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colour inside

Medical electrical equipment –
Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

FOREWORD

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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 60601-2-43:2010+AMD1:2017+AMD2:2019 CSV. 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 60601-2-43 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This third edition cancels and replaces the second edition published in 2010, Amendment 1:2017 and Amendment 2:2019. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the changes in IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-54:2022. It also contains corrections and technical improvements. Significant technical changes with respect to the previous edition are as follows:

a) a new specific term DOSIMETER is introduced to replace the general term DOSEMETER as in IEC 60601-2-54:2022;

b) several terms and definitions that are moved from IEC TR 60788:2004 to 201.3 of IEC 60601-2-54:2022 are also referenced from IEC 60601-2-54:2022.

c) the collateral standards IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are applicable if MANUFACTURER so declares;

d) the former subclause 201.11.101 “Protection against excessive temperature of X-RAY TUBE ASSEMBLIES” is removed since covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017, and the former subclause 201.11.102 is renumbered as 201.11.101, as in IEC 60601-2-54:2022;

e) to adopt changes in subclause 7.8.1 “Colours of indicator lights” in IEC 60601-1:2005/AMD2:2020, clarification of requirements is provided in 201.7.8.1 to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT, as in IEC 60601-2-54:2022;

f) explanation of the term ESSENTIAL PERFORMANCE is provided in Annex AA to emphasize the performance of the clinical function under NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

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

Draft	Report on voting
62B/1297/FDIS	62B/1309/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/standardsdev/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 and IEC 80601 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,
- replaced by a revised edition, or
- amended.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The purpose of this new edition is to introduce changes to reference the Amendment 2 (2020) to IEC 60601-1:2005 and some minor technical clarifications.

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES ~~may~~ can subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT ~~may~~ can be the occurrence of deterministic injury when RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES also include many newly developing and emerging applications in a wide range of medical and surgical specialties.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which ~~may~~ sometimes do not align with the provisions of this document.

~~INTRODUCTION to Amendment 1~~

~~The purpose of this first amendment to IEC 60601-2-43:2010 is to introduce changes as follows:~~

~~– refer to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its applicable collateral standards;~~
~~– refer to IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 and consequent subclause adaptations;~~
~~– include a requirement to have a maximum time of 10 min to recover all functions after a recoverable failure in 201.4.101;~~
~~– include several aspects from IEC 61910-1:2014 and remove the reference to IEC PAS 61910-1:2007 in 201.4.102;~~
~~– include an alternative way of testing in 201.11.6.5.103;~~
~~– include a clarification for tableside controls in 201.12.4.106.~~

~~In addition, a number of technical errors have been corrected.~~

~~INTRODUCTION to Amendment 2~~

~~The purpose of this second amendment to IEC 60601-2-43:2010 is to introduce changes as follows:~~

~~– scope clarification with regards to MOBILE X-ray equipment and applicability of IEC 60601-2-54 subclauses;~~
~~– reference to IEC 60601-2-54:2009/AMD2:2018 for common subclauses;~~

- alignment of 201.7.9.1 with IEC 60601-2-54:2009/AMD2:2018 – 201.7.9.1 is no longer modified;
- inclusion of adapted requirements or recommendations from IEC 60601-2-54:2009/AMD2:2018 for
  - management of radioscopy image storage in 203.6.1.101,
  - display of last image hold (LIH RADIOGRAM) in 203.6.7.101, and
  - graphical indication of the boundaries of the X-RAY FIELD in 203.8.102.2;
- inclusion of a recommendation for protection of gantry enclosures in 201.11.6.5.103;
- inclusion of a requirement for X-RADIATION pulse repetition frequency during radioscopy in 203.6.3.103;
- inclusion of a recommendation for a DOSE MAP in 203.6.4.5 with additional definitions in 201.3;
- inclusion of a requirement for display unit of dose area product in 203.6.4.5;
- addition of a number of technical clarifications.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

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 document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of both FIXED and MOBILE X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, hereafter referred to as INTERVENTIONAL X-RAY EQUIPMENT. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;

– equipment for COMPUTED TOMOGRAPHY;

– ACCESSORIES intended to be introduced into the PATIENT;

– mammographic X-RAY EQUIPMENT;

– dental X-RAY EQUIPMENT.

NOTE 1 Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of INTERVENTIONAL X-RAY EQUIPMENT complying with this document is recommended, are given in Annex AA.

NOTE 2 Specific requirements for magnetic navigation devices, and for the use of INTERVENTIONAL X-RAY EQUIPMENT in an operating room environment were not considered in this document; therefore, no specific requirements have been developed for these devices or uses. In any case, such devices or uses remain under the general clause requirements.

NOTE 3 INTERVENTIONAL X-RAY EQUIPMENT, when used for cone-beam CT mode, is covered by this document and not by IEC 60601-2-44 [1][2]. No additional requirements for operation in cone-beam CT mode were identified for this document (see also Note 5 in 203.6.4.5).

INTERVENTIONAL X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this document.

If a clause or subclause is specifically intended to be applicable to INTERVENTIONAL X-RAY EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to INTERVENTIONAL X-RAY EQUIPMENT and to ME SYSTEMS, as relevant.

~~NOTE 4 See also 4.2 of the general standard.~~

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

2 Numbers in square brackets refer to the Bibliography.

~~The subclauses of this standard supersede IEC 60601-2-54 subclauses.~~ IEC 60601-2-54 applies only with regards to the cited subclauses; non-cited subclauses of IEC 60601-2-54 do not apply.

201.1.2 Object

Replacement:

The object of this document is:

– to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the design and manufacture of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, as defined in 201.3.205.

– to specify information which ~~is to~~ shall be provided with such INTERVENTIONAL X-RAY EQUIPMENT for the assistance of the RESPONSIBLE ORGANIZATION and OPERATOR in managing the RADIATION RISK and equipment failure RISK arising from these RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES which could affect PATIENTS or staff.

201.1.3 Collateral standards

Addition:

~~This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.~~

~~IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and Clause 203 respectively.~~

~~IEC 60601-1-8[3], IEC 60601-1-9[4], IEC 60601-1-10[5], IEC 60601-1-11[6] and IEC 60601-1-12[7] do not apply.~~

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, as modified in 201.2.

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply as modified in Clause 202 and Clause 203 respectively.

IEC 60601-1-8 [2], IEC 60601-1-9 [3], IEC 60601-1-10 [4] do not apply.

NOTE OPERATORS of INTERVENTIONAL X-RAY EQUIPMENT are used to audible signals as specified in this document rather than the concepts of IEC 60601-1-8.

~~3) IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*~~

~~4) IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*~~

~~5) IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*~~

~~6) IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*~~

~~7) IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*~~

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [5] apply only if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in a HOME HEALTHCARE ENVIRONMENT, and otherwise do not apply.

IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 [6] apply only if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in an EMERGENCY MEDICAL SERVICES ENVIRONMENT, and otherwise do not apply.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in ~~the general standard~~ 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 ~~the general standard~~ 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 particular standard corresponds to that of ~~the general standard~~ 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 addresses the content of Clause 1 of ~~the general standard~~ 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.101" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the ~~general~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of ~~the general standard~~ 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 ~~the general standard~~ 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 are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

~~The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.~~

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the ~~general standard~~ 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 the ~~general standard~~ 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 particular standard.

201.2 Normative references

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

NOTE Informative references are listed in the Bibliography.

Amendment:

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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

IEC 60601-1-3:2008, *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

Delete the reference to IEC 60601-1-8 and its amendments.

Addition:

IEC 60580:~~2000~~2019, *Medical electrical equipment – Dose area product meters*

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 60601-2-54:~~2009~~2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
~~IEC 60601-2-54:2009/AMD1:2015~~
~~IEC 60601-2-54:2009/AMD2:2018~~

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

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

~~IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*~~

IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

ISO 14971, *Medical devices – Application of risk management to medical devices*

201.3.206
SKIN DOSE
estimated ABSORBED DOSE to the skin at a specific point

201.3.207
SKIN DOSE MAP
DOSE MAP of the SKIN DOSE

201.4 General requirements

Clause 4 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Subclause 201.4.3 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies, except as follows:

Addition:

NOTE Subclause 203.6.4.3.104.2 (Accuracy of LOADING FACTORS in automatic control mode) of IEC 60601-2-54:2022 specifies a limitation in applying subclause 203.6.4.3.104.3 (Accuracy of X-RAY TUBE VOLTAGE) and 203.6.4.3.104.4 (Accuracy of X-RAY TUBE CURRENT) of IEC 60601-2-54:2022. This limitation is also valid for the ESSENTIAL PERFORMANCE list.

Additional potential ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by the MANUFACTURER in the RISK MANAGEMENT analysis

Requirement	Subclause
Recovery management	201.4.101
RADIATION dose documentation	201.4.102

201.4.10.2 SUPPLY MAINS FOR ME EQUIPMENT and ME SYSTEMS

Subclause 201.4.10.2 of IEC 60601-2-54:~~2009~~2022 applies.

Additional subclauses:

201.4.101 * Recovery management

The time to recover all of the functions necessary for performing EMERGENCY RADIOSCOPY, after a failure recoverable automatically or by the OPERATOR shall be as short as reasonably practicable. The RISK MANAGEMENT shall take into account the availability of emergency power supply in the determination of the recovery time.

When the recovery is complete, a reinitiation of IRRADIATION shall be required to produce further IRRADIATION.

The time to recover all functions, after a failure recoverable automatically or by the OPERATOR, shall be as short as reasonably practicable.

In case of a manually recoverable failure, the time to recover all functions shall not exceed 10 min from the time the OPERATOR has initiated the recovery to the time the INTERVENTIONAL X-RAY EQUIPMENT has all functions available.

In case of an automatically detected and automatically recoverable failure, the time to recover all functions shall not exceed 10 min from the time of the failure of the INTERVENTIONAL X-RAY EQUIPMENT to the time the INTERVENTIONAL X-RAY EQUIPMENT has all functions available.

INTERVENTIONAL X-RAY EQUIPMENT ~~may~~ can have both recovery modes.

NOTE Less than 1 min is a desirable value for the time to recover all functions for performing EMERGENCY RADIOSCOPY. Less than 3 min is a desirable value to recover all functions.

The instructions for use shall indicate:

– the time necessary to get all functions for EMERGENCY RADIOSCOPY operable;
– the time to restore all functions of the INTERVENTIONAL X-RAY EQUIPMENT;
– for failures recoverable by the OPERATOR, the required PROCEDURE which the OPERATOR ~~must~~ can follow to perform this recovery.

When the system is in the EMERGENCY RADIOSCOPY mode, this mode shall be indicated at the working position of the OPERATOR.

The functions necessary for performing EMERGENCY RADIOSCOPY shall include, at minimum:

– RADIOSCOPY MODE OF OPERATION, in priority order:
  • RADIOSCOPY in the MODE OF OPERATION that was used at the time of the recoverable equipment failure;
  • or, if this is not possible, RADIOSCOPY in the MODE OF OPERATION as close as possible to the one which was used at the time of the recoverable equipment failure;
– normal operation of the PATIENT SUPPORT;
– normal operation of the GANTRY;
– normal operation of tableside controls for all functions described above;
– normal operation of the IRRADIATION disabling switch (see 203.6.103);
– normal operation of the motion disabling switch (see 201.9.2.3.1 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022);
– normal operation of anti-collision functions (see 201.9.2.4).

Compliance is checked by inspection of the instructions for use and the RISK MANAGEMENT FILE and by functional tests.

201.4.102 * RADIATION dose documentation

The INTERVENTIONAL X-RAY EQUIPMENT shall create RADIATION DOSE STRUCTURED REPORTS (RDSR) and shall have the ability to perform RDSR END OF PROCEDURE TRANSMISSION.

The RDSR shall contain the data elements that are required ('shall') in 5.1.2 and 5.1.3 of IEC 61910-1:2014.

The RDSR should contain the data elements that are recommended ('should') in 5.1.2 and 5.1.3 of IEC 61910-1:2014.

NOTE The conditional statements associated with the data elements in IEC 61910-1:2014 are considered to be part of these data elements.

If the INTERVENTIONAL X-RAY EQUIPMENT does not have means to determine GANTRY angulations, the RDSR need not contain the data elements related to positioner angles.

The data elements shall be populated with the specified data.

Compliance is checked by appropriate inspection and functional test.

201.5 General requirements for testing ~~of~~ ME EQUIPMENT

Clause 5 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT that is ~~to be~~ used only in controlled environments, as specified in the ACCOMPANYING DOCUMENTS, no humidity preconditioning treatment is required. The ACCOMPANYING DOCUMENTS shall include the time period ~~that~~ to maintain the room environmental operating conditions ~~need to be maintained~~ prior to powering the system on.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 Electrical input power from the SUPPLY MAINS

Subclause 201.7.2.7 of IEC 60601-2-54:~~2009~~2022 applies.

201.7.2.15 Cooling conditions

Subclause 201.7.2.15 of IEC 60601-2-54:~~2009~~2022 applies.

Additional subclauses:

201.7.2.101 BEAM LIMITING DEVICE

Subclause 201.7.2.101 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies.

201.7.2.102 * PATIENT SUPPORT load

The PATIENT SUPPORT shall be marked with the maximum permissible mass in kilograms for NORMAL USE, excluding use for cardiopulmonary resuscitation (CPR).

This maximum permissible mass shall be the SAFE WORKING LOAD minus the CPR loading (see 201.9.8.3.1 for CPR loading value).

201.7.2.103 Cardiopulmonary resuscitation (CPR)

The PATIENT SUPPORT shall be marked with abbreviated instructions on configuring the INTERVENTIONAL X-RAY EQUIPMENT for CPR.

201.7.2.104 Marking of compliance

If~~, for INTERVENTIONAL X-RAY EQUIPMENT,~~ compliance with this document is ~~to be~~ marked on the outside of the INTERVENTIONAL X-RAY EQUIPMENT, the marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

INTERVENTIONAL X-RAY EQUIPMENT [model or type reference] IEC 60601-2-43:~~2010, IEC 60601-2-43:2010/AMD1:2017 and IEC 60601-2-43:2010/AMD2:2019~~2022.

201.7.2.105 * Protection against ingress of liquids

~~Specific parts~~ ENCLOSURES of the INTERVENTIONAL X-RAY EQUIPMENT, which are located in the PATIENT vicinity (or around the PATIENT), shall be marked with the degree of protection as defined in IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013. When an ACCESSORY is required for protection against ingress of liquids, this shall be stated in the instructions for use.

~~NOTE 1 This is an addition compared to the first edition of IEC 60601-2-43:2000.~~

NOTE ~~2~~ 1 See also 201.11.6.5.103.

NOTE ~~3~~ 2 The marking of parts that are IPX0 ~~need not be marked~~ is optional.

201.7.8.1 Colours of indicator lights

~~The indication of X-RAY related states shall be excluded from subclause 7.8 in the general standard. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead.~~

Subclause 201.7.8.1 of IEC 60601-2-54:2022 applies.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Subclause 201.7.9.1 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Subclause 201.7.9.2.1 of IEC 60601-2-54:~~2009~~2022 applies.

201.7.9.2.12 * Cleaning, disinfection and sterilization

Addition:

NOTE In order to satisfy 11.6.6 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the information given ~~has to exclude~~ preferably excludes commonly used but possibly corrosive substances, such as sodium hypochlorite, if the use of such substances would present a RISK of damage to the parts of the INTERVENTIONAL X-RAY EQUIPMENT concerned.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Subclause 201.7.9.2.17 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies.

NOTE The corresponding requirements in 203.5 cited in subclause 201.7.9.2.17 of IEC 60601-2-54:2022 are located in 203.5 of this document and not in subclause 203.5 of IEC 60601-2-54:2022.

Additional subclauses:

201.7.9.2.101 PROTECTIVE DEVICES and ACCESSORIES

A list shall be provided of PROTECTIVE DEVICES and ACCESSORIES recommended when the INTERVENTIONAL X-RAY EQUIPMENT is employed for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. There may be different lists for different types of RGI PROCEDURES. The listing ~~may~~ can include PROTECTIVE DEVICES such as PROTECTIVE CLOTHING, recommended for use but not forming part of the INTERVENTIONAL X-RAY EQUIPMENT.

201.7.9.2.102 * Provisions for cardiopulmonary resuscitation (CPR)

~~Instructions shall be given~~ The instruction for use shall include instructions for at least one method of configuring the INTERVENTIONAL X-RAY EQUIPMENT to permit CPR including the use of any necessary ACCESSORIES provided with the INTERVENTIONAL X-RAY EQUIPMENT. These instructions shall not call for the use of ACCESSORIES that are not provided with the INTERVENTIONAL X-RAY EQUIPMENT.

If instructions differ between NORMAL USE and in cases of SINGLE FAULT CONDITIONS, the instructions shall be given for all appropriate cases.

~~NOTE This last sentence is an addition compared to the first edition of IEC 60601-2-43:2000.~~

201.7.9.2.103 * Emergency instructions

Emergency instructions shall be provided in non-electronic form, resistant to manipulation, water damage and cleaning.

The content of the emergency instructions should be reproduced in a single location in the complete instructions for use.

Emergency instructions shall contain only instructions related to emergency functions and situations.

At minimum, emergency instructions shall include instructions for the following cases:

- configuring the INTERVENTIONAL X-RAY EQUIPMENT for CPR (only for INTERVENTIONAL X-RAY EQUIPMENT including a PATIENT SUPPORT) (see 201.7.9.2.102);
- the re-starting PROCEDURE in case of recoverable failure by the OPERATOR (see 201.4.101);
- the re-starting PROCEDURE for the INTERVENTIONAL X-RAY EQUIPMENT in the event of failure of SUPPLY MAINS (see 201.7.9.2.104);
- the re-starting PROCEDURE for the INTERVENTIONAL X-RAY EQUIPMENT in the case of the use of an emergency power supply requiring such actions (see 201.7.9.2.104);
- the location, function and operation of the IRRADIATION disabling switch (see 203.5.2.4.101);
- the location, function and operation of the motion disabling switch (see 201.9.2.3.1 in IEC 60601-2-54:2022);
- the list of emergency functions, as defined in 201.4.101;
- if the complete instructions for use are only available in electronic form, instructions for accessing the complete instructions for use.

~~NOTE This is an addition compared to the first edition of IEC 60601-2-43:2000.~~

Compliance is determined by inspection and by the appropriate functional tests.

201.7.9.2.104 Failure of SUPPLY MAINS

The instructions for use shall describe the functional response and re-starting PROCEDURE for the INTERVENTIONAL X-RAY EQUIPMENT in the event of failure of the SUPPLY MAINS. ~~Details shall be given of the possibilities for provisions being made in the installation of emergency power supply for the following cases:~~

~~– for the preservation of stored images only;~~

~~– for emergency RADIOSCOPY (as described in 201.4.101);~~

~~– for minimum equipment motion (limited motion of GANTRY, table and source-to-image motion as determined by the MANUFACTURER);~~

~~– for all functions for performing RADIOSCOPY and RADIOGRAPHY.~~

~~– for placing the INTERVENTIONAL X-RAY EQUIPMENT in CPR position in case of the failure of SUPPLY MAINS, if placing the INTERVENTIONAL X-RAY EQUIPMENT IN CPR configuration requires electrical power.~~

~~This information is necessary so that the RESPONSIBLE ORGANIZATION is able to decide on an appropriate level of protection to be provided against such failures.~~

Compliance is determined by inspection of the instructions for use.

~~NOTE See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.12.4.108 for requirements on operation of the emergency power supply.~~

201.7.9.2.105 Description of the protection against ingress of liquids

The instructions for use shall explain the IPXY marking used on the INTERVENTIONAL X-RAY EQUIPMENT.

NOTE ~~1~~ See also 201.7.2.105.

~~NOTE 2 This is an addition compared to the first edition of IEC 60601-2-43:2000.~~

201.7.9.3 Technical Description

Additional subclauses:

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

Subclause 201.7.9.3.101 of IEC 60601-2-54:~~2009~~2022 applies.

201.7.9.3.102 Installation

For PERMANENTLY INSTALLED INTERVENTIONAL X-RAY EQUIPMENT, the technical description shall contain the following recommendations concerning the installation of the INTERVENTIONAL X-RAY EQUIPMENT:

– INTERLOCKS must not be present on the doors of the room containing the INTERVENTIONAL X-RAY EQUIPMENT. No other measures, whether or not employed for RADIATION PROTECTION, should be able to cause the interruption of IRRADIATION or any other disturbance of a RGI PROCEDURE in progress, unless the OPERATOR has the means to prevent such action from occurring during the RGI PROCEDURE;

– all emergency stop controls ~~in~~ for the system must be protected against accidental actuation;

– sufficient space must be available around the PATIENT SUPPORT for the unimpeded conduct of CPR;

– one or more warning lights must be present in order to indicate the LOADING STATE to persons at all positions in the room containing the INTERVENTIONAL X-RAY EQUIPMENT~~;~~ (see also requirement of 203.13.4);

– appropriate warning lights to indicate the LOADING STATE must be present adjacent to doors opening into the procedure room when warning lights within the procedure room are not visible.

NOTE 1 This list is a set of information for the RESPONSIBLE ORGANIZATION, therefore the verb 'must' is used to clearly distinguish these from requirements on the INTERVENTIONAL X-RAY EQUIPMENT itself.

The ACCOMPANYING DOCUMENTS shall give the possibilities for provisions being made in the installation of emergency power supply for the following cases:

– for the preservation of stored images only;
– for EMERGENCY RADIOSCOPY (as described in 201.4.101);
– for minimum equipment motion (limited motion of GANTRY, table and source-to-image motion as determined by the MANUFACTURER);
– for all functions for performing RADIOSCOPY and RADIOGRAPHY;
– for placing the INTERVENTIONAL X-RAY EQUIPMENT in CPR position in case of the failure of SUPPLY MAINS, if placing the INTERVENTIONAL X-RAY EQUIPMENT IN CPR configuration requires electrical power.

NOTE 2 This information is necessary so that the RESPONSIBLE ORGANIZATION is able to decide on an appropriate level of protection to be provided against such failures.

NOTE 3 See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.12.4.108 for requirements on operation of the emergency power supply.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS.

~~*Additional subclauses:*~~

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Additional requirements for statements in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Table 201.C.102 of IEC 60601-2-54:~~2009~~2022 and in Table 201.102.

IEC 60601-2-43

Edition 3.0 2022-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

Appareils électromédicaux –
Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions

IEC 60601-2-43:2022-12(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

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

IEC 60601-2-43 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This third edition cancels and replaces the second edition published in 2010, Amendment 1:2017 and Amendment 2:2019. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the changes in IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-54:2022. It also contains corrections and technical improvements. Significant technical changes with respect to the previous edition are as follows:

a) a new specific term DOSIMETER is introduced to replace the general term DOSEMETER as in IEC 60601-2-54:2022;
b) several terms and definitions that are moved from IEC TR 60788:2004 to 201.3 of IEC 60601-2-54:2022 are also referenced from IEC 60601-2-54:2022.

c) the collateral standards IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are applicable if MANUFACTURER so declares;

d) the former subclause 201.11.101 “Protection against excessive temperature of X-RAY TUBE ASSEMBLIES” is removed since covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017, and the former subclause 201.11.102 is renumbered as 201.11.101, as in IEC 60601-2-54:2022;

e) to adopt changes in subclause 7.8.1 “Colours of indicator lights” in IEC 60601-1:2005/AMD2:2020, clarification of requirements is provided in 201.7.8.1 to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT, as in IEC 60601-2-54:2022;

f) explanation of the term ESSENTIAL PERFORMANCE is provided in Annex AA to emphasize the performance of the clinical function under NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

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

Draft	Report on voting
62B/1297/FDIS	62B/1309/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/standardsdev/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 and IEC 80601 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,
- replaced by a revised edition, or
- amended.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The purpose of this new edition is to introduce changes to reference the Amendment 2 (2020) to IEC 60601-1:2005 and some minor technical clarifications.

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES can subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT can be the occurrence of deterministic injury when RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES also include many newly developing and emerging applications in a wide range of medical and surgical specialties.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which sometimes do not align with the provisions of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of both FIXED and MOBILE X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, hereafter referred to as INTERVENTIONAL X-RAY EQUIPMENT. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;

– equipment for COMPUTED TOMOGRAPHY;

– ACCESSORIES intended to be introduced into the PATIENT;

– mammographic X-RAY EQUIPMENT;

– dental X-RAY EQUIPMENT.

NOTE 1 Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of INTERVENTIONAL X-RAY EQUIPMENT complying with this document is recommended, are given in Annex AA.

NOTE 2 Specific requirements for magnetic navigation devices, and for the use of INTERVENTIONAL X-RAY EQUIPMENT in an operating room environment were not considered in this document; therefore, no specific requirements have been developed for these devices or uses. In any case, such devices or uses remain under the general clause requirements.

NOTE 3 INTERVENTIONAL X-RAY EQUIPMENT, when used for cone-beam CT mode, is covered by this document and not by IEC 60601-2-44 [1][1]. No additional requirements for operation in cone-beam CT mode were identified for this document (see also Note 5 in 203.6.4.5).

INTERVENTIONAL X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this document.

If a clause or subclause is specifically intended to be applicable to INTERVENTIONAL X-RAY EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to INTERVENTIONAL X-RAY EQUIPMENT and to ME SYSTEMS, as relevant.

IEC 60601-2-54 applies only with regards to the cited subclauses; non-cited subclauses of IEC 60601-2-54 do not apply.

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1 Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The object of this document is:

– to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the design and manufacture of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, as defined in 201.3.205.

– to specify information which shall be provided with such INTERVENTIONAL X-RAY EQUIPMENT for the assistance of the RESPONSIBLE ORGANIZATION and OPERATOR in managing the RADIATION RISK and equipment failure RISK arising from these RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES which could affect PATIENTS or staff.

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, as modified in 201.2.

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply as modified in Clause 202 and Clause 203 respectively.

IEC 60601-1-8 [2], IEC 60601-1-9 [3], IEC 60601-1-10 [4] do not apply.

NOTE OPERATORS of INTERVENTIONAL X-RAY EQUIPMENT are used to audible signals as specified in this document rather than the concepts of IEC 60601-1-8.

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [5] apply only if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in a HOME HEALTHCARE ENVIRONMENT, and otherwise do not apply.

IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 [6] apply only if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in an EMERGENCY MEDICAL SERVICES ENVIRONMENT, and otherwise do not apply.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in 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 particular standard 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 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.101" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard 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 the applicable collateral standard is replaced completely by the text of this particular standard.

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

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 are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the 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 the 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 particular standard.

201.2 Normative references

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

NOTE Informative references are listed in the Bibliography.

Amendment:

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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

Delete the reference to IEC 60601-1-8 and its amendments.

Addition:

IEC 60580:2019, *Medical electrical equipment – Dose area product meters*

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 60601-2-54:2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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

IEC 61910-1:2014*, Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

ISO 14971*, Medical devices – Application of risk management to medical devices*

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions

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.
2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-43 a été établie par le sous-comité 62B: Appareils d'imagerie de diagnostic, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale. Il s'agit d'une norme internationale.

Cette troisième édition annule et remplace la deuxième édition parue en 2010, l'Amendement 1:2017 et l'Amendement 2:2019. Cette édition constitue une révision technique.

Cette édition inclut des modifications rédactionnelles et techniques pour refléter les modifications dans l'IEC 60601-1:2005/AMD2:2020 et l'IEC 60601-2-54:2022. Elle contient également des corrections et des améliorations techniques. Les modifications techniques majeures par rapport à l'édition précédente sont les suivantes:

a) un nouveau terme spécifique DOSIMETRE est utilisé pour remplacer le terme général DOSIMETRE comme dans l'IEC 60601-2-54:2022;

b) plusieurs termes et définitions de l'IEC TR 60788:2004 déplacés dans l'Article 201.3 de l'IEC 60601-2-54:2022 sont aussi référencés à partir de l'IEC 60601-2-54:2022;

c) les normes collatérales IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 et IEC 60601-1-12:2014/AMD1:2020 sont applicables lorsque le FABRICANT les déclare telles quelles;

d) l'ancien paragraphe 201.11.101 "Protection contre les températures excessives des GAINES EQUIPEES" est supprimé car il est couvert par l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, l'IEC 60601-1:2005/AMD2:2020 et l'IEC 60601-2-28:2017 et l'ancien paragraphe 201.11.102 est renuméroté en 201.11.101, comme dans l'IEC 60601-2-54:2022;

e) pour adopter les modifications du paragraphe 7.8.1 "Couleurs des voyants lumineux" de l'IEC 60601-1:2005/AMD2:2020, une clarification des exigences est fournie en 201.7.8.1 pour éviter les contradictions avec les exigences des voyants lumineux stipulées pour les APPAREILS A RAYONNEMENT X, comme dans l'IEC 60601-2-54:2022;

f) une explication du terme PERFORMANCE ESSENTIELLE est donnée à l'Annexe AA pour mettre l'accent sur les performances de la fonction clinique dans les CONDITIONS NORMALES et les CONDITIONS DE PREMIER DEFAUT.

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

Projet	Rapport de vote
62B/1297/FDIS	62B/1309/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/standardsdev/publications.

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

– exigences et définitions: caractères romains.

– *spécifications d'essais: caractères italiques;*

– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS à 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 présent document ou comme notes: PETITES CAPITALES.

Concernant la structure du présent document, le terme

– "article" désigne l'une des dix-sept sections numérotées dans le sommaire, 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, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à 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" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison de 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:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document;
– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

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

Une liste de toutes les parties des séries IEC 60601 et IEC 80601, publiées sous le titre général *Appareils électromédicaux* peut être consultée 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,
- remplacé par une édition révisée, ou
- amendé.

IMPORTANT – Le logo "colour inside" qui se trouve sur la page de couverture de cette publication indique qu'elle contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer cette publication en utilisant une imprimante couleur.

INTRODUCTION

La présente nouvelle édition a pour objet d'introduire des modifications en référence à l'Amendement 2 (2020) à l'IEC 60601-1:2005 et quelques clarifications techniques mineures.

Les APPAREILS A RAYONNEMENT X pour INTERVENTIONS GUIDEES PAR RADIOSCOPIE peuvent soumettre les PATIENTS et les OPERATEURS à des niveaux de RAYONNEMENTS supérieurs à ceux qui sont normalement émis au cours des interventions de diagnostic utilisant l'imagerie à rayonnement X. Pour le PATIENT, une des conséquences peut être l'apparition de lésions déterministes lorsque les INTERVENTIONS GUIDEES PAR RADIOSCOPIE impliquent la délivrance de quantités importantes de RAYONNEMENTS à des zones localisées. Une autre conséquence peut être un RISQUE accru d'effets stochastiques comme le cancer. Ces problèmes de santé concernent également l'OPERATEUR. En outre, il est nécessaire que ce type particulier d'appareils comporte des fonctions essentielles avec des périodes de perte minimales.

Les INTERVENTIONS GUIDEES PAR RADIOSCOPIE de ce type sont très courantes dans les domaines cliniques suivants:

– cardiologie invasive;
– RADIOLOGIE d'intervention;
– neuroradiologie d'intervention.

Ces INTERVENTIONS GUIDEES PAR RADIOSCOPIE incluent également de nombreuses applications émergentes ou se développant depuis peu dans un grand nombre de spécialités médicales et chirurgicales.

NOTE L'attention du lecteur est attirée sur l'existence, dans certains pays, d'une législation sur la PROTECTION RADIOLOGIQUE qui présente parfois des différences avec les dispositions du présent document.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions

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:

Le présent document s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS A RAYONNEMENT X FIXES et MOBILES déclarés par leur FABRICANT comme étant adaptés aux INTERVENTIONS GUIDEES PAR RADIOSCOPIE, désignés ci-après par le terme APPAREILS A RAYONNEMENT X D'INTERVENTION. Son domaine d'application exclut en particulier:

– les équipements de RADIOTHERAPIE;
– les équipements de TOMODENSITOMETRIE;
– les ACCESSOIRES destinés à être introduits dans le corps du PATIENT;
– les APPAREILS de mammographie A RAYONNEMENT X;
– les APPAREILS de radiographie dentaire A RAYONNEMENT X.

NOTE 1 Des exemples d'INTERVENTIONS GUIDEES PAR RADIOSCOPIE, pour lesquelles l'utilisation d'APPAREILS A RAYONNEMENT X D'INTERVENTION conformes au présent document est recommandée sont donnés à l'Annexe AA.

NOTE 2 Les exigences spécifiques aux appareils de navigation magnétique, et pour l'utilisation des APPAREILS A RAYONNEMENT X D'INTERVENTION dans un environnement de salle d'opération n'ont pas été prises en considération dans le présent document; c'est la raison pour laquelle, aucune exigence spécifique n'a été établie pour ces dispositifs ou usages. Dans tous les cas, de tels dispositifs ou usages se voient appliquer les exigences des articles généraux.

NOTE 3 Les APPAREILS A RAYONNEMENT X D'INTERVENTION, lorsqu'ils sont utilisés en mode CT à faisceau conique, sont couverts par le présent document et non par l'IEC 60601-2-44 [1][1]. Aucune exigence supplémentaire relative au fonctionnement en mode CT à faisceau conique n'a été identifiée pour le présent document (voir également la Note 5 du 203.6.4.5).

Les APPAREILS A RAYONNEMENT X D'INTERVENTION déclarés par le FABRICANT comme étant adaptés aux INTERVENTIONS GUIDEES PAR RADIOSCOPIE, qui n'incluent pas le SUPPORT PATIENT sont exemptés des dispositions du présent document applicables au SUPPORT PATIENT.

Lorsqu'un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS A RAYONNEMENT X D'INTERVENTION ou uniquement aux SYSTEMES EM, le titre et le contenu de l'article ou du paragraphe concerné l'indiquent. Si tel n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS A RAYONNEMENT X D'INTERVENTION et aux SYSTEMES EM, selon le cas.

L'IEC 60601-2-54 s'applique uniquement en ce qui concerne les paragraphes cités; les paragraphes non cités de l'IEC 60601-2-54 ne s'appliquent pas.

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1 Les chiffres entre crochets renvoient à la Bibliographie.

201.1.2 Objet

Remplacement:

Le présent document a pour objet:

– d'établir des exigences particulières de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES pour la conception et la fabrication des APPAREILS A RAYONNEMENT X pour les INTERVENTIONS GUIDEES PAR RADIOSCOPIE, comme cela est défini en 201.3.205;

– de spécifier les informations qui doivent être fournies avec de tels APPAREILS A RAYONNEMENT X D'INTERVENTION pour aider l'ORGANISME RESPONSABLE et l'OPERATEUR à gérer le RISQUE de RAYONNEMENT et le RISQUE de défaillance des équipements découlant de ces INTERVENTIONS GUIDEES PAR RADIOSCOPIE et qui peuvent affecter les PATIENTS ou le personnel.

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, telles qu'elles sont modifiées en 201.2.

L'IEC 60601-1-2:2014, l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021 s'appliquent telles qu'elles sont modifiées respectivement par l'Article 202 et l'Article 203.

L'IEC 60601-1-8 [2], l'IEC 60601-1-9 [3], l'IEC 60601-1-10 [4] ne s'appliquent pas.

NOTE Les OPERATEURS d'APPAREILS A RAYONNEMENT X D'INTERVENTION sont habitués aux signaux sonores spécifiés dans le présent document plutôt qu'aux concepts de l'IEC 60601-1-8.

L'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 [5] s'appliquent si et seulement si le FABRICANT déclare que l'APPAREIL EM ou le système EM est destiné à fonctionner dans un ENVIRONNEMENT DES SOINS A DOMICILE. Dans le cas contraire, elles ne s'appliquent pas.

L'IEC 60601-1-12:2014 et l'IEC 60601-1-12:2014/AMD1:2020 [6] s'appliquent si et seulement si le FABRICANT déclare que l'APPAREIL EM ou le système EM est destiné à fonctionner dans un ENVIRONNEMENT DES SERVICES MEDICAUX D'URGENCE. Dans le cas contraire, elles ne s'appliquent pas.

Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles qu'elles sont 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 ce qui est approprié à l'APPAREIL EM à l'étude, et elles peuvent ajouter d'autres exigences 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 paragraphes de la présente norme particulière 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 201.1 couvre 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 de la norme collatérale applicable avec le préfixe "20x.101", où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple 202.4 couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 couvre 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 de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable sont spécifiées par l'utilisation des 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 de la présente norme particulière.

"*Addition*" signifie que le texte de la présente norme particulière 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 de la présente norme particulière.

Les paragraphes, figures ou tableaux qui s'ajoutent 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 3.1 à 3.154, les définitions complémentaires sont numérotées à partir de 201.3.201. Les annexes qui sont ajoutées sont numérotées AA, BB, etc., et les éléments supplémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à 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.

Lorsque la présente norme particulière 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 la présente norme particulière.

201.2 Références normatives

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:

NOTE Une liste de références informatives est donnée dans la Bibliographie.

Amendement:

IEC 60529:1989, *Degrés de protection procurés par les enveloppes (Code IP)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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

Supprimer la référence à l'IEC 60601-1-8 et ses amendements.

Addition:

IEC 60580:2019, *Appareils électromédicaux – Radiamètres de produit exposition-surface*

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 60601-2-54:2022, *Appareils électromédicaux – Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie*

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

IEC 61910-1:2014*, Appareils électromédicaux – Documentation sur la dose de rayonnement – Partie 1: Rapports structurés sur la dose de rayonnement pour la radiographie et la radioscopie*

IEC 62220-1-1:2015, *Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie à rayonnement X – Partie 1-1: Détermination de l'efficacité quantique de détection – Détecteurs utilisés en imagerie radiographique*

ISO 14971*, Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*