~ the RESPONSIBLE ORGANIZATION by 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, and
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

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

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-IGRT EQUIPMENT and X-IGRT EBE SYSTEMS.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-3 and IEC 60601-1-6 apply as modified in Clause 203 and Clause 206 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.~~139~~154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

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

201.2 Normative references

NOTE Informative references are listed in the bibliography.

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

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

~~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 60601-1:2005/AMD2:2020

IEC 60601-2-1:~~2009~~2020, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

~~IEC 60601-2-44:2012, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*~~

~~IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*~~

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

~~IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*~~

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*

~~IEC 61223-3-5:2004, *Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*~~

~~IEC 61262-7:1995, *Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 7: Determination of the modulation transfer function*~~

~~IEC 62083:2009, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*~~

~~IEC 62274:2005, *Medical electrical equipment – Safety of radiotherapy record and verify systems*~~

~~IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*~~

~~IEC 62396-1:2012, *Process management for avionics – Atmospheric radiation effects – Part 1: Accommodation of atmospheric radiation effects via single event effects within avionics electronic equipment*~~

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*

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

~~NOTE Informative references are listed in the bibliography beginning on page 58.~~

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

Appareils électromédicaux – Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60601-2-68 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

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

a) alignment with the new editions of the relevant standards:
   – IEC 60601-2-1:2020;

  - IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016;
  - IEC 60601-2-64:2014;

b) clarification of the use of IEC 60601-2-68 for CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE);

c) introduction of updated requirements related to MECHANICAL HAZARDS, RADIATION HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

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

Draft	Report on voting
62C/927/FDIS	62C/941/RVD

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

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

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

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT 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 document are by number only.

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

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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.

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

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMES/critical structures may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy can extend over many days, during which the TARGET VOLUME/PATIENT can shrink or grow or move. Hence, the exact location of the TARGET VOLUME/critical structures can change between the time of TREATMENT PLANNING imaging and the actual administration of a TREATMENT.

IMAGE-GUIDED RADIOTHERAPY (IGRT) combines planar or volumetric imaging during the course of RADIOTHERAPY to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs or other reference features, to compensate for anatomical changes including internal organ motions or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

This document establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with an EXTERNAL BEAM EQUIPMENT such as an ELECTRON ACCELERATOR, LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT, for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, the IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1:2009). However, since IGRT usage does not necessarily have such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

This document deals with the safety aspect of image acquisitions, image analysis, data transfer and TREATMENT replanning or EBE/PATIENT repositioning.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT, and REAL-TIME X-IGRT.

X-IGRT EQUIPMENT is also related to the following current publications:

– IEC 60601-2-1
– IEC 60601-2-44
– IEC 60601-2-64
– IEC 62083
– IEC 61217
– IEC 62274

This document will focus on the safety aspects of the primary function of X-IGRT. It will not focus on emerging technologies within the field so as to not hinder progress, yet it will define a safe way of achieving X-IGRT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-ray based IMAGE-GUIDED RADIOTHERAPY equipment for use with EXTERNAL BEAM EQUIPMENT (EBE).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices integrated in a specified geometrical relationship with EBE for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EBE SYSTEM. For example, in the case of ONLINE X-IGRT, the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

This document does not apply to CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY, that are not intended for use for IGRT.

Requirements that are being tested according to another standard can be identified by the manufacturer. If these requirements are equivalent, retesting is not required, but instead evidence can refer to the CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY for RADIOSCOPY manufacturer's compliance statements or test reports.

If the X-IGRT EQUIPMENT is combined with an MEE, any requirement that is the same for the X-IGRT EQUIPMENT and the MEE, such as a PATIENT POSITIONER, is not required to be tested twice, but can be accepted as tested by the MEE.

This document applies to X-RAY EQUIPMENT for RADIOGRAPHY, RADIOSCOPY, and COMPUTER TOMOGRAPHY used for IGRT.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE SYSTEMS, the content of that clause or subclause will say so. Where that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

This document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS 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, and
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

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

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-IGRT EQUIPMENT and X-IGRT EBE SYSTEMS.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-3 and IEC 60601-1-6 apply as modified in Clause 203 and Clause 206 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

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

201.2 Normative references

NOTE Informative references are listed in the bibliography.

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

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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

IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

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*

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1*: *Evaluation methods*

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

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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9) L'IEC attire l'attention sur le fait que la mise en application du présent document peut entraîner l'utilisation d'un ou de plusieurs brevets. L'IEC ne prend pas position quant à la preuve, à la validité et à l'applicabilité de tout droit de brevet revendiqué à cet égard. À la date de publication du présent document, l'IEC n'avait pas reçu notification qu'un ou plusieurs brevets pouvaient être nécessaires à sa mise en application. Toutefois, il y a lieu d'avertir les responsables de la mise en application du présent document que des informations plus récentes sont susceptibles de figurer dans la base de données de brevets, disponible à l'adresse https://patents.iec.ch. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-68 a été établie par le sous-comité 62C: Appareils de radiothérapie, de médecine nucléaire et de dosimétrie du rayonnement, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette deuxième édition annule et remplace la première édition parue en 2014. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) alignement sur les nouvelles éditions des normes pertinentes:
   – IEC 60601-2-1:2020;
   – IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 et IEC 60601-2-44:2009/AMD2:2016;
   – IEC 60601-2-64:2014;
b) clarification de l'utilisation de l'IEC 60601-2-68 pour les TOMODENSITOMETRES, les APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE et la RADIOSCOPIE utilisés dans la même salle avec un APPAREIL DE RADIOTHERAPIE EXTERNE (EBE);
c) introduction d'exigences actualisées relatives aux DANGERS MECANIQUES, aux DANGERS DUS AU RAYONNEMENT, aux SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP), à la DOCUMENTATION D'ACCOMPAGNEMENT d'un SYSTEME EM, et au FONCTIONNEMENT A DISTANCE.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62C/927/FDIS	62C/941/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;
– *modalités d'essais: caractères italiques;*
– indications de nature informative qui apparaissent hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
– TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, L'IEC 60601-1:2005/AMD1:2012 ET L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU COMME CELA EST NOTE: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, le 7.1, le 7.2 et le 7.2.1 sont tous des paragraphes de l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" a la valeur d'un "ou inclusif". Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– le verbe "devoir" signifie que la conformité à une exigence ou à un essai est obligatoire pour assurer la conformité au présent document;
– l'expression "il convient" signifie que la conformité à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour assurer la conformité au présent document;
– le verbe "pouvoir" est utilisé afin de décrire un moyen admissible pour assurer la conformité à exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties des séries IEC 60601, publiées sous le titre général *Appareils électromédicaux*, se trouve sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

INTRODUCTION

Les pratiques de RADIOTHERAPIE modernes utilisent des informations issues de différentes modalités d'imagerie, acquises avant de lancer la thérapie, afin de planifier le TRAITEMENT à engager. L'imagerie fournit des informations sur l'emplacement du VOLUME CIBLE et d'autres caractéristiques anatomiques, de manière à pouvoir établir un PLAN DE TRAITEMENT qui permet une distribution optimale de la dose afin de réunir au mieux les conditions d'obtention de l'effet de TRAITEMENT prévu, tout en réduisant le plus possible les effets secondaires.

Des difficultés surgissent cependant lorsqu'il s'agit d'appliquer le RAYONNEMENT, du fait du mouvement constant des VOLUMES CIBLES/structures critiques à l'intérieur du corps. Par exemple, dans les parties du corps mobiles en phase de respiration, la position ou la forme des VOLUMES CIBLES/structures critiques peut varier au cours de l'application du FAISCEAU DE RAYONNEMENT sur toute fraction donnée. De plus, un programme de thérapie peut se prolonger sur plusieurs jours, au cours desquels le VOLUME CIBLE/PATIENT peut rétrécir, croître ou bouger. De ce fait, l'emplacement exact du VOLUME CIBLE/des structures critiques peut être modifié entre le cycle d'imagerie de PLANIFICATION des TRAITEMENTS et l'administration réelle d'un TRAITEMENT.

La RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE (IGRT, *Image-Guided RadioTherapy*) combine image planaire ou volumétrique au cours du programme de RADIOTHERAPIE pour ajuster l'administration du TRAITEMENT en fonction de l'anatomie du PATIENT et de sa position. Ceci permet à l'OPERATEUR ou à l'APPAREIL DE RADIOTHERAPIE EXTERNE (EBE) d'ajuster l'application du FAISCEAU DE RAYONNEMENT en fonction des informations d'imagerie, telles que la position du VOLUME CIBLE, les organes critiques ou d'autres caractéristiques de référence, afin de compenser les changements anatomiques, y compris les déplacements d'organes internes ou les incertitudes liées à la définition du TRAITEMENT. Les plus grandes exactitude et précision obtenues permettent d'appliquer des doses plus élevées de RAYONNEMENT au VOLUME CIBLE et de réduire la proportion de cellules saines affectées par le RAYONNEMENT. Cette pratique est souvent associée à d'autres appareils de surveillance.

Le présent document définit les exigences auxquelles les FABRICANTS sont tenus de satisfaire dans la conception et la construction des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE (X-IGRT).

Le présent document couvre les aspects de sécurité des dispositifs d'imagerie à rayonnement X sous kilotension (kV) et sous mégatension (MV) dans une relation géométrique connue avec un APPAREIL DE RADIOTHERAPIE EXTERNE tel qu'un ACCELERATEUR D'ELECTRONS, un APPAREIL ELECTROMEDICAL PAR FAISCEAU D'IONS LEGERS ou un APPAREILS DE THERAPIE PAR FAISCEAU DE RADIONUCLEIDES, à des fins de RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE. Il couvre les aspects de communication et les relations entre les APPAREILS DE RADIOTHERAPIE EXTERNES et les dispositifs d'imagerie à rayonnement X fixés ou non directement fixés, mais présents dans la même zone protégée contre le RAYONNEMENT que les APPAREILS DE RADIOTHERAPIE EXTERNES, et destinés à être utilisés uniquement avec ces appareils.

Il convient que le FABRICANT tienne compte des normes de diagnostic pertinentes lorsqu'il effectue une ANALYSE DE DANGER. Par exemple, la qualité des DISPOSITIFS DE VISUALISATION DES IMAGES est spécifiée dans les documents IEC concernant l'application pratique des diagnostics (par exemple, IEC 62563-1:2009). Toutefois, dans la mesure où l'application de la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE n'implique pas nécessairement des exigences si sévères, la spécification de ce qu'exige l'utilisation des APPAREILS X-IGRT incombe à leur FABRICANT.

Le présent document traite des aspects de sécurité liés aux acquisitions et à l'analyse des images, ainsi qu'au transfert de données et à la replanification des TRAITEMENTS, ou au repositionnement des APPAREILS DE RADIOTHERAPIE EXTERNES/du PATIENT.

Le présent document traite des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE HORS LIGNE, EN LIGNE et EN TEMPS REEL.

Les APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE sont également associés aux publications actuelles suivantes:

– IEC 60601-2-1
– IEC 60601-2-44
– IEC 60601-2-64
– IEC 62083
– IEC 61217
– IEC 62274

Le présent document cible les aspects de sécurité liés à la fonction principale de la RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE. Il ne cible pas les nouvelles technologies du domaine de manière à ne pas entraver leur évolution, mais définit cependant une méthode sûre de réalisation de la RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE destinés à être utilisés avec les APPAREILS DE RADIOTHERAPIE EXTERNES (EBE).

Le présent document couvre les aspects de sécurité des dispositifs d'imagerie à rayonnement X sous kilotension (kV) et sous mégatension (MV) intégrés dans une relation géométrique spécifiée avec les EBE à des fins de RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE. Il couvre les aspects de communication et les relations entre les APPAREILS DE RADIOTHERAPIE EXTERNES et les dispositifs d'imagerie à rayonnement X fixés ou non directement fixés, mais présents dans la même zone protégée contre le RAYONNEMENT que les APPAREILS DE RADIOTHERAPIE EXTERNES, et destinés à être utilisés uniquement avec ces appareils.

Le présent document traite des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE HORS LIGNE, EN LIGNE et EN TEMPS REEL. Il couvre les procédures de réduction du risque de confiance excessive envers le SYSTEME EBE X-IGRT. Par exemple, dans le cas d'une RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE EN LIGNE, le FABRICANT fournit une interface interactive destinée à l'interaction des utilisateurs avec la correction proposée par le système.

Le présent document ne s'applique pas aux TOMODENSITOMETRES, aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE et aux APPAREILS A RAYONNEMENT X pour la RADIOSCOPIE, qui ne sont pas conçus pour être utilisés pour la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE.

Les exigences soumises à l'essai conformément à une autre norme peuvent être identifiées par le fabricant. Lorsque ces exigences sont équivalentes, de nouveaux essais ne sont pas exigés, mais la conformité peut être prouvée par les déclarations de conformité ou les rapports d'essai relatifs aux TOMODENSITOMETRES, aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE ou aux APPAREILS A RAYONNEMENT X pour les APPAREILS DE RADIOSCOPIE fournis par le fabricant.

Lorsqu'un APPAREIL DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE est combiné à un APPAREIL ELECTROMEDICAL, toutes les exigences communes à l'APPAREIL DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE et à l'APPAREIL ELECTROMEDICAL (par exemple, un POSITIONNEUR DE PATIENT) n'ont pas besoin d'être soumises à l'essai deux fois, mais peuvent être admises comme ayant été soumises à l'essai par l'APPAREIL ELECTROMEDICAL.

Le présent document s'applique aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE, la RADIOSCOPIE et la TOMODENSITOMETRIE utilisées pour la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE.

Si un article ou un paragraphe est destiné spécifiquement à s'appliquer aux SYSTEMES EBE X-IGRT, le contenu de cet article ou de ce paragraphe l'indique de manière explicite. Si tel n'est pas le cas, l'article ou le paragraphe s'applique uniquement aux APPAREILS X-IGRT.

Le présent document, y compris les ESSAIS DE TYPE et les ESSAIS SUR LE SITE, s'applique respectivement au FABRICANT et à certains aspects d'installation des SYSTEMES EBE X-IGRT destinés à être

- pour une UTILISATION NORMALE, manipulés, sous la responsabilité de l'ORGANISME RESPONSABLE, par des PERSONNES QUALIFIEES qui disposent des compétences exigées pour une application médicale particulière, à des fins cliniques spécifiées particulières, par exemple RADIOTHERAPIE A CHAMP FIXE ou RADIOTHERAPIE CINETIQUE,
- entretenus selon les recommandations données dans les INSTRUCTIONS D'UTILISATION, et
- vérifiés périodiquement par une PERSONNE QUALIFIEE selon un programme d'assurance qualité qui porte sur le contrôle des performances et de l'étalonnage.

NOTE Dans le présent document, toutes les références à l'installation se rapportent à l'installation dans les locaux de l'ORGANISME RESPONSABLE.

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS X-IGRT et des SYSTEMES EBE X-IGRT.

201.1.3 Normes collatérales

Addition:

Le présent document fait référence aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et à l'Article 201.2 du présent document.

L'IEC 60601-1-3 et l'IEC 60601-1-6 s'appliquent telles qu'elles sont modifiées à l'Article 203 et à l'Article 206, respectivement. Les normes IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 et IEC 60601-1-11 ne s'appliquent pas. Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et dans les normes collatérales en fonction de l'APPAREIL EM concerné. Elles peuvent également ajouter des exigences supplémentaires pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, le 201.1 du présent document concerne le contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x représente le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, le 202.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, le 203.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte du présent document.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte du présent document.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotées de 3.1 à 3.154, les définitions qui sont ajoutées dans le présent document sont numérotées à partir de 201.3.201. Les annexes qui sont ajoutées sont notées AA, BB, etc., et les éléments qui sont ajoutés aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, à toutes les normes collatérales applicables et au présent document, pris en compte ensemble.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

201.2 Références normatives

NOTE Une liste des références informatives est donnée dans la bibliographie.

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-3:2008, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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

IEC 60601-2-4:2010, *Appareils électromédicaux – Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

IEC 61000-4-3, *Compatibilité électromagnétique (CEM) – Partie 4-3: Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61217:2011, *Appareils utilisés en radiothérapie – Coordonnées, mouvements et échelles*

IEC 62563-1, *Appareils électromédicaux – Systèmes d'imagerie médicale – Partie 1: Méthodes d'évaluation*

CISPR 11, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*