BS EN IEC 60601-2-68:2025

BSI Standards Publication

# 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

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Full document details: BS EN IEC 60601-2-68:2025

# National foreword

This British Standard is the UK implementation of EN IEC 60601-2-68:2025. It is identical to IEC 60601-2-68:2025. It supersedes BS EN 60601-2-68:2015, which will be withdrawn on 30 April 2028.

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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**Amendments/corrigenda issued since publication**

| Date | Text affected |
|---|---|

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN IEC 60601-2-68

April 2025

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Supersedes EN 60601-2-68:2015

English Version

# 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 (IEC 60601-2-68:2025)

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 (IEC 60601-2-68:2025)

Medizinische elektrische Geräte - Teil 2-68: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von röntgenstrahlungsbasierten Geräten für die bildgesteuerte Strahlentherapie zur Verwendung mit Elektronenbeschleunigern, Leichtionen-Strahlentherapiesystemen und Radionuklid-Strahlentherapiesystemen (IEC 60601-2-68:2025)

This European Standard was approved by CENELEC on 2025-03-11. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

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# European foreword

The text of document 62C/927/FDIS, future edition 2 of IEC 60601-2-68, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-68:2025.

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) 2026-04-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-04-30

This document supersedes EN 60601-2-68:2015 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

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

## Endorsement notice

The text of the International Standard IEC 60601-2-68:2025 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 standard indicated:

| | | |
|---|---|---|
| IEC 60336:2020 | NOTE | Approved as EN IEC 60336:2021 (not modified) |
| IEC 60364-7-710:2021 | NOTE | Approved as HD 60364-7-710:—[1] (not modified) + A11:—[2] |
| IEC 60601-1-9 | NOTE | Approved as EN 60601-1-9 |
| IEC 60601-1-10 | NOTE | Approved as EN 60601-1-10 |
| IEC 60601-2-4:2010 | NOTE | Approved as EN 60601-2-4:2011 (not modified) |
| IEC 60601-2-8 | NOTE | Approved as EN 60601-2-8 |
| IEC 60601-2-11:2013 | NOTE | Approved as EN 60601-2-11:2015 (not modified) |
| IEC 60601-2-17 | NOTE | Approved as EN 60601-2-17 |
| IEC 60601-2-28:2017 | NOTE | Approved as EN IEC 60601-2-28:2019 (not modified) |
| IEC 60601-2-44:2009 | NOTE | Approved as EN 60601-2-44:2009 (not modified) + A11:2011 |

[1] Under preparation. Stage at the time of publication: HD 60364-7-710:2025.

[2] Under preparation. Stage at the time of publication: HD 60364-7-710:2025/A11:2025.

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| | | |
|---|---|---|
| IEC 60601-2-44:2009/A1:2012 | NOTE | Approved as EN 60601-2-44:2009/A1:2012 (not modified) |
| IEC 60601-2-44:2009/A2:2016 | NOTE | Approved as EN 60601-2-44:2009/A2:2016 (not modified) |
| IEC 60601-2-54 | NOTE | Approved as EN IEC 60601-2-54 |
| IEC 60601-2-64:2014 | NOTE | Approved as EN 60601-2-64:2015 (not modified) |
| IEC 60731:2011 | NOTE | Approved as EN 60731:2012 (not modified) |
| IEC 60976:2007 | NOTE | Approved as EN 60976:2007 (not modified) |
| IEC 61223-3-5:2019 | NOTE | Approved as EN IEC 61223-3-5:2019 (not modified) |
| IEC 61262-7:1995 | NOTE | Approved as EN 61262-7:1995 (not modified) |
| IEC 61674 | NOTE | Approved as EN IEC 61674 |
| IEC 62083:2009 | NOTE | Approved as EN 62083:2009 (not modified) |
| IEC 62220-1-1:2015 | NOTE | Approved as EN 62220-1-1:2015 (not modified) |
| IEC 62274:2005 | NOTE | Approved as EN 62274:2005 (not modified) |
| IEC 62366-1:2015 | NOTE | Approved as EN 62366-1:2015 (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.cencenelec.eu.

*Clause 2 of EN 60601-1:2006[3] applies, except as follows:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| *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 | EN 60601-1-3 | 2008 |
| - | - | | + corrigendum Mar. | 2010 |
| + A1 | 2013 | | + A1 | 2013 |
| - | - | | + AC | 2014 |
| - | - | | + A11 | 2016 |
| + A2 | 2021 | | + A2 | 2021 |
| *Addition:* | | | | |
| 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 |
| + A2 | 2020 | | + A2 | 2021 |
| - | - | | + A13 | 2024 |

[3] As impacted by EN 60601-1:2006/Corrigendum Mar. 2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024,

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| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| 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 | EN IEC 60601-2-1 | 2021 |
| IEC 60601-2-4 | 2010 | Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators | EN 60601-2-4 | 2011 |
| 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 | EN IEC 61000-4-3 | - |
| IEC 61217 | 2011 | Radiotherapy equipment - Coordinates, movements and scales | EN 61217 | 2012 |
| IEC 62563-1 | 2009 | Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods | EN 62563-1 | 2010 |
| CISPR 11 | 2024 | Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement | - | - |

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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.
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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;

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  - 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.

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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.

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# 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

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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.

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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

## 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.

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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.

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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.

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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*

## 201.3 Terms and definitions

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

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

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

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*Additional terms and definitions:*

**201.3.201**
**COMPUTED TOMOGRAPHY DOSE INDEX 100**
***CTDI*$_{100}$**
integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following:

for $N \times T$ less than or equal to 40 mm

$$CTDI_{100} = \int_{-50\,\mathrm{mm}}^{+50\,\mathrm{mm}} \frac{D(y)}{N \times T} dy$$

for $N \times T$ greater than 40 mm (all IGRT IMAGING PROTOCOL except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50\,\mathrm{mm}}^{+50\,\mathrm{mm}} \frac{D_{\mathrm{Ref}}(y)}{(N \times T)_{\mathrm{Ref}}} dy \times \frac{CTDI_{\text{free air, } N \times T}}{CTDI_{\text{free air, Ref}}}$$

where

| | |
|---|---|
| $D(y)$ | is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2); |
| $(N \times T)_{\mathrm{Ref}}$ | is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm; |
| $D_{\mathrm{Ref}}(y)$ | is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2) for $(N \times T)_{\mathrm{Ref}}$; |
| $CTDI_{\text{free air, } N \times T}$ | is the $CTDI_{\text{free air}}$ (201.3.202) for a specific value of $N \times T$; |
| $CTDI_{\text{free air, Ref}}$ | is the $CTDI_{\text{free air}}$ (201.3.202) for $(N \times T)_{\mathrm{Ref}}$; |
| $N$ | is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source; |
| $T$ | is the NOMINAL TOMOGRAPHIC SECTION THICKNESS. |

Note 1 to entry: The dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

Note 2 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$.

Note 3 to entry: A single axial scan is typically a 360° rotation of the X-ray source. For CBCT partial rotations are still considered as a single axial scan.

Note 4 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "y-flying FOCAL SPOT" or with CBCT modes that merge multiple scans, the denominator of the integral needs to be replaced by the total nominal width along $y$ of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced with 0,5 x $N$ x $T$.

Note 5 to entry: Typically, the $y$-axis is the axis of rotation (the $y$-axis corresponds to the $z$-axis in the DICOM coordinate system).

Note 6 to entry: The $CTDI_{100}$ is designed to include most of the scattered RADIATION.

Note 7 to entry: See IEC 60601-2-44:2009/AMD1:2012, Annex CC for more explanation.

Note 8 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber is used.

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[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modified – Notes 3, 4 and 5 to entry have been extended, and Note 8 to entry added.]

**201.3.202**
**COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR**
***CTDI*$_{\text{free air}}$**
integral of the DOSE PROFILE representative of a single axial scan along a line through the ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(y)}{N \times T} dy$$

where

*D(y)* is the DOSE PROFILE representative of a single axial scan along a line through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

*N* is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

*T* is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

*L* is at least $(N \times T)$ +40 mm.

Note 1 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$. The y axis corresponds to the z axis in the DICOM coordinate system.

Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "*y*-flying FOCAL SPOT" or with CBCT modes that merges multiple scans, the denominator of the integral needs to be replaced by the total nominal width along *y* of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by $0{,}5 \times N \times T$.

Note 3 to entry: Typically, a RADIATION DETECTOR of length *L* or longer is used. Annex DD provides an example for alternate measurements.

Note 4 to entry: For CBCT, the imaging is not slice based and $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber or ion chamber, and a build-up cap is used.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modified – Note 1 and 2 to entry have been extended and Notes 4 and 5 to entry added.]

**201.3.203**
**CONE BEAM COMPUTED TOMOGRAPHY**
**CBCT**
computed tomography performed using a cone beam of X-RADIATION

**201.3.204**
**CONTRAST TO NOISE RATIO**
**CNR**
physical quantity describing the ability to distinguish between various contrast objects of a digital image and the inherent noise within the image, defined as the difference of mean pixel values of the contrast objects and image background, and divided by the standard deviation of the image background pixel value

Note 1 to entry: $C = \frac{|S_A - S_B|}{\sigma_0}$

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$S_A$ and $S_B$ are signal intensities for the signal producing structures A and B in the region of interest and $\sigma_0$ is the standard deviation of the image noise. The MANUFACTURER specifies the structures defining A and B.

[SOURCE: IEC 61223-3-2:2007, 3.8, modified – Two notes to entry have been added.]

**201.3.205**
**DOSE-LENGTH PRODUCT**
**DLP**
index characterizing the product of the $CTDI_{vol}$ and the total length scanned

a) For axial scanning

$$DLP = CTDI_{vol} \times \Delta d \times n$$

where

$\Delta d$ is the PATIENT SUPPORT travel in y-direction between consecutive scans;

$n$ is the number of scans in the series.

b) For helical scanning

$$DLP = CTDI_{vol} \times L$$

where

$L$ is the table travel during the entire LOADING, adjusted for dynamic collimation modes where applicable.

Note 1 to entry: $L$ might be longer than the programmed scan length.

Note 2 to entry: The time weighted average of $CTDI_{vol}$ is to be used if $CTDI_{vol}$ is variable.

Note 3 to entry: A way for obtaining $L$ could be to use the FWHM along a line perpendicular to the TOMOGRAPHIC PLANE at isocentre of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.

c) For scanning without movement of the PATIENT SUPPORT

$$DLP = CTDI_{vol} \times N \times T$$

where

$N$ is the number of TOMOGRAPHIC SECTIONS PRODUCED in a single axial scan of the X-ray source;

$T$ is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

Note 4 to entry: For CBCT, usually only c) is applicable where $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: Typically, the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

d) For axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$DLP = CTDI_{vol} \times \left( (N \times T) + R \right)$$

where

$N$ is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

$T$ is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

$R$ is the distance between the two positions.

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[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.214, modified – Notes 4 and 5 to entry have been added.]

**201.3.206**
**DOSE PROFILE**
representation of the dose as a function of position along a line

[SOURCE: IEC 60601-2-44:2009, 201.3.205]

**201.3.207**
**EQUIPMENT REFERENCE POINT**
**ERP**
point in space used for referencing dimensions and positions of equipment and performing dosimetry measurements

**201.3.208**
**EXTERNAL BEAM EQUIPMENT**
**EBE**
external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, light ion beam medical electrical equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

**201.3.209**
**IGRT EQUIPMENT**
ME EQUIPMENT that provides IGRT functionality

**201.3.210**
*** IGRT LATENCY**
time from initiation of image acquisition to output signal by X-IGRT EQUIPMENT to the EBE

Note 1 to entry: It is expected that the EBE can also state its latency time from receiving the signal to providing the correction.

Note 2 to entry: The IGRT LATENCY includes the hardware and software latencies.

Note 3 to entry: Network transfer times vary from one installation to another as there are too many factors involved that are supplied by the RESPONSIBLE ORGANIZATION. Network transfer latency therefore is not considered as part of the IGRT LATENCY time.

**201.3.211**
**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 beam to TARGET VOLUME

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

[SOURCE: IEC 60976:2007, 3.8, modified — Addition of Note 1 to entry.]

**201.3.212**
**IMAGING PROTOCOL**
set of parameters necessary to perform imaging

Note 1 to entry: The following modes are examples of different types of imaging: radiography, radioscopy, helical, axial, axial series, scanning without movement of the PATIENT POSITIONER and shuttle mode.

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Note 2 to entry: To maintain consistency with their respective user interfaces and documentation, various X-IGRT EQUIPMENT might use terminology different from "IMAGING PROTOCOL", e.g., "scan", "scan group", "scan series", "presets", "CBCT modes" etc.

Note 3 to entry: An IMAGING PROTOCOL is typically associated with a IGRT task, anatomical region, age or size group.

**201.3.213**
**IMAGE RECONSTRUCTION**
method to process acquired data into an image data set that can be used for analysis

Note 1 to entry: The analysis of the reconstructed image data set can be for the purpose of IMAGE REGISTRATION against reference data.

**201.3.214**
**IMAGE REGISTRATION**
method for mapping or registering corresponding points from one image data set to another

Note 1 to entry: IMAGE REGISTRATION can be rigid or deformable.

**201.3.215**
**IMAGING SESSION**
length of continuous time that images are taken of the PATIENT while the PATIENT remains on the PATIENT positioning device

Note 1 to entry: If the PATIENT is removed from the PATIENT positioning device, the imaging session is ended.

**201.3.216**
**KILOVOLTAGE X-IGRT EQUIPMENT**
X-IGRT EQUIPMENT using kilovoltage X-RADIATION

**201.3.217**
**MEGAVOLTAGE X-IGRT EQUIPMENT**
X-IGRT EQUIPMENT using megavoltage X RADIATION

**201.3.218**
**MODULATION TRANSFER FUNCTION**
**MTF**
modulus of the generally complex OPTICAL TRANSFER FUNCTION, expressed as a function of SPATIAL FREQUENCIES $u$ and $v$

Note 1 to entry: The MTF can be determined in several ways, e.g., from the Fourier transforms of the point spread function (PSF), the line spread function (LSF) and the edge spread function (ESF). Any method is acceptable if performed correctly.

[SOURCE: IEC 62220-1-1:2015, 3.10, modified – A note to entry has been added, and the symbol for the term has been changed.]

**201.3.219**
**NOMINAL REFERENCE DISTANCE**
<X-RADIATION> SPECIFIED distance along the REFERENCE AXIS, which is for X-RADIATION, from the TARGET surface of the exiting beam to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT of the X-IGRT EQUIPMENT

**201.3.220**
**NORMAL USE**
operation, including routine inspection and adjustments by any OPERATOR, and STAND-BY, according to the INSTRUCTIONS FOR USE

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Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: NORMAL USE is all functions performed by the OPERATOR. This includes warmup, calibration, and other testing "physics" modes.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.71, modified – Note 2 has been added.]

**201.3.221**
**OFFLINE IGRT**
IGRT for the purpose of PATIENT setup or TREATMENT PLAN adjustment to be applied in subsequent TREATMENT delivery

**201.3.222**
**ONLINE IGRT**
IGRT for the purpose of PATIENT setup or TREATMENT PLAN adjustment 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 imaging and TREATMENT.

**201.3.223**
**OPTICAL TRANSFER FUNCTION**
**OTF**
two-dimensional Fourier transform of the imaging system's point spread function.

Note 1 to entry: See ISO 9334:2012.

Note 2 to entry: For the OPTICAL TRANSFER FUNCTION to have significance, it is essential that the imaging system is working in its LINEAR RANGE, and that an ISOPLANATIC REGION is considered.

[SOURCE: IEC 61262-7:1995, 3.1.14]

**201.3.224**
**RADIOGRAPHY**
technique for obtaining, recording and optionally processing directly or after TRANSFER, information contained in an X-RAY PATTERN at an IMAGE RECEPTION AREA intended to be analysed during a time independent from the IRRADIATION time

[SOURCE: IEC 60601-1-3:2008, 3.64]

**201.3.225**
**RADIOSCOPY**
technique for obtaining continuously or periodically a sequence of X-RAY PATTERNS and presenting them directly or through a TRANSFER and optional processing simultaneously and continuously as visible images, intended to provide real-time guidance to an ongoing action

[SOURCE: IEC 60601-1-3:2008, 3.69]

**201.3.226**
**REAL-TIME IGRT**
IGRT that images throughout therapeutic IRRADIATION and based upon that information, allows automatic adjustments of TREATMENT PARAMETERs throughout the therapeutic IRRADIATION without OPERATOR intervention

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**201.3.227**
**REFERENCE IMAGE**
an image related to the TREATMENT PLAN to which subsequent images will be compared to align the PATIENT or adjust the TREATMENT PLAN

Note 1 to entry: REFERENCE IMAGES could be acquired during the first or subsequent TREATMENT fraction from an ELECTRONIC PORTAL IMAGING DEVICE.

Note 2 to entry: There can be more than one REFERENCE IMAGE.

Note 3 to entry: Examples of REFERENCE IMAGES can be digital reconstructed radiographs generated by the planning system for comparison to 2D images taken at time of TREATMENT or TREATMENT planning CT images used for CBCT registration, or the image generated by IGRT based on the CT and the TREATMENT PLAN.

**201.3.228**
**SENSITIVITY PROFILE**
relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

[SOURCE: IEC 60601-2-44:2009, 201.3.207]

**201.3.229**
**SPATIAL RESOLUTION**
resolution also known as HIGH-CONTRAST RESOLUTION and described by the MODULATION TRANSFER FUNCTION

**201.3.230**
**SPATIAL RESOLUTION OF AN IMAGE DISPLAY SYSTEM**
measure of the ability of an image display system to distinguish spatial features of interest within an image

Note 1 to entry: Systems designed with adequate spatial resolution characteristics are necessary to assure that spatial details of interest are preserved when a medical image is displayed. Portraying image data on an image display device with insufficient resolution will compromise the accuracy of the radiological interpretation.

[SOURCE: IEC 62563-1:2009, 3.1.20, modified – Addition of Note 1 to entry.]

**201.3.231**
**USABILITY**
characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR satisfaction

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.136, modified — The definition was rephrased.]

**201.3.232.1**
**VOLUME $CTDI_W$**
**$CTDI_{vol}$**
<axial scanning>

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_W$$

where
$N$ is the number of tomographic sections produced in a single axial scan of the X-ray source;
$T$ is the nominal tomographic section thickness;
$\Delta d$ is the patient support travel in y-direction between consecutive scans.

Note 1 to entry: For the selected IGRT IMAGING PROTOCOL , but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_W$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration

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