IEC 60601-2-43

Edition 3.0 2022-12
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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

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CONTENTS

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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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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.

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 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021, IEC 60601-2-54:~~2009, IEC 60601-2-54:2009/AMD1:2015 and IEC 60601-2-54:2009/AMD2:2018~~2022, IEC TR 60788:2004, IEC 61910-1:2014, IEC 62220-1-1:2015 and the following apply.

NOTE ~~1~~ The location of defined terms is listed in the Index of defined terms.

~~NOTE 2 The reference point labelled as 'interventional reference point' in Edition 1 is replaced by PATIENT ENTRANCE REFERENCE POINT in this edition.~~

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

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

Addition:

201.3.~~205~~201
DOSE MAP
representation of the spatial distribution of a RADIATION dose quantity

201.3.~~204~~202
EMERGENCY RADIOSCOPY
RADIOSCOPY with availability of a limited set of functions (emergency functions), for use during recovery from a recoverable failure of the INTERVENTIONAL X-RAY EQUIPMENT

201.3.~~201~~203
*** IMAGE DISPLAY DELAY**
during RADIOSCOPY or RADIOGRAPHY, time delay between an event captured during an X-RAY LOADING used to create an image and the DISPLAY of this event on the image

201.3.~~202~~204
INTERVENTIONAL X-RAY EQUIPMENT
X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

201.3.~~203~~205
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
RGI PROCEDURE
invasive procedure (involving the introduction of a device, such as a needle or a catheter into the PATIENT) using RADIOSCOPY as the principal means of guidance, and intended to effect treatment or diagnosis of the medical condition of the PATIENT

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.

Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS

Subclause	Heading
201.4.101	Recovery management
201.7.2.105	Protection against ingress of liquids
201.9.8.3.1	Strength of PATIENT or OPERATOR support or suspension systems – General
201.11.6.1	Overflow, spillage, etc. – General
201.11.6.5.102	Sources of dust and other particles
201.12.4.101.2	Management of image storage capacity
201.12.4.102	IMAGE DISPLAY DELAY
201.12.4.107	Measuring functions
201.15.102	Attachment of sterile drapes
203.5.2.4.5	Deterministic effects
203.5.2.4.101	IRRADIATION disabling switch
203.6.4.2	Indication of LOADING STATE
203.13.4	Designated SIGNIFICANT ZONES OF OCCUPANCY
201.5.7	Humidity preconditioning treatment
201.11.6.5.103	ENCLOSURES
203.5.2.4.102	EXAMINATION PROTOCOLS
203.6.4.5	Dosimetric indications
NOTE While Table 201.C.102 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 lists the following subclauses "203.6.4.5 Dosimetric indications" and "203.5.2.4.5.101 Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY", the corresponding requirements for statements in ACCOMPANYING DOCUMENTS are located in this document and not in IEC 60601-2-54:~~2009~~2022 ~~and its amendments~~.	

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Replacement:

Clause 201.8 of IEC 60601-2-54:~~2009~~2022 applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 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:

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.2 TRAPPING ZONE

201.9.2.2.4 GUARDS and other RISK CONTROL measures

Subclause 201.9.2.2.4.4 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies.

201.9.2.2.5 Continuous activation

Subclause 201.9.2.2.5 of IEC 60601-2-54:~~2009~~2022 applies.

201.9.2.2.6 Speed of movement(s)

Subclause 201.9.2.2.6 of IEC 60601-2-54:~~2009~~2022 applies.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

Subclause 201.9.2.3 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies.

201.9.2.4 * Emergency stopping devices

Addition:

aa) In order to prevent HAZARDS arising from the unintended interruption of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, the operation of anti-collision devices in INTERVENTIONAL X-RAY EQUIPMENT shall not automatically switch off IRRADIATION and shall not impair other functions of the INTERVENTIONAL X-RAY EQUIPMENT, except movements connected with the potential collision. Means shall be provided for any movement disabled by the actuation of an anti-collision device to be caused to recover from collision within 5 s after a positive action taken at the working position of the OPERATOR.

Additional subclause:

201.9.2.4.101 Controls

Subclause 201.9.2.4.101 of IEC 60601-2-54:~~2009~~2022 applies.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Addition:

In INTERVENTIONAL X-RAY EQUIPMENT, the load for which the PATIENT SUPPORT is designed shall be the normal load imposed by the PATIENT (as specified and marked, or otherwise as required in this subclause), with the addition of a mass of not less than 50 kg to provide for additional load imposed in the performance of CPR. This additional load shall be assumed to be applied uniformly over a length of 1 500 mm from the head-end of the PATIENT SUPPORT, or over the whole length if it is less than 1 500 mm, when the INTERVENTIONAL X-RAY EQUIPMENT is configured for CPR in accordance with the instructions for use, including the fitting of any ACCESSORIES specified for use in CPR.

Addition to the description of the compliance test:

For INTERVENTIONAL X-RAY EQUIPMENT, the test shall be carried out in the least favourable position other than when configured for CPR, and also in the least favourable position when configured for CPR. When configured for CPR, the test shall include the application of additional weight evenly over the portion of the PATIENT SUPPORT from the head-end up to a length of 1 500 mm or the maximum available length if less than 1 500 mm. This additional weight shall be applied after an interval of 1 min or more subsequent to the application of the testing weight representing the normal load.

For a test of INTERVENTIONAL X-RAY EQUIPMENT in the CPR configuration, the system shall be free from flexing or resonance effects that would impede the conduct of CPR.

201.9.8.3.3 Dynamic forces due to loading from persons

Subclause 201.9.8.3.3 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Subclause 201.9.8.4 of IEC 60601-2-54:~~2009~~2022 applies.

Additional subclause:

201.9.8.101 Shock absorbing means

Subclause 201.9.8.101 of IEC 60601-2-54:~~2009~~2022 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 201.10 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

NOTE See Clause 203.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 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:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 * Maximum temperature during NORMAL USE

Addition:

Table 24 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 shall be used for INTERVENTIONAL X-RAY EQUIPMENT parts which can, in NORMAL USE, have prolonged contact with the PATIENT.

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.1 * General

Addition:

All components which can come into contact with PATIENTS' secretions, excretions, other body fluids, or other fluids shall be constructed so that:

– covers or drapes can be employed to divert these fluids away from the INTERVENTIONAL X-RAY EQUIPMENT, and

– the INTERVENTIONAL X-RAY EQUIPMENT surfaces over which the fluids can flow are suitable for cleaning and disinfection.

Guidance shall be provided for the use of the cleaning and disinfecting agents listed in the ACCOMPANYING DOCUMENTS.

Surfaces of the INTERVENTIONAL X-RAY EQUIPMENT likely to be exposed to specified cleaning and disinfecting agents shall be designed so that they are protected from, or are otherwise tolerant, of the agents concerned.

It should be assumed that all external surfaces of the X-RAY SOURCE ASSEMBLY, the GANTRY, the X-RAY IMAGE RECEPTOR assembly, the PATIENT SUPPORT and the tableside controls ~~may~~ can be contaminated by PATIENTS' body fluids in the course of NORMAL USE.

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

NOTE ~~2~~ Attention is drawn to the additional requirements in 201.7.9.2.12 concerning cleaning and disinfection.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Additional subclauses:

201.11.6.5.101 Footswitches

The footswitches of INTERVENTIONAL X-RAY EQUIPMENT, that are located at the table side, shall be operable even if the floor is covered with 25 mm of a saline solution.

NOTE Attention is drawn to the limitation of operating voltage imposed by 8.10.4 in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Compliance is determined by mechanically actuating and releasing the footswitch (with no electrical power source connected) 900 times in 25 mm depth of a saline solution of at least 0,9 % weight to volume of sodium chloride in water over a period of 1 h; then checking its functionality and electrical safety in accordance with ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. In addition, there shall be no evidence of fluid having reached mechanical parts that might deteriorate if they remain wet indefinitely.

Tableside connections of footswitch cable should be at least 25 mm above floor level.

Compliance is determined by inspection.

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

201.11.6.5.102 * Sources of dust and other particles

Sources of dust or other particles due to the INTERVENTIONAL X-RAY EQUIPMENT shall not be directed towards the PATIENT.

Parts of the INTERVENTIONAL X-RAY EQUIPMENT mounted above the PATIENT shall be designed to minimize the accumulation of dust, which could otherwise fall onto the PATIENT.

The instructions for use shall specify the PROCEDURE for removal of dust from parts of the INTERVENTIONAL X-RAY EQUIPMENT that are mounted above the PATIENT.

Compliance is checked by inspection.

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

201.11.6.5.103 * ENCLOSURES

The degree of protection without ACCESSORIES is as follows:

– Footswitches shall have a minimum degree of protection of IPX7.
– Tableside controls should have a minimum degree of protection of IPX3.
– PATIENT SUPPORT should have a minimum degree of protection of IPX2 or should be protected against spraying water at any angle up to 15° from the vertical. For the PATIENT SUPPORT test, testing may be considered sufficient by angulating the PATIENT SUPPORT 15° from the horizontal position.

~~– Image monitor may be IPX0 (i.e. no marking required)~~

– X-RAY TUBE ASSEMBLY and associated GANTRY elements should have a minimum degree of protection of IPX2, except for INTERVENTIONAL X-RAY EQUIPMENT with a FIXED over-table X-RAY SOURCE ASSEMBLY. The ACCOMPANYING DOCUMENTS shall describe the associated GANTRY elements that are included within the IPX2 classification. Testing may be considered sufficient by tilting the C-arm in the least favourable position with a maximum of 15° in any direction from the vertical position.

There shall be no ingress of water under the specified test conditions of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013.

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

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Subclause 201.11.8 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

Additional subclauses:

~~**201.11.101 Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES**~~

~~Subclause 201.11.101 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 applies.~~

201.11.10~~2~~1 Protection against excessive temperatures of BEAM LIMITING DEVICES

Subclause 201.11.10~~2~~1 of IEC 60601-2-54:~~2009~~2022 applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 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 In accordance with subclause 12.4.5 of the ~~general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the dose related aspects of this topic are addressed in 203.6.4.3.

201.12.4 * Protection against hazardous output

201.12.4.5.2 Diagnostic X-RAY EQUIPMENT

Replacement:

INTERVENTIONAL X-RAY EQUIPMENT shall comply with IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021as modified ~~by this particular standard~~ in Clause 203.

Compliance is checked as specified in IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021as modified ~~by this particular standard~~ in Clause 203.

Additional subclauses:

201.12.4.101 Information to the OPERATOR

201.12.4.101.1 * PATIENT data

Information shall be available on the DISPLAY concerning the identity of the PATIENT and the medical procedure to which displayed images relate.

In the case of emergency interventions, this requirement is exempted.

Compliance is determined by inspection and functional tests.

201.12.4.101.2 Management of image storage capacity

In the instructions for use, the need to check regularly the available storage capacity and secure/archive important records shall be stated.

Upon completion of entry of the PATIENT data at the beginning of a new case, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate the available image storage capacity.

When the operating parameters have been entered, prior to acquiring any run, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate if there is insufficient storage space to store the run completely under the programmed conditions or shall state the number of frames possible or the ~~acquisition~~ IRRADIATION TIME available, at the frame rate and resolution selected.

When there is not sufficient storage space, it shall be indicated at the working position of the OPERATOR.

In the event of the INTERVENTIONAL X-RAY EQUIPMENT reaching a zero storage space condition, RADIOGRAPHY either shall not be possible or be stopped, unless data has been stored elsewhere and the INTERVENTIONAL X-RAY EQUIPMENT has a means to determine that data has been stored successfully elsewhere.

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

Compliance is determined by inspection and functional tests.

201.12.4.101.3 * Image DISPLAYS

During RADIOSCOPY, the live image shall always occupy the same DISPLAY location. The status of all displayed images, in particular whether they are currently live or stored and, if stored, whether they are ~~"last-image-hold" images~~ a LIH RADIOGRAM or previously stored reference images, shall be indicated at their relevant DISPLAY locations.

Compliance is determined by inspection and functional tests.

201.12.4.101.4 Indications of emergency power supply

For PERMANENTLY INSTALLED INTERVENTIONAL X-RAY EQUIPMENT, if an emergency power supply is provided with the INTERVENTIONAL X-RAY EQUIPMENT, a visual indicator shall be displayed in the event of failure of the SUPPLY MAINS indicating that the INTERVENTIONAL X-RAY EQUIPMENT is operating on the emergency power supply.

This indicator shall be visible at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

NOTE ~~1~~ See also 201.7.9.2.104 for requirements on ACCOMPANYING DOCUMENTS. See also 201.12.4.108 for requirements on operation of the emergency power supply.

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

201.12.4.102 * IMAGE DISPLAY DELAY

IMAGE DISPLAY DELAY during RADIOSCOPY shall be as short as reasonably practicable. The appropriate limit shall be determined in the RISK MANAGEMENT FILE.

The instructions for use shall state that, if the RADIOGRAPHY mode is misused on purpose by the OPERATOR for real-time imaging, the IMAGE DISPLAY DELAY ~~may~~ can be longer than in RADIOSCOPY.

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

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

201.12.4.103 * Documentation of image orientation

If it is possible for the OPERATOR to change the image orientation, the INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the image orientation on both the displayed and stored images.

The INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the PATIENT orientation.

Compliance is checked by functional tests.

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

201.12.4.104 * Availability of RADIOSCOPY during networking activities

Networking activities shall not have an impact on the availability of RADIOSCOPY.

Compliance is checked by functional tests.

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

201.12.4.105 * Appropriate mask location for subtracted images

When automatic subtraction means are provided for ~~imaging~~ MODES OF OPERATION where several mask images are acquired at different equipment positions, for any given image to be subtracted, the corresponding mask image shall be selected so that the difference between the position of the equipment at which this mask image was acquired and the position of the equipment for the image to be subtracted with this mask is minimized.

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

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

201.12.4.106 * Tableside controls

For tableside controls, as a minimum, the following user interface controls, requiring operation by touch, shall be individually and unambiguously identifiable both by touch alone and also by sight alone:

– GANTRY and PATIENT SUPPORT motions controls (not including motion controls for preselecting INTERVENTIONAL X-RAY EQUIPMENT positions);

– IRRADIATION SWITCHES (other than footswitches);

– ~~collimation~~ beam limitation blade control (not including WEDGE FILTER control).

~~Collimation~~ Beam limitation blade control may additionally be operated by a duplicated tableside control, such as a touchscreen user interface.

All tableside controls shall be identifiable under the lighting conditions for the INTENDED USE, and if applicable, when covered by transparent protective drapes.

Compliance is checked by inspection and by functional tests.

NOTE A tableside control is a control that can be operated adjacent to the PATIENT during a RGI PROCEDURE regardless of whether or not it is physically attached to the PATIENT SUPPORT. A footswitch is not a tableside control for the purposes of this subclause.

201.12.4.107 * Image measuring functions

The instructions for use shall describe the image measuring functions, their units and their related inaccuracies with regards to the INTENDED USE.

The errors in image measuring functions introduced by the INTERVENTIONAL X-RAY EQUIPMENT shall be as small as reasonably practicable depending on the MODE OF OPERATION and INTENDED USE.

For measurements displayed by the INTERVENTIONAL X-RAY EQUIPMENT having a measuring function, each value shall be displayed together with its unit.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and appropriate inspection and functional tests.

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

201.12.4.108 Provision for emergency power supply

The requirements in this subclause apply only for INTERVENTIONAL X-RAY EQUIPMENT that is PERMANENTLY INSTALLED and that is provided with an emergency power supply. For such INTERVENTIONAL X-RAY EQUIPMENT, the return to the SUPPLY MAINS in case of power failure shall be as follows:

a) If RADIOSCOPY is currently being performed,
   - in the case of automated return to SUPPLY MAINS, the SUPPLY MAINS return shall be performed without interruption of RADIOSCOPY;
   - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS, to allow for initiating the switching back to SUPPLY MAINS by the OPERATOR. This indicator shall be visible at the working positions of the OPERATOR.

b) If RADIOSCOPY is currently not being performed,
   - in the case of automated return to SUPPLY MAINS, there shall be no interruption in the availability of RADIOSCOPY;
   - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS. This indicator shall be visible at the working positions of the OPERATOR. An immediate switching back by the OPERATOR shall be possible when the SUPPLY MAINS is indicated to be available.

Compliance is checked by functional tests.

NOTE 1 See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.7.9.~~2.104~~3.102 for requirements on ACCOMPANYING DOCUMENTS.

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

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 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:

Additional subclauses:

201.15.101 * Configuration for cardiopulmonary resuscitation (CPR)

In NORMAL CONDITION, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can be placed in a configuration designated for CPR within 15 s. This period ~~may be~~ is increased by 1 s for each 15° of tilt that the current working position of the PATIENT SUPPORT deviates from the CPR position.

In SINGLE FAULT CONDITIONS excluding SUPPLY MAINS failure, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can either comply with the CPR configuration time in NORMAL USE or shall be able to release or properly position the PATIENT within a time as low as reasonably practicable.

Compliance is determined by inspection of the RISK MANAGEMENT FILE and by appropriate functional tests.

In case of SUPPLY MAINS failure, the requirement for the NORMAL CONDITION applies.

Compliance is checked by disconnecting the INTERVENTIONAL X-RAY EQUIPMENT from the SUPPLY MAINS and verifying that the EQUIPMENT can be placed in CPR conditions.

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

201.15.102 Attachment of sterile drapes

Means shall be provided, and described in the instructions for use, for allowing sterile drapes to be attached to the INTERVENTIONAL X-RAY EQUIPMENT or its ACCESSORIES to enable RGI PROCEDURES to be conducted with an appropriate level of sterility.

Compliance is determined by inspection of the INTERVENTIONAL X-RAY EQUIPMENT and the instructions for use.

201.16 ME SYSTEMS

Clause 16 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:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Replacement:

Subclause 201.16.8 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 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:

Amendment of the compliance method:

Compliance is checked as specified in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, except where modified by Clause 202.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

Additional clause:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Subclause 202.101 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD1:2015~~2022 applies.

203 RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If~~, for INTERVENTIONAL X-RAY EQUIPMENT,~~ compliance with this document is ~~to be~~ stated, the statement shall ~~be made in~~ include the followings:

– 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.

Additional subclause:

203.4.101 Qualifying conditions for defined terms

Clause 203.4.101 of IEC 60601-2-54:~~2009~~2022 applies.

203.5.2.1 References in subclauses

~~**Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS**~~

Amendment:

In Table 2 of IEC 60601-1-3:2008, the line about Clinical protocols, Subclause 5.2.4.4, does not apply.

203.5.2.4 Instructions for use

203.5.2.4.4 Clinical protocols

Subclause 5.2.4.4 of IEC 60601-1-3:2008 does not apply.

203.5.2.4.5 Deterministic effects

Additional subclauses:

203.5.2.4.5.101 * Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY

NOTE Differences related to the same subclause in IEC 60601-2-54:2022 include: point b): item 1), item 2) and item 5); point c): the variations due to selectable ADDED FILTERS, etc. are ~~to be~~ given for all settings and not for only two settings.

a) SKIN DOSE levels

The instructions for use shall draw attention to the RISK of local SKIN DOSE levels that cause deterministic effects (tissue reactions) under the INTENDED USE in the case of repetitive or prolonged exposure. The effect of the various selectable settings available in both RADIOSCOPY and RADIOGRAPHY on the RADIATION QUALITY, the delivered REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE shall be described.

Compliance is checked by inspection of the instructions for use.

b) Available settings

In the instructions for use, information shall be provided on the available configurations delivered by the MANUFACTURER such as MODES OF OPERATION, settings of LOADING FACTORS and other operating parameters that affect the RADIATION QUALITY or the prevailing value of REFERENCE AIR KERMA (RATE) in the INTENDED USE. If applicable this information shall include:

1) the values of the REFERENCE AIR KERMA (RATE) applying to the MODES OF OPERATION in RADIOSCOPY designated normal and low in accordance with 203.6.101;
2) details of all other MODES OF OPERATION, giving the default values of the REFERENCE AIR KERMA (RATE), and the available ranges for any factor that can be varied after the MODE OF OPERATION has been selected;
3) the settings of LOADING FACTORS and other operating parameters in RADIOSCOPY delivering the highest available REFERENCE AIR KERMA RATE;
4) the settings of LOADING FACTORS and other operating parameters in RADIOGRAPHY delivering the highest available REFERENCE AIR KERMA per frame;
5) one set of REFERENCE AIR KERMA (RATE) values typical of RADIOGRAPHY for distinctive types of ~~procedure~~ RGI PROCEDURES for which the INTERVENTIONAL X-RAY EQUIPMENT is intended to be used.

Compliance is checked by inspection of the instructions for use.

c) RADIATION data

In the instructions for use, for the MODES OF OPERATION and sets of values described in accordance with the settings in b) above, representative values of REFERENCE AIR KERMA (RATE) shall be given, based on measurement by the method described in 203.5.2.4.5.102.

In addition, representative values of REFERENCE AIR KERMA (RATE) based on measurement by the method described in 203.5.2.4.5.102 shall be given in the instructions for use, for respectively the MODES OF OPERATION and sets of values described in accordance with the settings in b) 1) and b) 2) of this subclause, and if they are adjustable by the OPERATOR in the MODE OF OPERATION concerned, for all settings of the following factors:

– selectable ADDED FILTERS;
– ENTRANCE FIELD SIZE;
– X-RADIATION pulse repetition frequency.

Information shall be given on the configurations of the INTERVENTIONAL X-RAY EQUIPMENT and the test geometries that can be used in the PROCEDURE described in 203.5.2.4.5.102 to verify the values given. Although it is required to provide details to enable verification by measurement in accordance with 203.5.2.4.5.102, the stated values may be determined originally by other methods, including calculation, leading to values that are in compliance, subject to the permitted tolerances, when verified by the method given in 203.5.2.4.5.102.

MEASURED VALUES shall not deviate from stated values by more than 50 %.

Compliance is checked by functional tests and inspection of the instructions for use. The stated values REFERENCE AIR KERMA (RATE) and statements concerning the variation of these values are verified by the method described in 203.5.2.4.5.102, using configurations and test geometries and settings described in the instructions for use.

d) PATIENT ENTRANCE REFERENCE POINT

In the instructions for use, the location of the PATIENT ENTRANCE REFERENCE POINT shall be described as specified for the type of INTERVENTIONAL X-RAY EQUIPMENT:

The PATIENT ENTRANCE REFERENCE POINT is located:

– 1 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT;
– 30 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT;
– 15 cm from the ISOCENTRE in the direction of the FOCAL SPOT for C-arm INTERVENTIONAL X-RAY EQUIPMENT or
  - for C-arm INTERVENTIONAL X-RAY EQUIPMENT without an ISOCENTRE, a point along the X-RAY BEAM AXIS defined by the MANUFACTURER as being representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT SURFACE. In this case, the statement in the instructions for use shall include the rationale for the choice of position made by the MANUFACTURER or
  - at the point representing the minimum FOCAL SPOT TO SKIN DISTANCE for C-arm INTERVENTIONAL X-RAY EQUIPMENT with FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm,
– for INTERVENTIONAL X-RAY EQUIPMENT not listed above the PATIENT ENTRANCE REFERENCE POINT shall be specified by the MANUFACTURER.

Compliance is checked by inspection of the instructions for use

203.5.2.4.5.102 * Test for dosimetric information

a) Relevant parameters

It is required in 203.5.2.4.5.101 to provide, in the instructions for use, a description of the configurations and test geometries applying to the stated values of REFERENCE AIR KERMA (RATE). The following are examples of factors that ~~need to~~ could be referenced, when relevant to the INTERVENTIONAL X-RAY EQUIPMENT settings concerned.

i) Equipment configuration

1) Orientation of the X-RAY BEAM

2) PATIENT SUPPORT in or out

3) ANTI-SCATTER GRID in or out

4) Appropriate ENTRANCE FIELD SIZE selected

ii) Operating settings (representative of NORMAL USE)

1) Technical details of parameters included in each MODE OF OPERATION

2) Frame rate

3) Selectable ADDED FILTERS automatically applied

4) Selectable ADDED FILTERS manually applied

iii) Test geometry

1) FOCAL SPOT TO IMAGE RECEPTOR DISTANCE

2) Distance of FOCAL SPOT to measuring detector

3) RADIATION FIELD size at the measuring detector

4) Positioning of PHANTOM (see item c) below)

5) Positioning of measuring detector (see item c) below)

b) Checking the test conditions

Before any dosimetric measurements are made, verify that the particulars of the INTERVENTIONAL X-RAY EQUIPMENT settings under test and the associated measuring arrangements given in the instructions for use are in compliance with 203.5.2.4.5.101.

c) Measurements and test conditions:

– *Use a 20 cm polymethyl-methacrylate (PMMA) PHANTOM (the PHANTOM may be fabricated from layers of material) comprising of rectangular blocks with sides equal to or exceeding 25 cm. Area density of the nominal 20 cm PHANTOM: 23,5 g/cm^2, with a relative tolerance of ± 5 %.*

– *Use a DOSIMETER with a measuring detector small enough to cover not more than 80 % of the area of the X-RAY BEAM in the plane of measurement~~, and the area of its surface perpendicular to the source-detector axis shall not exceed 30 cm^2~~.*

– *The PHANTOM is placed near the X-RAY IMAGE RECEPTOR, leaving as much of the available distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM.*

– *Position the measuring detector at a point that is either:*

  • *the PATIENT ENTRANCE REFERENCE POINT (only if there is at least 20 cm distance between the measuring detector and the PHANTOM)*

  or

  • *half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM. In that case, the~~ readings are to be corrected~~ MEASURED VALUES include scaling to the appropriate distance.*

– *Measure the AIR KERMA RATE for the RADIOSCOPY settings for which a value of REFERENCE AIR KERMA RATE is required to be stated in 203.5.2.4.5.101 c).*

– *Measure the AIR KERMA per image for RADIOGRAPHY settings as required to be stated in 203.5.2.4.5.101 c).*

– *For each setting required in 203.5.2.4.5.101, measure the AIR KERMA (RATE) using the PHANTOM described:*

  • *for all representative OPERATOR selectable ENTRANCE FIELD SIZES;*

  • *for all representative OPERATOR selectable ADDED FILTERS;*

  • *for all representative OPERATOR selectable pulse repetition frequencies.*

– *The surface of the PHANTOM shall be aligned perpendicular to the X-RAY BEAM AXIS within ±2 ° in all directions.*

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

Additional subclauses:

203.5.2.4.101 Instruction for use of the IRRADIATION disabling switch

The instructions for use shall ~~recommend~~ mention that the IRRADIATION disabling switch be used at all times, except when a RGI PROCEDURE is in progress, to prevent the possibility of RADIATION being emitted through the inadvertent actuation of an IRRADIATION SWITCH.

203.5.2.4.102 EXAMINATION PROTOCOLS

Subclause 203.5.2.4.101 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

NOTE The numbering of the cited subclause from IEC 60601-2-54 is different.

203.6 RADIATION management

203.6.1 General

Additional subclauses:

203.6.1.101 Management of RADIOSCOPY image storage

INTERVENTIONAL X-RAY EQUIPMENT shall provide the capability to store a RADIOSCOPY REPLAY IMAGE SEQUENCE for DISPLAY. This capability may be limited to storage of images as follows:

– at pulse rates up to 10 pulses per second, the last 30 s of RADIOSCOPY;
– for pulse rates greater than 10 pulses per second, the last 300 images;
– for continuous RADIOSCOPY, the last 10 s of RADIOSCOPY.

This requirement does not apply to MOBILE X-RAY EQUIPMENT with a maximum FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm and that is specified for extremities use only in its INTENDED USE.

NOTE The storage is not required to be a permanent storage.

Compliance is checked by functional test.

203.6.1.102 Management of EXAMINATION PROTOCOLS

Subclause 203.6.1.102 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.6.2 Initiation and termination of the IRRADIATION

Subclause 203.6.2 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Subclause 203.6.3.1 of IEC 60601-2-54:~~2009~~2022 applies except that the additional manual control without the use of the AUTOMATIC CONTROL SYSTEM in subclause 203.6.3.1 b) of IEC 60601-2-54:~~2009~~2022 is not possible.

203.6.3.2 Reproducibility of the RADIATION output

Subclause 203.6.3.2 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

Additional subclauses:

203.6.3.101 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

Subclause 203.6.3.101 of IEC 60601-2-54:~~2009~~2022 applies.

203.6.3.102 High-level control (HLC)

Subclause 203.6.3.102 of IEC 60601-2-54:~~2009~~2022 applies.

203.6.3.103 * X-RADIATION pulse repetition frequency during RADIOSCOPY

If the RADIOSCOPY pulse rate is selectable, the minimum pulse rate shall be less than or equal to 4 pulses per second.

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

The LOADING STATE shall be indicated by a yellow indicator on the CONTROL PANEL.

At the initiation of IRRADIATION, a brief audible signal shall be indicated at the working position of the OPERATOR. The audible signal shall be different for RADIOSCOPY and for RADIOGRAPHY. Means shall be provided to adjust or inactivate these audible signals and shall be described in the ACCOMPANYING DOCUMENTS. All of these requirements do not apply to high-level control (HLC) RADIOSCOPY.

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

Compliance is checked by inspection.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Subclause 203.6.4.3 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.6.4.4 Indication of automatic modes

Subclause 203.6.4.4 of IEC 60601-2-54:~~2009~~2022 applies.

203.6.4.5 * Dosimetric indications

Addition:

NOTE 1 Differences related to the same subclause in IEC 60601-2-54:~~2009, IEC 60601-2-54:2009/AMD1:2015 and IEC 60601-2-54:2009/AMD2:2018~~2022 include: the 1st dash of the 3rd paragraph is applicable also to SERIAL RADIOGRAPHY; in the 4th paragraph, the minimal value is 2,5 Gy·cm^2 instead of 5 µGy·m^2, i.e. is 50 times larger; the recommended unit for displaying the DOSE AREA PRODUCT is Gy·cm^2; a requirement to have means for configuring the display unit of the DOSE AREA PRODUCT is present; additional requirements and recommendations are present after the requirement about DOSE AREA PRODUCT METERS, including additional requirement and recommendation about DOSE MAP and SKIN DOSE MAP; and also, unlike in IEC 60601-2-54, there is no specific requirement for INDIRECT RADIOGRAPHY and DIRECT RADIOGRAPHY.

The ACCOMPANYING DOCUMENTS shall provide information on the performance of the dosimetric indications and describe the operations required to maintain this performance within specification.

Means shall be provided to reset to zero the values of all the cumulative dosimetric indications prior to the commencement of a new ~~examination or~~ RGI PROCEDURE.

INTERVENTIONAL X-RAY EQUIPMENT specified for either RADIOSCOPY or RADIOSCOPY and RADIOGRAPHY shall satisfy the following requirements.

– The value of the mean REFERENCE AIR KERMA RATE shall be displayed during RADIOSCOPY and during SERIAL RADIOGRAPHY in mGy/min together with this unit. This value shall be

continuously displayed at the working position of the OPERATOR during the actuation of the IRRADIATION SWITCH and updated at least once every second.

– The value of the cumulative REFERENCE AIR KERMA resulting from RADIOSCOPY and RADIOGRAPHY since the last reset operation shall be

  • continuously displayed at the working position of the OPERATOR in mGy together with this unit and updated at least once every 5 s; or

  • displayed not later than 5 s after the interruption or termination of LOADING.

– The values for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be clearly distinguishable from each other.

– The REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall not deviate from their respective displayed values by more than ± 35 % over the range of 6 mGy/min and 100 mGy to the maximum values.

– The displayed values of REFERENCE AIR KERMA RATE and cumulative REFERENCE AIR KERMA may be measured or calculated.

INTERVENTIONAL X-RAY EQUIPMENT shall be provided with an indication of the cumulative DOSE AREA PRODUCT resulting from RADIOGRAPHY and from RADIOSCOPY since the last reset operation. The DOSE AREA PRODUCT may be measured or calculated. The value should be expressed in Gy·cm^2. Means shall be provided to the RESPONSIBLE ORGANIZATION to allow configuring the unit for display of DOSE AREA PRODUCT at least among all the following:

– Gy·cm^2;

– µGy·m^2 or cGy·cm^2;

– mGy·cm^2.

The instructions for use shall indicate that the unit for display of DOSE AREA PRODUCT is configurable.

The overall uncertainty of the displayed values of the cumulative DOSE AREA PRODUCT above 2,50 Gy·cm^2 shall not exceed 35 %.

NOTE 2 The DOSE AREA PRODUCT indication ~~need~~ is not mandatory to be provided at the working position of the OPERATOR.

If part of the INTERVENTIONAL X-RAY EQUIPMENT, DOSE AREA PRODUCT METERS shall comply with IEC 60580:2019.

The indications of cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE shall be CLEARLY LEGIBLE 2,5 m from the DISPLAY in the procedure room. This DISPLAY may be included on an image monitor or it may be a separate device.

The display label for the cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT shall not be designated as SKIN DOSE and SKIN DOSE rate respectively.

When the cumulative REFERENCE AIR KERMA displayed on the INTERVENTIONAL X-RAY EQUIPMENT exceeds a threshold expected to produce skin injury, the INTERVENTIONAL X-RAY EQUIPMENT should display a visual warning to the OPERATOR. When such a DISPLAY is provided, the threshold value shall be adjustable.

The INTERVENTIONAL X-RAY EQUIPMENT should have a DOSE MAP.

NOTE ~~2~~3 If a DOSE MAP is provided, it is intended for display during the RGI PROCEDURE and to be available for export at the end of the RGI PROCEDURE.

NOTE ~~3~~4 A SKIN DOSE MAP is preferred over other DOSE MAPS. An example of a DOSE MAP can be obtained by cumulating the values of REFERENCE AIR KERMA over ranges of the available parameters that influence the location of

the X-RAY BEAM relative to the PATIENT. When the INTERVENTIONAL X-RAY EQUIPMENT cannot determine the orientation of the X-RAY BEAM AXIS, creation of a DOSE MAP is not practical. Mapping head, chest, abdomen and pelvic anatomy is of primary value; mapping extremities is of secondary value due to smaller body part thickness and their variability in position on the PATIENT SUPPORT.

A DOSE MAP shall not be designated as a SKIN DOSE MAP, unless the RADIATION dose quantity is SKIN DOSE.

NOTE 45 Dosimetric indications apply also for operation in cone-beam CT mode. This provides a means to combine the RADIATION dose for all MODES OF OPERATIONS.

Compliance is checked by inspection and by the appropriate functional tests. The tests for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be performed with a LOADING STATE of duration longer than 3 s.

During RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, indications of one or more of the following items should be made available:

– cumulative LOADING TIME of RADIOSCOPY for the whole RGI PROCEDURE;
– cumulative LOADING TIME of RADIOSCOPY for at least one part of the RGI PROCEDURE determined by the OPERATOR;
– cumulative number of IRRADIATIONS from RADIOGRAPHY for the whole RGI PROCEDURE;
– cumulative number of IRRADIATIONS from RADIOGRAPHY for at least one part of the RGI PROCEDURE determined by the OPERATOR;
– cumulative REFERENCE AIR KERMA for at least one part of the RGI PROCEDURE determined by the OPERATOR.

Additional subclause:

203.6.4.101 Indication of READY STATE

Subclause 203.6.4.101 of IEC 60601-2-54:~~2009~~2022 applies.

203.6.5 AUTOMATIC CONTROL SYSTEM

Subclause 203.6.5 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.6.6 SCATTERED RADIATION reduction

Subclause 203.6.6 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies, except as follows:

Addition:

INTERVENTIONAL X-RAY EQUIPMENT specified for paediatric applications shall have means to easily remove the ANTI-SCATTER GRID without the use of TOOLS.

Compliance is determined by inspection and functional tests.

203.6.7 Imaging performance

Additional subclause:

203.6.7.101 * Display of LAST IMAGE HOLD RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE

INTERVENTIONAL X-RAY EQUIPMENT shall be equipped with means to display either a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE following termination of the radioscopic IRRADIATION and shall comply with the following.

1) When the LIH RADIOGRAM is displayed, it shall be displayed following termination of the radioscopic IRRADIATION and shall remain visible either until an action by the OPERATOR or until display of the RADIOSCOPY REPLAY IMAGE SEQUENCE.
2) Means shall be provided to clearly indicate to the OPERATOR whether a displayed image is
   – a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE, or
   – from ongoing RADIOSCOPY.
3) DISPLAY of the LIH RADIOGRAM or the RADIOSCOPY REPLAY IMAGE SEQUENCE shall be replaced by the RADIOSCOPY image concurrently with reinitiation of radioscopic IRRADIATION, unless a separate DISPLAY is provided for the RADIOSCOPY images.
4) For a LIH RADIOGRAM obtained by retaining pre-termination RADIOSCOPY images, if the number of images and method of combining images are selectable by the OPERATOR, the selection shall be indicated prior to the initiation of the radioscopic IRRADIATION.

Compliance is checked by inspection and functional tests.

Additional subclauses:

203.6.101 Range of AIR KERMA RATES in RADIOSCOPY

For RADIOSCOPY the MODES OF OPERATION provided for NORMAL USE shall include two modes, designated normal and low respectively, producing different REFERENCE AIR KERMA RATES, such that the value for the low mode does not exceed 50 % of the value for the normal mode. Additional MODES OF OPERATION may be provided, with REFERENCE AIR KERMA RATES less or greater than the values for the normal and low modes.

A control for the selection of any of these MODES OF OPERATION shall not also perform the function of an IRRADIATION SWITCH.

An indication of the selected MODE OF OPERATION shall be provided at the working position of the OPERATOR.

The INTERVENTIONAL X-RAY EQUIPMENT shall not default to a setting with a REFERENCE AIR KERMA RATE higher than that of the normal setting, when the INTERVENTIONAL X-RAY EQUIPMENT is being prepared for the commencement of a RGI PROCEDURE.

Compliance is determined by inspection and functional tests and also by the test PROCEDURE given in 203.5.2.4.5.102 using the 20 cm polymethyl-methacrylate (PMMA) PHANTOM in order to verify the ratio of the REFERENCE AIR KERMA RATES at the designated normal and low MODES OF OPERATION.

203.6.102 * Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

Means to switch between RADIOSCOPY and RADIOGRAPHY shall be provided at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

203.6.103 IRRADIATION disabling switch

A switch shall be provided to disable/enable the LOADING STATE without affecting any other functions of the INTERVENTIONAL X-RAY EQUIPMENT. The operation of this switch shall not, in itself, be capable of initiating the LOADING STATE.

The state of the IRRADIATION disabling switch shall be displayed at the working position of the OPERATOR. The switch should be configured to minimize the likelihood of accidental operation.

Compliance is determined by inspection and functional tests.

203.6.104 * Last-image-hold (LIH)

For RADIOSCOPY sequences that have not been stored, the INTERVENTIONAL X-RAY EQUIPMENT shall be equipped with means to store the LIH RADIOGRAM with other stored images.

NOTE 1 Storage of the LIH RADIOGRAM is subject to 201.12.4.101.2.

NOTE 2 ~~This item is an addition compared to the first edition of IEC 60601-2-43:2000.~~ The requirement for having a last-image-hold can be found in 203.6.7.101 of IEC 60601-2-54:2022.

Compliance is determined by inspection and functional tests.

203.6.105 Limitation of RADIATION output

In the case of SINGLE FAULT CONDITIONS, there shall be no unwanted IRRADIATIONS.

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

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

203.7 RADIATION QUALITY

Subclause 203.7 of IEC 60601-2-54:~~2009, IEC 60601-2-54:2009/AMD1:2015 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Subclause 203.8.4 of IEC 60601-2-54:~~2009~~2022 applies.

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 * Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Subclause 203.8.5.3 of IEC 60601-2-54:~~2009~~2022 applies, except as follows:

Addition:

Regardless of the shape of the IMAGE RECEPTION AREA (circular and non-circular shape), when the X-RAY BEAM is perpendicular to the IMAGE ~~RECEPTOR~~ RECEPTION PLANE, the maximum area of the X-RAY FIELD shall conform to the following requirements:

a) at least 80 % of the area of the X-RAY FIELD shall overlie the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION AREAS smaller than 10 cm in diameter or less than 10 cm in length on any side are exempted;

b) the X-RAY FIELD measured from the centre of the IMAGE RECEPTION AREA in the direction of greatest misalignment with the IMAGE RECEPTION AREA shall not extend beyond the boundary of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm.

The additional requirement is applicable for all magnification steps and for minimum and maximum positions of the ~~source~~ FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and for horizontal and vertical positions of the GANTRY.

Compliance is checked by inspection and testing of the equipment by measurement of the X-RAY FIELDS. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, in order for the automatic mechanism to complete any adjustment occurring during the tests (see Annex AA).

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Subclause 203.8.5.4 of IEC 60601-2-54:~~2009~~2022 applies.

Additional subclauses:

203.8.101 Boundary and dimensions of the X-RAY FIELD

Subclause 203.8.101 of IEC 60601-2-54:~~2009~~2022 applies.

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

~~*Additional subclauses:*~~

203.8.102.1 General

Subclause 203.8.102.1 of IEC 60601-2-54:~~2009~~2022 applies.

203.8.102.2 Indication on the X-RAY EQUIPMENT

INTERVENTIONAL X-RAY EQUIPMENT shall provide a graphical representation of the boundaries of the X-RAY FIELD on the image DISPLAY while the BEAM LIMITING DEVICE is adjusted when no IRRADIATION SWITCH is actuated. This representation shall be

– provided at the working position of the OPERATOR, and
– updated during BEAM LIMITING DEVICE adjustment.

203.8.102.3 Indication in the instructions for use

Subclause 203.8.102.3 of IEC 60601-2-54:~~2009~~2022 applies.

203.8.102.4 Accuracy of marked and written indications

Subclause 203.8.102.4 of IEC 60601-2-54:~~2009~~2022 applies.

203.8.103 Interception of the X-RAY BEAM in RADIOSCOPY

Subclause 203.8.103 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.8.104 Positioning of the X-RAY BEAM AXIS

Subclause 203.8.104 of IEC 60601-2-54:~~2009~~2022 applies.

203.9 FOCAL SPOT TO SKIN DISTANCE

Subclause 203.9 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Subclause 203.10 of IEC 60601-2-54:~~2009~~2022 applies.

203.11 Protection against RESIDUAL RADIATION

Subclause 203.11 of IEC 60601-2-54:~~2009~~2022 applies.

203.12 Protection against LEAKAGE RADIATION

Subclause 203.12 of IEC 60601-2-54:~~2009~~2022 applies.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Subclause 203.13.2 of IEC 60601-2-54:~~2009~~2022 applies.

203.13.3 Protection by distance

Subclause 203.13.3 of IEC 60601-2-54:~~2009~~2022 applies.

203.13.4 Designated SIGNIFICANT ZONES OF OCCUPANCY

Subclause 13.4 of IEC 60601-1-3:2008 applies, except as follows:

Replacement of the third dashed item in the third paragraph in 13.4 of IEC 60601-1-3:2008:

– Isokerma maps shall be provided in the ACCOMPANYING DOCUMENTS, describing the distribution of STRAY RADIATION around the INTERVENTIONAL X-RAY EQUIPMENT. These maps shall apply to typical configurations of the INTERVENTIONAL X-RAY EQUIPMENT when operated at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and shall satisfy the following conditions:

- information shall be given for at least one typical configuration with the X-RAY BEAM horizontal and one with the X-RAY BEAM vertical;
- the isokerma maps shall be presented as isokerma curves normalised to a DOSE AREA PRODUCT of 1 Gy·cm^2;
- the isokerma maps shall be given at heights of 1,0 m and 1,5 m above the floor and may be given additionally for other planes;
- the values of adjacent curves of the isokerma map shall not differ by more than a factor of 2;
- the measurement geometry on which the data are based shall be compatible with the arrangements used for verification as described in Annex BB*;*
- the data presented shall be accurate within ±50 % at all points more than 15 cm from the INTERVENTIONAL X-RAY EQUIPMENT or PHANTOM and within 3 m of the PATIENT ENTRANCE REFERENCE POINT or down to 0,1 μGy/(Gy·cm^2).

The information shall also include, for each configuration, a scaled schematic representation of the arrangement of the INTERVENTIONAL X-RAY EQUIPMENT showing the projection of the FOCAL SPOT on to the plane of the drawing. Details shall also be given of the applicable measurement geometry, FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, X-RAY TUBE VOLTAGE and ENTRANCE FIELD SIZE.

NOTE Examples of the presentation of isokerma maps are given in Figure BB.1 and Figure BB.2.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS. The isokerma maps are checked by the PROCEDURE described in Annex BB.

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT, means to switch into and out of the LOADING STATE shall be available for use by an OPERATOR located in the following positions:

a) In any of the designated SIGNIFICANT ZONES OF OCCUPANCY, with the INTERVENTIONAL X-RAY EQUIPMENT appropriately configured; a single footswitch with a sufficiently long cable may be used for several SIGNIFICANT ZONES OF OCCUPANCY near the PATIENT;

b) At least 2 m from the irradiated region of the PATIENT, or within a PROTECTED AREA if provided in the installation.

For INTERVENTIONAL X-RAY EQUIPMENT, all visual and audible signals required by 203.6.4.2 shall be provided in such a way that they are perceptible to the OPERATOR in all the locations of items

a) and b) above. The presence of an image on the monitor shall not be considered as satisfying this requirement.

Additional subclauses:

203.13.4.101 SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION

Subclause 203.13.4.101 of IEC 60601-2-54:~~2009~~2022 applies.

203.13.4.102 Control from a designated SIGNIFICANT ZONE OF OCCUPANCY

Subclause 203.13.4.102 of IEC 60601-2-54:~~2009~~2022 applies.

203.13.5 Handgrips and control devices

Subclause 203.13.5 of IEC 60601-2-54:~~2009~~2022 applies.

203.13.6 Test for STRAY RADIATION

For testing 203.13.4, subclause 13.6 of IEC 60601-1-3:2008 does not apply and Annex BB applies.

For testing 203.13.4.101 and 203.13.5, subclause 203.13.6 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022 applies.

Additional subclause:

203.101 DIRECT RADIOSCOPY

DIRECT RADIOSCOPY shall not be permitted on INTERVENTIONAL X-RAY EQUIPMENT.

Annexes

The annexes of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of this document. Its purpose is to promote effective application of this document by explaining the reasons for the requirements and provide additional guidance where appropriate.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

Indications for the need to use INTERVENTIONAL X-RAY EQUIPMENT complying with this document.

Since the early 1980s, there has been a substantial increase in the use of RADIOSCOPY for visualisation in a wide range of diagnostic ~~and interventional~~ procedures and RGI PROCEDURES. All indications are that this increase will continue in the near future. These ~~interventional~~ RGI PROCEDURES sometimes require long periods of RADIOSCOPY operation with, in some cases, an unchanged position of the RADIATION FIELD on the PATIENT SURFACE. It should be noted that these RGI PROCEDURES usually provide significant advantages over alternative therapies in terms of overall clinical outcome for the PATIENT. Table AA.1 provides examples of ~~interventional~~ RGI PROCEDURES which ~~may~~ can involve prolonged RADIOSCOPY IRRADIATION TIMES. In addition, these RGI PROCEDURES are performed by a variety of clinicians with different degrees of training in RADIOLOGICAL PROTECTION. Because of these characteristics, these ~~interventional~~ RGI PROCEDURES are different from procedures in medical diagnostic RADIOLOGY in that the possibility of deterministic effects such as RADIATION-induced skin injury cannot be excluded.

Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible

Radio-frequency cardiac catheter ablations
Transjugular intrahepatic portosystemic shunt (TIPS)
Embolizations
Cardiac and non-cardiac vascular reconstructions

The concern over confirmed RADIATION-induced skin injuries as a result of some ~~interventional~~ RGI PROCEDURES has prompted some countries to issue special advice on the avoidance of injuries during RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES [8], [9]. This special advice has included a recommendation for INTERVENTIONAL X-RAY EQUIPMENT features that permit estimation of the ABSORBED DOSE to the skin. The purpose of this recommendation is to encourage identification of those areas of the skin which are irradiated to levels of ABSORBED DOSE that approach or exceed the threshold for deterministic injury. Such identification would be important for communication and PATIENT care upon the onset of symptoms of RADIATION injury or where additional IRRADIATION in the same skin area is being considered. In addition, the information ~~may~~ can assist medical practitioners and health-care organisations in improving ~~interventional~~ RGI PROCEDURES, thereby reducing the potential for injury in the future.

There are also a number of ~~interventional~~ RGI PROCEDURES in which these particular radiations RISKS do not arise by the nature of the RGI PROCEDURE but for which a part or all of other interventional RISKS apply, such as bleeding, infection, blood vessel damage. Some examples of these RGI PROCEDURES are given in Table AA.2.

Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely

IVC filter placement
Venous access
Biopsy
Dialysis access maintenance

The decision to offer equipment complying with this document rests with the MANUFACTURER. The decision to use interventionally labelled EQUIPMENT rests with the RESPONSIBLE ORGANIZATION and OPERATOR of the INTERVENTIONAL X-RAY EQUIPMENT.

See also references [10], [11].

Subclause 201.3.~~201~~203 – IMAGE DISPLAY DELAY

The IMAGE DISPLAY DELAY relates to the latency between the physical production of any X-ray pulse and the appearance of the corresponding image.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 state that the term ESSENTIAL PERFORMANCE is directly related to the performance of a clinical function (definition 3.27 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012). Table 201.101 provides a list of requirements that can be correlated with the performance of a clinical function and that could therefore be ESSENTIAL PERFORMANCE. The decision on whether any of these requirements constitutes ESSENTIAL PERFORMANCE is subject to a RISK EVALUATION that considers the INTENDED USE of the X-RAY EQUIPMENT.

The identification of potential ESSENTIAL PERFORMANCE requirements is justified because the RISK associated with ionizing X-RADIATION is overweighed by the benefits expected from the examination.

The intent of the requirements in this document is to support MANUFACTURERS in providing state-of-the-art X-RAY EQUIPMENT that is safe under NORMAL CONDITIONS.

Requirements under SINGLE FAULT CONDITIONS are either stipulated in this document or determined by the RISK EVALUATION. There can be cases in which simply detection of SINGLE FAULT CONDITIONS during regular checks within a maintenance or a QUALITY CONTROL PROCEDURE is considered sufficient. In some other cases, a RISK which occurs under SINGLE FAULT CONDITIONS is considered acceptable due to its low probability or low SEVERITY. However, SINGLE FAULT CONDITIONS that result in an unacceptable RISK due to the probability of HARM or the SEVERITY of HARM require additional RISK CONTROL measures. These RISK CONTROL measures are selected according to ISO 14971 and can include frequent functional self-monitoring, installation of redundant parts, or appropriate protective measures.

Subclause 201.4.101 – Recovery management

A failure recoverable by the OPERATOR (for example a reset of the equipment) is a failure for which a series of practical actions can be made by the OPERATOR with the means available with the equipment and described in the instructions for use.

A failure that would not be recoverable by the OPERATOR would require external help such as a service intervention or means that are not provided with the equipment.

Returning to the MODE OF OPERATION which was used at the time of the recoverable equipment failure is important in the sense that some RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES require the use of magnification and high RADIATION doses in order to visualize devices such as small stents, catheters, etc. These devices can be minimally radiopaque. In order to ensure that these devices can be safely placed or safely removed, it is necessary to return to the previous mode of RADIOSCOPY used by the OPERATOR to visualize them.

The normal operation of many controls as mentioned in the requirement is important. Because recoverable equipment failure should be uncommon, when it does occur there will be confusion on the part of the OPERATOR. Emergency functions should be operated using the same controls and in the same way as during non-emergency operation, in order to minimize this confusion.

Subclause 201.4.102 – RADIATION dose documentation

Recording manually the displayed dose values is not considered as being robust enough to provide freedom from the RISK arising from the lack of dose information.

There are two reasons why the ability to export dose data is a potential ESSENTIAL PERFORMANCE. The first is the need to know the PATIENT's RADIATION dose from previous ~~interventional~~ RGI PROCEDURES. The second is the need to know the PATIENT's RADIATION dose from the current RGI PROCEDURE.

In the first case, the HAZARD to the PATIENT is the absence of information regarding the PATIENT's RADIATION dose from previous RGI PROCEDURES. Previous RADIATION to the skin sensitizes it and lowers the threshold for deterministic effects with subsequent IRRADIATION. Without knowledge of the amount of RADIATION previously delivered to the skin, the OPERATOR cannot judge the likelihood of causing HARM and will have difficulty performing the RGI PROCEDURE so as to minimize the RISK of causing HARM. The RISK due to this HAZARD is therefore the increased likelihood of HARM due to RADIATION; specifically, deterministic injury to the skin. The SEVERITY of this HARM can be extreme: a skin lesion that is painful, disfiguring, causes inability to work and loss of income, requires surgery to treat and ~~may~~ can take years to heal. ([12], [13])

In the second case, the HAZARD to a PATIENT who has undergone ~~an interventional~~ a RGI PROCEDURE and has received a dose high enough to cause deterministic effects is the absence of information regarding RADIATION dose from that RGI PROCEDURE. The HARM is the inability to provide the PATIENT with a diagnosis and prognosis for the deterministic injury unless the physician who performed the RGI PROCEDURE has separately recorded the dose data. The SEVERITY of the deterministic injury is directly proportional to the SKIN DOSE, and appropriate management depends on knowledge of the dose.

The RISK is high for the ~~interventional~~ RGI PROCEDURES that are the INTENDED USE of equipment subject to this document. ([14],[15],[16],[17], [20], [23]) The importance of recording and preserving dose data for PATIENTS undergoing ~~interventional~~ RGI PROCEDURES is so great that in some countries recording these data is mandatory.([18])

The ~~ESSENTIAL~~ performance required to ~~provide freedom from unacceptable~~ reduce the RISK is the ability to export dose data, with or without image data, in a publicly available form. A publicly available form is necessary so that a physician reviewing previous RGI PROCEDURES will have these dose data available. One cannot assume that the physician will be able to access dose data recorded in a proprietary format.

For EQUIPMENT intended for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, dose data export capability as described in subclause 201.4.~~2~~102 is needed – dose data are recorded in public fields, the output is DICOM compatible, and the data recorded are sufficient to permit a medical physicist to reconstruct actual SKIN DOSE from overlapping RADIATION FIELDS. SKIN DOSE

reconstructions are more accurate than the crude estimates of SKIN DOSE that are provided by measurements of overall dose, such as cumulative dose and DAP. ([14], [19], [21], [22])

~~See also reference [19].~~

Subclause 201.7.2.102 – PATIENT SUPPORT load

Removing the CPR loading from the SAFE WORKING LOAD in the marked value is to allow for CPR provision.

Subclause 201.7.2.105 – Protection against ingress of liquids

Ingress of body fluids ~~may~~ can create HAZARDOUS SITUATIONS for person working/servicing the INTERVENTIONAL X-RAY EQUIPMENT. When attached protective covers are used, although they contribute to this protection, they are not taken into account for the IPXY markings in accordance with definition 3.1 of IEC 60529:1989.

It is desirable that the location "in the PATIENT vicinity (or around the PATIENT)" means locations within 1,5 m from the ~~TABLE~~ PATIENT SUPPORT.

Subclause 201.7.9.2.12 – Cleaning, disinfection and sterilization

The need for the development of this document in this area arises from the nature of ~~interventional~~ RGI PROCEDURES and the heightened awareness of the RISK of transmission of potentially lethal organisms. Whilst incisions made during ~~interventional~~ RGI PROCEDURES are small, large blood vessels and collections of body fluids (for example, abscesses) are frequently directly accessed with catheters or tubes. Arising from this, blood and body fluids ~~may~~ can spill on to or contaminate the work environment and the INTERVENTIONAL X-RAY EQUIPMENT. Some RGI PROCEDURES also involve copious quantities of fluids being used to wash or flush away debris during RGI PROCEDURES. These fluids have been known to enter and lodge in cavities and crevices in the INTERVENTIONAL X-RAY EQUIPMENT, thereby producing both electrical and infection control HAZARDS. The latter ~~may~~ can be a serious problem for maintenance technicians who ~~may~~ can have to approach INTERVENTIONAL X-RAY EQUIPMENT containing up to several litres of saline and miscellaneous body fluids of unknown origin. The possibility of such occurrences ~~may~~ can be greatly reduced or even eliminated at the design stage of the INTERVENTIONAL X-RAY EQUIPMENT, by giving careful thought to the issues involved.

The possibility that INTERVENTIONAL X-RAY EQUIPMENT ~~may~~ can become contaminated or have fluids or deposits lodge in cracks and crevices, gives rise to the need for cleaning and disinfection. This, in turn, gives rise to the use of cleaning and disinfection agents which ~~may~~ can achieve their own aims admirably but, in doing so, can give rise to electrical HAZARDS or damage the INTERVENTIONAL X-RAY EQUIPMENT surfaces to which they are applied. Again, such problems can be greatly reduced at the design stage, and by giving explicit instructions on cleaning and disinfection.

Subclause 201.7.9.2.102 – Provisions for cardiopulmonary resuscitation (CPR)

The INTERVENTIONAL X-RAY EQUIPMENT is not designed primarily to perform CPR and does not need to provide all the necessary ACCESSORIES to perform CPR. However, it is important that the INTERVENTIONAL X-RAY EQUIPMENT be designed so that CPR can be given to the PATIENT when the INTERVENTIONAL X-RAY EQUIPMENT is properly configured. If, in order to configure the system for the performance of CPR, it is necessary to use or to remove specific ACCESSORIES that are part of the INTERVENTIONAL X-RAY EQUIPMENT, then the instructions for use have to describe this.

Subclause 201.7.9.2.103 – Emergency instructions

It is intended that the emergency instructions be immediately available, and they are therefore exposed and susceptible to damage and fluids. The resistance to manipulation, water damage and cleaning is related to the durability of the emergency instructions. A plasticized set of sheets is an example of durable emergency instructions.

Limiting the content of emergency instructions to include only key material will be ~~particular~~ important for their effective use during an emergency when there is no time to consult a long version of the instructions for use or when it is not possible to consult an electronic version due to loss of power. The intention is that these emergency instructions be brief.

Subclause 201.9.2.4 – Emergency stopping devices

In INTERVENTIONAL X-RAY EQUIPMENT, HAZARDS can arise if functionality is unnecessarily affected by the operation of safety devices such as anti-collision devices.

Subclause 201.11.1.1 – Maximum temperature during NORMAL USE

A part of the INTERVENTIONAL X-RAY EQUIPMENT that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT.

Subclause 201.11.6.1 – General (within subclause 201.11.6 "Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the me equipment")

In RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, there can be relatively large quantities of body and other fluids which ~~may~~ can, directly or through deposits left behind, give rise to damage to the INTERVENTIONAL X-RAY EQUIPMENT, or cause electrical, toxic or infectious HAZARDS to PATIENTS, OPERATORS and service personnel.

Subclause 201.11.6.5.102 – Sources of dust and other particles

To avoid inadvertent PATIENT infection, sources of dust and other particles that can reach the PATIENT ~~are to~~ shall be avoided. Sources of dust and other particles comprise e.g., fan directed towards the PATIENT, fall of dust from devices/ACCESSORIES above the PATIENT, etc.

It is desirable to have no sources of dust and other particles in the volume defined horizontally by a distance from the PATIENT SUPPORT of at least 2 m and vertically from floor to ceiling.

Subclause 201.11.6.5.103 – ENCLOSURES

For convenience, here is a brief description of the degree of protection from Table 3 of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013:

– IPX0: non-protected
– IPX2: protected against vertically falling water drops when ENCLOSURE tilted up to 15°
– IPX3: protected against spraying water
– IPX7: protected against the effects of temporary immersion in water

Image monitor can be IPX0 with optional marking.

Subclause 201.12.4 – Protection against hazardous output

The provisions in the additional subclauses recognize that protection against hazardous output from INTERVENTIONAL X-RAY EQUIPMENT requires flexibility in the delivery of the intended RADIATION and the avoidance of confusion in the presentation of image data to the OPERATOR during the course of a RGI PROCEDURE.

Subclause 201.12.4.101.1 – PATIENT data

Information about the identity of the PATIENT and the medical procedure will typically include at least the name and date of birth of the PATIENT, and the date and time of the RGI PROCEDURE.

Subclause 201.12.4.101.3 – Image DISPLAYS

A DISPLAY location ~~may~~ can be one of several separate monitor screens or a logical subdivision of the area of an individual monitor screen.

These requirements arise from the extreme danger that occurs if an OPERATOR undertakes ~~an IMAGE~~ a RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE on the mistaken assumption that a currently displayed image is, for example, a live one.

Subclause 201.12.4.102 – IMAGE DISPLAY DELAY

IMAGE DISPLAY DELAY is linked to the hand-eye coordination when performing interventions.

Subclause 201.12.4.103 – Documentation of image orientation

This requirement is meant to avoid RISKS associated with potential OPERATOR misinterpretation of the PATIENT orientation on the image, e.g., mirror effect: left/right, top/bottom.

Subclause 201.12.4.104 – Availability of RADIOSCOPY during networking activities

Examples of networking activities include the sending of an examination sequence to a workstation, etc.

Subclause 201.12.4.105 – Appropriate mask location for subtracted images

In subtracted imaging modes with rotational GANTRY motion (e.g., subtracted 3D) or longitudinal table motion, etc., it is important to select the most appropriate mask in order to minimize subtraction artifacts.

Subclause 201.12.4.106 – Tableside controls

For the other tableside controls (other than GANTRY and PATIENT SUPPORT motions controls, IRRADIATION SWITCHES, and ~~collimation~~ beam limitation blade control), the identification could be made by light indicator, by touch or something else. This requirement is necessary because this type of INTERVENTIONAL X-RAY EQUIPMENT is typically used in a darkened room, and these controls are otherwise difficult for the OPERATOR to see and identify, even with a fully transparent means for protection against non-sterile conditions.

Subclause 201.12.4.107 – Image measuring functions

There are several sources of inaccuracy such as initial calibration, geometric distortion, marker position, etc.

Examples of image measuring function are vessel sizing, ventricular ejection fraction estimation, etc.

Subclause 201.15.101 – Configuration for cardiopulmonary resuscitation (CPR)

The time period to place the INTERVENTIONAL X-RAY EQUIPMENT during NORMAL USE in a configuration for CPR includes not only the possible table motion but all necessary GANTRY motion and removal of ACCESSORIES.

Subclause 203.5.2.4.5.101 – Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY

For b) available settings, item 5): This would, for example, include a typical vascular setting and a typical cardiac setting for INTERVENTIONAL X-RAY EQUIPMENT intended to be used for both applications.

For c) RADIATION data: the relatively large tolerance reflects the circumstances that MEASURED VALUES are being compared with stated values given in the instruction for use.

For d) PATIENT ENTRANCE REFERENCE POINT: For lateral positioning of a C-arm, the definition of PATIENT ENTRANCE REFERENCE POINT relative to the ISOCENTRE is ~~to be~~ the same as described for C-arms.

Subclause 203.5.2.4.5.102 – Test for dosimetric information

In this document, the required statements of AIR KERMA and AIR KERMA RATE are expressed as values of REFERENCE AIR KERMA (RATE), at the applicable position of the PATIENT ENTRANCE REFERENCE POINT ~~(refer to IEC 60601-2-54 for distance definition)~~. This position generally approximates to the position of the PATIENT SURFACE, but does not necessarily coincide with it under all conditions. The concept, supported by the measuring PROCEDURE described here, is intended to provide a uniform method for stating the AIR KERMA (RATE) produced by INTERVENTIONAL X-RAY EQUIPMENT in NORMAL USE. This test method is based on the use of specific polymethyl-methacrylate (PMMA) PHANTOMS under particular conditions. The compliance criteria stated in this PROCEDURE allow for manufacturing tolerances in the stated values, when these values are verified against the MEASURED VALUES resulting from the test. For this reason and also because of factors such as PATIENT variability and the actual clinical configuration of the INTERVENTIONAL X-RAY EQUIPMENT, the stated values are not ~~to be~~ regarded as accurate measures of RADIATION actually incident upon the skin of the PATIENT.

In addition to its purpose of verifying the compliance of statements made in accordance with this document, the method can be adapted for use in other situations, such as those where it is required to determine or verify levels of AIR KERMA (RATE) applying at any time to examples of INTERVENTIONAL X-RAY EQUIPMENT under conditions of NORMAL USE, or to investigate the dependence of the REFERENCE AIR KERMA (RATE) on selected MODES OF OPERATION or on the settings of variable operating parameters. Such additional uses, however, are not within the normative intent of this subclause.

About the measurements and test conditions:

Placing the PHANTOM near the X-RAY IMAGE RECEPTOR while leaving as much distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM, will minimize the effect of SCATTERED RADIATION on the measurements. Additionally, placing the measuring detector half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM will minimize the contribution of STRAY RADIATION to the readings; see also Figure 5 of reference [24].

Aligning the surface of the PHANTOM within ±2° allows, in the case of several rotational positions being contained within this limit, use of any of these rotational positions.

Subclause 203.6.3.103 – X-RADIATION pulse repetition frequency during RADIOSCOPY

RADIATION usage is optimised when the amount of RADIATION used to produce an image or an image series is the least possible that permits adequate visualization of the structures of interest. International and national guidelines from radiation protection organizations [25], [26] and medical professional societies [28], [29], [30] recommend that in interventional RADIOSCOPY, dose rate is reduced to the extent possible. Clinical circumstances can require a high or low dose per pulse independent of pulse rate. In these situations, the ability to select a low pulse rate independently of dose per pulse is essential for optimisation.

Subclause 203.6.101 already requires a minimum of two MODES OF OPERATION for NORMAL USE in RADIOSCOPY – "normal" and "low" REFERENCE AIR KERMA RATES – with the "low" MODE OF OPERATION providing a REFERENCE AIR KERMA RATE that does not exceed 50 % of the value for the normal mode. This permits the OPERATOR to select a low dose rate when clinically appropriate. When a selectable RADIOSCOPY pulse rate is available, the new requirement extends the OPERATOR'S ability to optimise RADIATION usage by specifying that at least one low pulse rate is available. This will permit the OPERATOR to select the lowest clinically acceptable pulse rate independently of dose rate.

Subclause 203.6.4.5 – Dosimetric indications

Provisions for fine-tuning the dosimetric indications by a qualified end-user are not included in this document since these indications ~~must already~~ shall comply with accuracy requirements as described in this document. Thus, further fine-tuning does not meet a need for avoiding unacceptable RISK and ~~may~~ can in contrast create problems in cases of uncontrolled fine-tuning.

The new value of accuracy is believed to represent the current state-of-the-art for dose indications that can be either measured or computed from technique factors. Refer also to [7].

In relation to DOSE AREA PRODUCT:

– Reference [25] mentions in its subsection D.3 that DAP can be ~~helpful in dose control~~ useful for stochastic effects to PATIENTS and OPERATORS, but ~~is~~ not ~~a practical method~~ for ~~estimating maximum cumulative absorbed dose to skin or useful for predicting~~ deterministic effects. See also reference [18].

– A single dosimetric indication unit is recommended, since allowing a free choice of displayed RADIATION units could be confusing to OPERATOR, particularly if OPERATORS use equipment from several MANUFACTURERS.

– The DOSE AREA PRODUCT, DOSE AREA PRODUCT RATE or related values ~~may~~ can be indicated, particularly in training situations. However, the DOSE AREA PRODUCT is primarily used as an indicator for stochastic effects and is not useful for predicting deterministic effects. It ~~may~~ can be useful to momentarily indicate the DOSE AREA PRODUCT RATE and the cumulative DOSE AREA PRODUCT at the position of the OPERATOR, by means of a toggle.

In relation to the display label not referring to skin: The PATIENT ENTRANCE REFERENCE POINT seldom corresponds to the actual position of the PATIENT's skin.

In relation to the threshold visual warning: A suggested default threshold is 2 Gy. Refer to ICRP-85 ([25]) for a description of other appropriate threshold values. See reference [13] also.

In relation to the cumulative number or IRRADIATIONS from RADIOGRAPHY: It is understood that all X-ray pulses performed during RADIOGRAPHY are to be counted and included in the cumulative number of IRRADIATIONS from RADIOGRAPHY.

In relation to notations:

REFERENCE AIR KERMA is sometimes written differently in the bibliography (e.g. in [26] and[27]) and denoted as $K_{a,r}$.

DOSE AREA PRODUCT is sometimes written differently in the bibliography (e.g. in [26] and[27]) and denoted as air kerma area product P_{KA}.

In relation to SKIN DOSE MAP:

Introduction:

The application of any form of RADIATION to a PATIENT is part of the practice of medicine. The practitioner has the responsibility of balancing the expected benefits of a RGI PROCEDURE against associated RISKS. To meet this goal, the practitioner needs to have timely access to appropriate information.

X-RAY EQUIPMENT that meets IEC 60601-2-43 or IEC 60601-2-54, or for example U.S. performance standards (21 CFR 1020 [7]) includes dosimetric displays. Depending on the applicable standard, this includes real time displays of cumulative REFERENCE AIR KERMA at the PATIENT ENTRANCE REFERENCE POINT, DOSE AREA PRODUCT, or both. The cumulative REFERENCE AIR KERMA is required to be visible at the OPERATOR's working position. SKIN DOSE MAPS were foreseen as a logical extension of these real time displays and were recommended in NCRP Report 168 [26] and ICRP Publication 120 [27]. However, when IEC 60601-2-43:2010 was published, the technology was not sufficiently developed to include a normative requirement for SKIN DOSE MAPS.

The distribution of IRRADIATION on the PATIENT has been intermittently available from various MANUFACTURERS since the late 1990's in various real-time or post-procedure modes. IEC 61910-1:2014 defines a RADIATION DOSE STRUCTURED REPORT (RDSR) with sufficient information ("extended dose documentation") to construct a SKIN DOSE MAP using additional geometric and anatomical information supplied externally to the imaging equipment. Depending on the use of IEC 61910-1:2014 and the supporting equipment, this might be either real-time or post-procedure. Some models of INTERVENTIONAL X-RAY EQUIPMENT already provide integrated SKIN DOSE MAPS using the equipment's own resources.

The clinical goal of these efforts is to provide the OPERATOR with sufficient real-time information to avoid unnecessary tissue reactions. Reducing the frequency and SEVERITY of tissue reactions is a requirement for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES above the requirements for general procedures (X-RAY EQUIPMENT within the scope of IEC 60601-2-54).

Real-time dosimetric displays:

RADIATION is one of many factors affecting the practitioner's ability to safely and effectively complete a RGI PROCEDURE. Automatic ~~alarms~~ notifications of any kind can result in poorer overall clinical results if they unnecessarily distract the OPERATOR's attention. Many non-RADIATION events that occur during a RGI PROCEDURE also require the OPERATOR's attention. Unless OPERATOR action is urgent, such notifications can be given to the OPERATOR by a knowledgeable participant in the RGI PROCEDURE (located either in the control room or the procedure room) as soon as it is safe to do so.

Continuous, real-time display provides immediate access to accumulated dosimetric information without requiring an action or distracting the OPERATOR's concentration. NCRP Report 168 [26], ICRP Publication 120 [27] and guidelines from interventional radiology [28] and interventional cardiology [29] societies recommend OPERATOR notification when specified dosimetric levels, including peak SKIN DOSE, are exceeded. RADIATION injuries do not have a binary dose-response function. Exceeding any nominal RADIATION threshold by a few tens of percent is highly unlikely to substantially affect the frequency or nature of any RADIATION injury.

Some equipment currently has the capability of non-distractively indicating when the cumulative REFERENCE AIR KERMA exceeds a threshold using means such as reversing the colours of a display and its background.

DOSE MAPS:

The simplest DOSE MAP is a display of the REFERENCE AIR KERMA as a function of GANTRY angle. Such maps typically display a single value for all of the IRRADIATION occurring in a range of angles (e.g. 30° x 30°). Their construction does not require any information about the PATIENT or the PATIENT's position relative to the beam. Nevertheless, these AIR KERMA maps ~~may~~ can be sufficient for certain aspects of operational RADIATION management.

During a RGI PROCEDURE, the availability of a current SKIN DOSE MAP displayed on a surface that reasonably represents the actual PATIENT is clinically important. This map ~~needs~~ is useful to indicate the size, shape, and location of the current X-RAY FIELD(S). Such a DISPLAY provides the OPERATOR with immediate information regarding the RISKS of continuing IRRADIATION and provides the information necessary to manage the RADIATION FIELDS so as to control the likelihood and SEVERITY of a cutaneous tissue reaction [32].

The skin surface of the PATIENT can be represented by a model. In that case, the PATIENT surface model can be a stylized representation of the skin surface of a human. The PATIENT surface model can be adaptable to the PATIENT under examination. The PATIENT surface model can exclude PATIENT extremities. For example, the PATIENT surface model could be based on the PATIENT's height and weight.

Isodose boundaries and colour codes:

OPERATORS ~~may~~ can work in one or more locations with different MANUFACTURERS' equipment. A consistent use of isodose boundaries and colour codes is useful to avoid confusion amongst OPERATORS when working between systems from different MANUFACTURERS.

Table AA.3 presents examples of colour and grayscale code with isodose boundaries. Isodose boundaries are derived from Table 2.5 from NCRP Report 168 [26]. Colour and grayscale codes are expressed in RGB space (see e.g., reference [33] for RGB space description). Lower isodose boundaries for AIR KERMA maps could be used to keep meaningful biological RISK indications. These could be 75 % of the SKIN DOSE MAP ones since AIR KERMA does not account for effects like backscatter.

Table AA.3 – Examples of isodose boundaries and colour codes for SKIN DOSE MAP and AIR KERMA map

SKIN DOSE MAP isodose boundaries	Air kerma map isodose boundaries	RGB colour	RGB grayscale
A. Example 1			
Base surface to < 0,1 Gy	Base surface to < 0,075 Gy	220,220,220	220,220,220
0,1 Gy	0,075 Gy	0,0,0	0,0,0
1,0 Gy	0,75 Gy	0,0,255	70,70,70
2,0 Gy	1,5 Gy	0,255,0	105,105,105
5,0 Gy	3,75 Gy	255,255,0	145,145,145
8,0 Gy	6,0 Gy	255,128,0	190,190,190
11,0 Gy	8,25 Gy	255,0,0	235,235,235
≥ 15,0 Gy	≥ 11,25 Gy	255,255,255	255,255,255
B. Example 2			
0,1 Gy	0,075 Gy	0,0,255	0,0,0
1,0 Gy	0,75 Gy	0,255,0	70,70,70
2,0 Gy	1,5 Gy	255,255,0	105,105,105
3,0 Gy	2,25 Gy	255,128,0	145,145,145
5,0 Gy	3,75 Gy	255,0,0	190,190,190
10,0 Gy	7,5 Gy	240,160,160	235,235,235
≥ 15,0 Gy	≥ 11,25 Gy	255,255,255	255,255,255

NOTE Except for the first and last table entry, the colours used to represent doses between isodose boundaries could be displayed as either a continuous transition between the values or as the lower dose value.

The following considerations are relevant as part of the design PROCESS for a SKIN DOSE MAP.

– The SKIN DOSE MAP is configurable by the OPERATOR to be displayed at least at the position of the RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE when LOADING in RADIOSCOPY or RADIOGRAPHY is not active. A second DISPLAY of the SKIN DOSE MAP in the control room is a helpful option for OPERATOR notification. The SKIN DOSE MAP includes at least the relevant anatomical region of the body.

– The PATIENT orientation is apparent on the SKIN DOSE MAP.

– An indication of the current location of the X-RAY FIELD(S) is displayed on the SKIN DOSE MAP.

– The SKIN DOSE MAP can be displayed as a grayscale or colour-coded image. A colour-coded map is preferred. When the SKIN DOSE MAP is intended to be displayed without colour, a dedicated grayscale scheme is necessary.

– Providing a mean to use colour or grayscale schemes different from those shown in Table AA.3 or provided by the MANUFACTURER is desirable because it promotes future standardization of the SKIN DOSE MAP display, and therefore could provide additional PATIENT safety.

– For clinically important values of SKIN DOSE, displayed values of SKIN DOSE are close to actual SKIN DOSE. The minimum value stated as part of the criterion for accuracy concerns only the accuracy of the displayed SKIN DOSE. It is not intended to be used to determine which values of SKIN DOSE are displayed.

– The current value of the highest SKIN DOSE within the current X-RAY FIELD(S) and the highest SKIN DOSE at any point on the SKIN DOSE MAP (peak SKIN DOSE) are displayed in conjunction with the SKIN DOSE MAP. These displayed values are CLEARLY LEGIBLE at 1,5 m from the DISPLAY, when configured by the OPERATOR.

– Use of tissue equivalent anthropomorphic PHANTOMS for quantifying accuracy.

The following information is relevant for inclusion in the ACCOMPANYING DOCUMENTS:

– description of the PATIENT surface model;
– description of the PHANTOM(S) for quantifying accuracy;
– test conditions and accuracy.

Subclause 203.6.7.101 – Display of LAST IMAGE HOLD RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE

INTERVENTIONAL X-RAY EQUIPMENT differs from non-interventional X-RAY EQUIPMENT with respect to display of a LIH RADIOGRAM. There are specific RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES (e.g. a coronary artery chronic total occlusion procedure) for which the OPERATOR ~~may need to have~~ can prefer having a DISPLAY of a reference acquisition image instead of a LIH display.

While the requirements for display of a LIH RADIOGRAM differ from 203.6.7.101 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022, the LIH RADIOGRAM definition is the same as in 201.3.212 of IEC 60601-2-54:~~2009 and IEC 60601-2-54:2009/AMD2:2018~~2022.

Subclause 203.6.102 – Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

This requirement is intended to ensure that switching can be achieved by a sole OPERATOR without change of location and without the intervention of a second member of the operating staff.

Subclause 203.6.104 – Last-image-hold (LIH)

Storage of the LIH RADIOGRAM is particularly important for paediatrics applications. INTERVENTIONAL X-RAY EQUIPMENT equipped with means for auto-replay of an optionally stored RADIOSCOPY sequence (whether fully or partially) which would replace the last-image-hold is not in contradiction with these requirements, as long as the LIH RADIOGRAM is displayable and storable when the RADIOSCOPY sequence has not been stored.

Subclause 203.8.5.3 – Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

The additional requirement implies higher precision for small X-RAY FIELDS in INTERVENTIONAL X-RAY EQUIPMENT as compared with the corresponding subclause in IEC 60601-2-54, reflecting the working conditions applicable for such equipment and the current state of the technology.

Annex BB
(normative)

Distribution maps of STRAY RADIATION

BB.1 ~~Introduction~~ General

This document contains requirements in 203.13.4 for isokerma maps of STRAY RADIATION to be provided with INTERVENTIONAL X-RAY EQUIPMENT. The purpose is to provide information on the distribution of the STRAY RADIATION for guidance in the RADIOLOGICAL PROTECTION of staff. This annex describes the PROCEDURE for verifying compliance. Since dosimetric information of this kind depends considerably on the operating conditions and measuring methods employed, the annex is also intended for the guidance of MANUFACTURERS in meeting the requirements.

The measurements obtained shall not be used for determining RADIATION shielding for a specific procedure room.

NOTE The measurements obtained are representative of the test situation only; they do not represent all clinical situations.

BB.2 Equipment configuration

The ACCOMPANYING DOCUMENTS are examined in relation to the configuration of the INTERVENTIONAL X-RAY EQUIPMENT and other data applying to the isokerma curves. For compliance:

– *the information shall be complete, as listed in 203.13.4;*
– *configurations shall be typical of the NORMAL USE of the INTERVENTIONAL X-RAY EQUIPMENT;*
– *the measuring arrangements described shall be compatible with those specified in this annex for verification of the values.*

If the information is compliant, the isokerma maps are verified as in BB.3 and BB.4, with the INTERVENTIONAL X-RAY EQUIPMENT configured and operated as described in the ACCOMPANYING DOCUMENTS.

BB.3 PHANTOM

The PHANTOM consists of a 25 cm cube of polymethyl-methacrylate (PMMA), which may be assembled from 25 cm square slabs.

BB.4 Measurement set-up

The X-RAY BEAM is aligned so that the centre of the ENTRANCE SURFACE of the PHANTOM is at the PATIENT ENTRANCE REFERENCE POINT. The X-RAY BEAM ~~must~~ shall not be aligned in such a way that its axis lies in the plane between adjacent slabs of PMMA. The RADIATION FIELD size shall be 100 cm^2 at the entrance of the PHANTOM.

Measurements are performed at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY.

Measurements are made at all locations within 3 m of the PATIENT ENTRANCE REFERENCE POINT or down to 0,1 µGy/(Gy·cm^2), except that measurements may be omitted:

– *within 15 cm of the PATIENT ENTRANCE REFERENCE POINT when placement of the measuring device is impractical, and*
– *at locations vertically over the INTERVENTIONAL X-RAY EQUIPMENT.*

Measurements are made for two orientations of the X-RAY BEAM, one horizontal and one vertical. When the X-RAY BEAM is vertical, the X-RAY SOURCE ASSEMBLY is oriented to the beam direction corresponding to the most frequent use of the INTERVENTIONAL X-RAY EQUIPMENT.

EXAMPLE For an isocentric system, the beam is directed vertically upward.

BB.5 Criteria for compliance

The MEASURED VALUES are normalised to a DOSE AREA PRODUCT of 1 Gy·cm^2. For compliance, all values of AIR KERMA represented by the curves in the ACCOMPANYING DOCUMENTS shall be within ±50 % of the normalised MEASURED VALUES determined by the test.

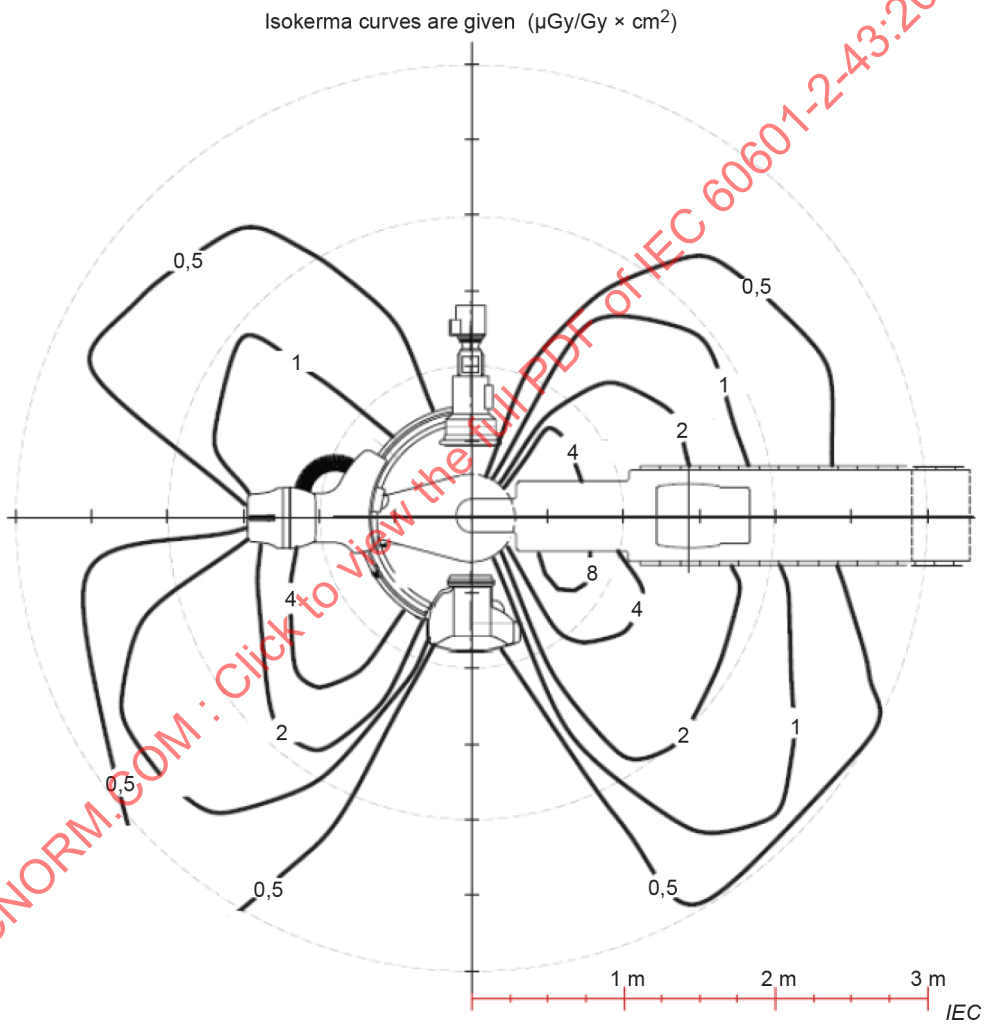

Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration

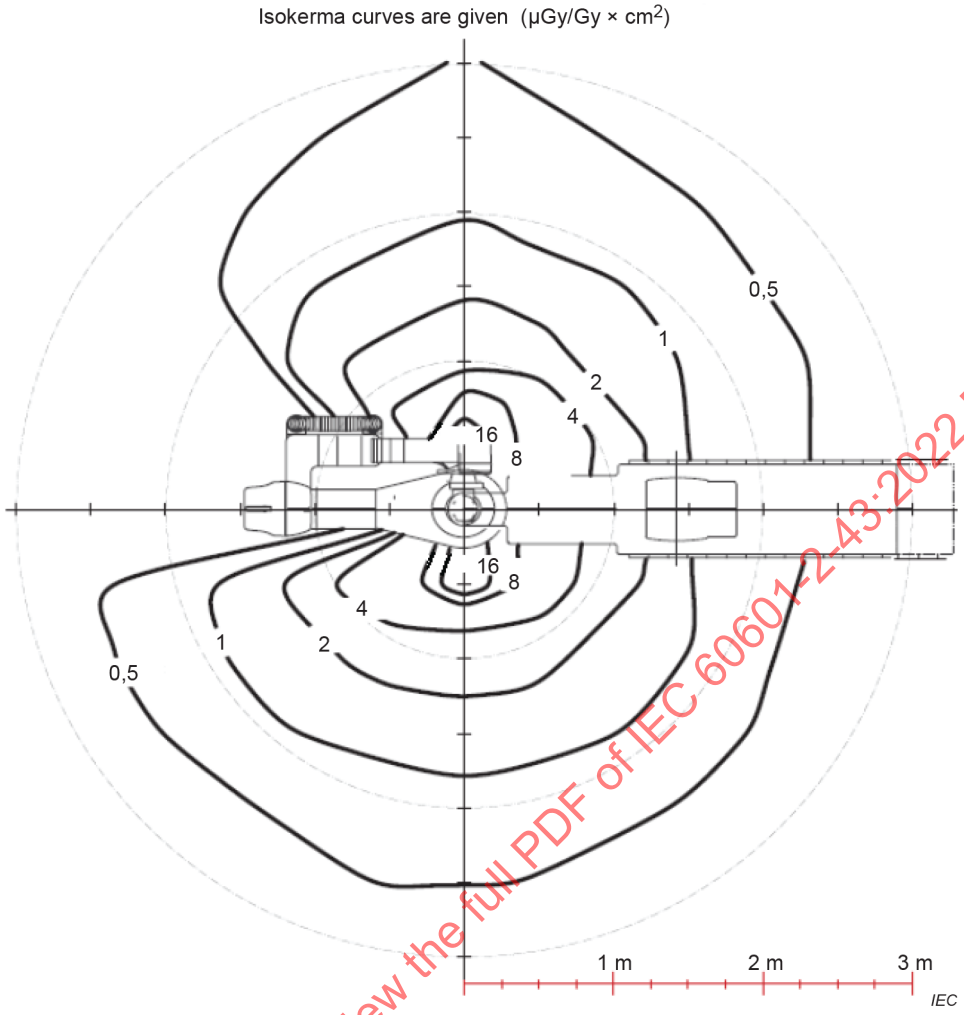

Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration

Annex CC
(informative)

Mapping between this Edition 2 of IEC 60601-2-43 and Edition 1

The 1st edition subclauses of this particular standard have been renumbered with the numbering correspondence as explained in 201.1.4. The selection criteria to renumber an item with a "201" prefix or a "203" prefix are as follows: a subclause directly related to Radiation Protection uses the "203" prefix while the other subclauses uses the "201" prefix.

NOTE Refer to IEC 62348 TR:2006 [1] for general subclause mapping.

Edition 1	Edition 2	Title/*Comments*
1	201.1	Scope, object and related standards
1.1	201.1.1	Scope
1.2	201.1.2	Object
1.3	201.1.4	Particular standards
2	201.3	Term and definitions
2.101	n.a.	*Removed since it is merged in* 201.3.203 *for simplification purpose*
2.102	201.3.203	RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
2.103	201.3.202	INTERVENTIONAL X-RAY EQUIPMENT
2.104	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
2.105	n.a.	*Removed since it is part of IEC 60601-2-54*
2.106	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
2.107	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
6	201.7	ME EQUIPMENT identification, marking and documents
6.1 aa)	201.7.2.102	PATIENT SUPPORT load
6.1 bb)	201.7.2.103	Cardiopulmonary resuscitation (CPR)
6.1 cc)	201.7.2.104	Marking of compliance
6.8.2 a)	n.a.	*Removed since it is part of the updated IEC 60601-1-3 and since the broader scope of this edition*
6.8.2 d)	201.7.9.2.12	Cleaning, disinfection and sterilization
6.8.2 aa)	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
6.8.2 bb)	203.5.2.4.5.101	Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY
6.8.2 cc)	203.5.2.4.5.101	Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY
6.8.2 dd)	201.7.9.2.101	PROTECTIVE DEVICES and ACCESSORIES
6.8.2 ee)	201.7.9.2.102	Provisions for CPR
6.8.2 ff)	203.5.2.4.5.101 d)	PATIENT ENTRANCE REFERENCE POINT
6.8.2 gg)	203.5.2.4.101	IRRADIATION disabling switch
6.8.2 hh)	201.9.2.2.4.4.101	Collision protection (incorporated from IEC 60601-2-54)
6.8.2 jj)	n.a.	*Removed since it is part of the instructions for use requirement of the updated IEC 60601-1-3*
Table 101	Table 201.102	Other subclauses containing normative references, etc.
6.8.3	201.7.9.3	Technical Description
6.8.3 a)	n.a.	*Removed since duplicate of 201.7.9.2.1*

Edition 1	Edition 2	Title/*Comments*
6.8.3 aa)	201.7.9.3.102	Installation
6.8.3 bb)	201.7.9.2.104	Failure of SUPPLY MAINS
6.8.101	203.4.1	Statement of compliance
10.2.1	n.a.	*Removed since obsolete*
21.3	201.9.8.3.1	General
22.7	201.9.2.4	Emergency stopping devices
29.201.2	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
Table 204	n.a.	*Removed since it is part of the updated IEC 60601-1-3*
29.201.4	203.7.1.101	FILTRATION in X-RAY SOURCE ASSEMBLIES (incorporated from IEC 60601-2-54)
29.203.4	203.8.5.3	Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA
29.208.3	203.13.4	Designated SIGNIFICANT ZONES OF OCCUPANCY
29.208.101	203.13.4	Designated SIGNIFICANT ZONES OF OCCUPANCY
42.1	201.11.1.1	Maximum temperature during NORMAL USE
44.1	201.11.6.1	General
44.6	201.11.6.5	Ingress of water or particulate matter into, etc.
44.6.101	201.11.6.5.101	Footswitches
51	201.12.4	Protection against hazardous output
51.101	n.a.	*Heading removed*
51.101.1	203.6.5	AUTOMATIC CONTROL SYSTEM (incorporated from IEC 60601-2-54)
51.101.2	203.6.6	SCATTERED RADIATION reduction
51.101.3	203.5.2.4.5.101 d)	PATIENT ENTRANCE REFERENCE POINT
51.101.4	203.6.101	Range of AIR KERMA RATES in RADIOSCOPY
51.101.5	203.6.102	Accessibility of switching between RADIOSCOPY etc.
51.101.6	203.6.103	IRRADIATION disabling switch
51.102	201.12.4.101	Information to the OPERATOR
51.102.1	201.12.4.101.1	PATIENT data
51.102.2	201.12.4.101.2	Management of image storage capacity
51.102.3	201.12.4.101.3	Image DISPLAYS
51.102.4	203.6.4.5	Dosimetric indications
51.102.5	203.6.4.5.101	Supplementary indications
51.102.6	203.6.4.5	Dosimetric indications
59.101	201.15.101	Configuration for cardiopulmonary resuscitation (CPR)
59.102	201.15.102	Attachment of protective drapes
Appendix L	201.2	Normative references
Annex AA	Last section	Index of defined terms used in this particular standard
Annex BB	AA.2	*Rationale of* Subclause 1.1
Annex CC	n.a.	*Removed for simplification of information (Annex CC was informative only)*
Annex DD	AA.2	*Rationale of* Subclause 201.7.9.2.12
Annex EE	203.5.2.4.5.102	Test for dosimetric indications
Annex FF	Annex BB	Distribution maps of STRAY RADIATION
Figure 101/102	Figure BB.1/BB.2	Examples of isokerma map

NOTE n.a. means not applicable

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FOCAL SPOT (EFFECTIVE FOCAL SPOT) ..... IEC TR 60788:2004, rm-20-13s
FOCAL SPOT TO IMAGE RECEPTOR DISTANCE ..... IEC 60601-1-3:2008, 3.25
FOCAL SPOT TO SKIN DISTANCE ..... IEC 60601-1-3:2008, 3.26

GANTRY ..... IEC TR 60788:2004, rm-30-04
GUARD ..... IEC 60601-1:2005, 3.36

HARM ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.38
HAZARD ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 3.40
HOME HEALTHCARE ENVIRONMENT ..... IEC 60601-1-11:2015, 3.1
IMAGE DISPLAY DELAY ..... 201.3.~~201~~203
IMAGE RECEPTION AREA ..... IEC 60601-1-3:2008, 3.28
~~IMAGE RECEPTOR PLANE ..... IEC TR 60788:2004, rm-37-15~~
IMAGE RECEPTION PLANE ..... IEC 60601-2-54:2022, 201.3.211
INDIRECT RADIOGRAPHY ..... IEC 60601-2-54:~~2009~~2022, 201.3.~~205~~212
INTENDED USE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44
INTERLOCK ..... IEC 60601-2-54:~~2009~~2022, 201.3.~~207~~214
INTERVENTIONAL X-RAY EQUIPMENT ..... 201.3.~~202~~204
IRRADIATION ..... IEC 60601-1-3:2008, 3.30
IRRADIATION SWITCH ..... IEC 60601-1-3:2008, 3.31
IRRADIATION TIME ..... IEC 60601-1-3:2008, 3.32
ISOCENTRE ..... ~~IEC TR 60788:2004, rm-37-32~~ IEC 60601-2-54:2022, 201.3.215

LAST IMAGE HOLD RADIOGRAM (LIH RADIOGRAM) ..... IEC 60601-2-54:~~2009/AMD2:2018~~2022, 201.3.~~212~~216
LOADING ..... IEC 60601-1-3:2008, 3.34
LOADING FACTOR ..... IEC 60601-1-3:2008, 3.35
LOADING STATE ..... IEC 60601-1-3:2008, 3.36
LOADING TIME ..... IEC 60601-1-3:2008, 3.37

MANUFACTURER ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.55
MEASURED VALUE ..... IEC 60601-1-3:2008, 3.38
MECHANICAL HAZARD ..... IEC 60601-1:2005, 3.61
MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) ..... IEC 60601-1:2005, 3.63
MEDICAL ELECTRICAL SYSTEM (ME SYSTEM) ..... IEC 60601-1:2005, 3.64
MOBILE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.65
MODE OF OPERATION ..... IEC 60601-1-3:2008, 3.40
MODEL OR TYPE REFERENCE ..... IEC 60601-1:2005, 3.66

NOMINAL X-RAY TUBE VOLTAGE ..... IEC 60601-1-3:2008, 3.42
NORMAL CONDITION ..... IEC 60601-1:2005, 3.70
NORMAL USE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.71

OPERATOR ..... IEC 60601-1:2005, 3.73

PATIENT ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76
PATIENT ENTRANCE REFERENCE POINT ..... IEC 60601-1-3:2008, 3.43
PATIENT SUPPORT ..... IEC TR 60788:2004, rm-30-02
PATIENT SURFACE ..... IEC TR 60788:2004, rm-37-18
PERMANENTLY INSTALLED ..... IEC 60601-1:2005, 3.84
PHANTOM ..... IEC 60601-1-3:2008, 3.46
PROCEDURE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.88
PROCESS ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.89
PROTECTED AREA ..... IEC 60601-1-3:2008, 3.48
~~PROTECTIVE CLOTHING ..... IEC 60601-1-3:2008, 3.50~~
PROTECTIVE CLOTHING (PROTECTIVE DEVICE) ..... IEC 60601-1-3:2008, 3.50+
PROTECTIVE DEVICE ..... IEC 60601-1-3:2008, 3.50

RADIATION ..... IEC 60601-1-3:2008, 3.53
RADIATION APERTURE ..... IEC 60601-1-3:2008, 3.54
RADIATION DOSE STRUCTURED REPORT (RDSR) ..... IEC 61910-1:2014, 3.3
RADIATION FIELD ..... IEC 60601-1-3:2008, 3.58
RADIATION PROTECTION ..... IEC 60601-1-3:2008, 3.59
RADIATION QUALITY ..... IEC 60601-1-3:2008, 3.60
RADIOGRAPHY ..... IEC 60601-1-3:2008, 3.64
RADIOLOGICAL PROTECTION ..... IEC TR 60788:2004, rm-60-03
RADIOLOGY ..... IEC TR 60788:2004, rm-40-01
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE (RGI PROCEDURE) ..... 201.3.~~203~~205
RADIOSCOPY ..... IEC 60601-1-3:2008, 3.69
RADIOSCOPY REPLAY IMAGE SEQUENCE ..... IEC 60601-2-54:~~2009/AMD2:2018~~2022, 201.3.~~214~~222
RADIOTHERAPY ..... IEC TR 60788:2004, rm-40-05
RDSR END OF PROCEDURE TRANSMISSION ..... IEC 61910-1:2014, 3.5
REFERENCE AIR KERMA ..... IEC 60601-1-3:2008, 3.70
REFERENCE AIR KERMA RATE ..... IEC 60601-1-3:2008, 3.71
RESPONSIBLE ORGANIZATION ..... IEC 60601-1:2005, 3.101
RISK ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.102
RISK CONTROL ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.105
RISK EVALUATION ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012

and IEC 60601-1:2005/AMD2:2020, 3.106

RISK MANAGEMENT ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.107

RISK MANAGEMENT FILE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.108

SAFE WORKING LOAD ..... IEC 60601-1:2005, 3.109

SCATTERED RADIATION ..... IEC 60601-1-3:2008, 3.73

SERIAL RADIOGRAPHY ..... IEC 60601-2-54:~~2009~~2022, 201.3.~~209~~224

SEVERITY ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.114

SIGNIFICANT ZONE OF OCCUPANCY ..... IEC 60601-1-3:2008, 3.74

SINGLE FAULT CONDITION ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.116

SKIN DOSE 201.3.206

SKIN DOSE MAP 201.3.207

STRAY RADIATION ..... IEC 60601-1-3:2008, 3.75

SUPPLY MAINS ..... IEC 60601-1:2005, 3.120

TOOL ..... IEC 60601-1:2005, 3.127

TRAPPING ZONE ..... IEC 60601-1:2005, 3.131

WEDGE FILTER ..... IEC TR 60788:2004, rm-35-10

X-RADIATION (RADIATION) ..... IEC 60601-1-3:2008, 3.53+

X-RAY BEAM (RADIATION BEAM) ..... IEC 60601-1-3:2008, 3.55+

X-RAY BEAM AXIS ..... ~~IEC TR 60788:2004, rm-37-06+~~ IEC 60601-2-54:2022, 201.3.228

X-RAY EQUIPMENT ..... IEC 60601-1-3:2008, 3.78

X-RAY FIELD (RADIATION FIELD) ..... IEC 60601-1-3:2008, 3.58+

X-RAY IMAGE RECEPTOR ..... IEC 60601-1-3:2008, 3.81

X-RAY SOURCE ASSEMBLY (RADIATION SOURCE ASSEMBLY) ..... IEC 60601-1-3:2008, 3.62+

X-RAY TUBE ASSEMBLY ..... IEC 60601-1-3:2008, 3.84

X-RAY TUBE CURRENT ..... IEC 60601-1-3:2008, 3.85

X-RAY TUBE VOLTAGE ..... IEC 60601-1-3:2008, 3.88

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)

CONTENTS

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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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.

[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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021, IEC 60601-2-54:2022, IEC TR 60788:2004, IEC 61910-1:2014, IEC 62220-1-1:2015 and the following apply.

NOTE The location of defined terms is listed in the Index of defined terms.

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

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

Addition:

201.3.201
DOSE MAP
representation of the spatial distribution of a RADIATION dose quantity

201.3.202
EMERGENCY RADIOSCOPY
RADIOSCOPY with availability of a limited set of functions (emergency functions), for use during recovery from a recoverable failure of the INTERVENTIONAL X-RAY EQUIPMENT

201.3.203
*** IMAGE DISPLAY DELAY**
during RADIOSCOPY or RADIOGRAPHY, time delay between an event captured during an X-RAY LOADING used to create an image and the DISPLAY of this event on the image

201.3.204
INTERVENTIONAL X-RAY EQUIPMENT
X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

201.3.205
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
RGI PROCEDURE
invasive procedure (involving the introduction of a device, such as a needle or a catheter into the PATIENT) using RADIOSCOPY as the principal means of guidance, and intended to effect treatment or diagnosis of the medical condition of the PATIENT

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 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 60601-2-54:2022 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 60601-2-54:2022 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 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 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 60601-2-54:2022);
– 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 ME EQUIPMENT

Clause 5 of 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 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 to maintain the room environmental operating conditions 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 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 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 60601-2-54:2022 applies.

201.7.2.15 Cooling conditions

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

Additional subclauses:

201.7.2.101 BEAM LIMITING DEVICE

Subclause 201.7.2.101 of IEC 60601-2-54:2022 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 compliance with this document is 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 60601-2-43:2022.

201.7.2.105 * Protection against ingress of liquids

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 See also 201.11.6.5.103.

NOTE 2 The marking of parts that are IPX0 is optional.

201.7.8.1 Colours of indicator lights

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 60601-2-54:2022 applies.

201.7.9.2 Instructions for use

201.7.9.2.1 General

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

201.7.9.2.12 * Cleaning, disinfection and sterilization

Addition:

NOTE In order to satisfy 11.6.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the information given 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 60601-2-54:2022 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 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)

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.

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.

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.

Compliance is determined by inspection of the instructions for use.

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 See also 201.7.2.105.

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 60601-2-54:2022 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 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.

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 60601-2-54:2022 and in Table 201.102.

Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS

Subclause	Heading
201.4.101	Recovery management
201.7.2.105	Protection against ingress of liquids
201.9.8.3.1	Strength of PATIENT or OPERATOR support or suspension systems – General
201.11.6.1	Overflow, spillage, etc. – General
201.11.6.5.102	Sources of dust and other particles
201.12.4.101.2	Management of image storage capacity
201.12.4.102	IMAGE DISPLAY DELAY
201.12.4.107	Measuring functions
201.15.102	Attachment of sterile drapes
203.5.2.4.5	Deterministic effects
203.5.2.4.101	IRRADIATION disabling switch
203.6.4.2	Indication of LOADING STATE
203.13.4	Designated SIGNIFICANT ZONES OF OCCUPANCY
201.5.7	Humidity preconditioning treatment
201.11.6.5.103	ENCLOSURES
203.5.2.4.102	EXAMINATION PROTOCOLS
203.6.4.5	Dosimetric indications
NOTE While Table 201.C.102 of IEC 60601-2-54:2022 lists the following subclauses "203.6.4.5 Dosimetric indications" and "203.5.2.4.5.101 Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY", the corresponding requirements for statements in ACCOMPANYING DOCUMENTS are located in this document and not in IEC 60601-2-54:2022.	

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Replacement:

Clause 201.8 of IEC 60601-2-54:2022 applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.2 TRAPPING ZONE

201.9.2.2.4 GUARDS and other RISK CONTROL measures

Subclause 201.9.2.2.4.4 of IEC 60601-2-54:2022 applies.

201.9.2.2.5 Continuous activation

Subclause 201.9.2.2.5 of IEC 60601-2-54:2022 applies.

201.9.2.2.6 Speed of movement(s)

Subclause 201.9.2.2.6 of IEC 60601-2-54:2022 applies.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

Subclause 201.9.2.3 of IEC 60601-2-54:2022 applies.

201.9.2.4 * Emergency stopping devices

Addition:

aa) In order to prevent HAZARDS arising from the unintended interruption of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, the operation of anti-collision devices in INTERVENTIONAL X-RAY EQUIPMENT shall not automatically switch off IRRADIATION and shall not impair other functions of the INTERVENTIONAL X-RAY EQUIPMENT, except movements connected with the potential collision. Means shall be provided for any movement disabled by the actuation of an anti-collision device to be caused to recover from collision within 5 s after a positive action taken at the working position of the OPERATOR.

Additional subclause:

201.9.2.4.101 Controls

Subclause 201.9.2.4.101 of IEC 60601-2-54:2022 applies.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 General

Addition:

In INTERVENTIONAL X-RAY EQUIPMENT, the load for which the PATIENT SUPPORT is designed shall be the normal load imposed by the PATIENT (as specified and marked, or otherwise as required in this subclause), with the addition of a mass of not less than 50 kg to provide for additional load imposed in the performance of CPR. This additional load shall be assumed to be applied uniformly over a length of 1 500 mm from the head-end of the PATIENT SUPPORT, or over the whole length if it is less than 1 500 mm, when the INTERVENTIONAL X-RAY EQUIPMENT is configured for CPR in accordance with the instructions for use, including the fitting of any ACCESSORIES specified for use in CPR.

Addition to the description of the compliance test:

For INTERVENTIONAL X-RAY EQUIPMENT, the test shall be carried out in the least favourable position other than when configured for CPR, and also in the least favourable position when configured for CPR. When configured for CPR, the test shall include the application of additional weight evenly over the portion of the PATIENT SUPPORT from the head-end up to a length of 1 500 mm or the maximum available length if less than 1 500 mm. This additional weight shall be applied after an interval of 1 min or more subsequent to the application of the testing weight representing the normal load.

For a test of INTERVENTIONAL X-RAY EQUIPMENT in the CPR configuration, the system shall be free from flexing or resonance effects that would impede the conduct of CPR.

201.9.8.3.3 Dynamic forces due to loading from persons

Subclause 201.9.8.3.3 of IEC 60601-2-54:2022 applies.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Subclause 201.9.8.4 of IEC 60601-2-54:2022 applies.

Additional subclause:

201.9.8.101 Shock absorbing means

Subclause 201.9.8.101 of IEC 60601-2-54:2022 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 201.10 of IEC 60601-2-54:2022 applies.

NOTE See Clause 203.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 * Maximum temperature during NORMAL USE

Addition:

Table 24 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 shall be used for INTERVENTIONAL X-RAY EQUIPMENT parts which can, in NORMAL USE, have prolonged contact with the PATIENT.

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.1 * General

Addition:

All components which can come into contact with PATIENTS' secretions, excretions, other body fluids, or other fluids shall be constructed so that:

– covers or drapes can be employed to divert these fluids away from the INTERVENTIONAL X-RAY EQUIPMENT, and

– the INTERVENTIONAL X-RAY EQUIPMENT surfaces over which the fluids can flow are suitable for cleaning and disinfection.

Guidance shall be provided for the use of the cleaning and disinfecting agents listed in the ACCOMPANYING DOCUMENTS.

Surfaces of the INTERVENTIONAL X-RAY EQUIPMENT likely to be exposed to specified cleaning and disinfecting agents shall be designed so that they are protected from, or are otherwise tolerant, of the agents concerned.

It should be assumed that all external surfaces of the X-RAY SOURCE ASSEMBLY, the GANTRY, the X-RAY IMAGE RECEPTOR assembly, the PATIENT SUPPORT and the tableside controls can be contaminated by PATIENTS' body fluids in the course of NORMAL USE.

NOTE Attention is drawn to the additional requirements in 201.7.9.2.12 concerning cleaning and disinfection.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Additional subclauses:

201.11.6.5.101 Footswitches

The footswitches of INTERVENTIONAL X-RAY EQUIPMENT, that are located at the table side, shall be operable even if the floor is covered with 25 mm of a saline solution.

NOTE Attention is drawn to the limitation of operating voltage imposed by 8.10.4 in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Compliance is determined by mechanically actuating and releasing the footswitch (with no electrical power source connected) 900 times in 25 mm depth of a saline solution of at least 0,9 % weight to volume of sodium chloride in water over a period of 1 h; then checking its functionality and electrical safety in accordance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. In addition, there shall be no evidence of fluid having reached mechanical parts that might deteriorate if they remain wet indefinitely.

Tableside connections of footswitch cable should be at least 25 mm above floor level.

Compliance is determined by inspection.

201.11.6.5.102 * Sources of dust and other particles

Sources of dust or other particles due to the INTERVENTIONAL X-RAY EQUIPMENT shall not be directed towards the PATIENT.

Parts of the INTERVENTIONAL X-RAY EQUIPMENT mounted above the PATIENT shall be designed to minimize the accumulation of dust, which could otherwise fall onto the PATIENT.

The instructions for use shall specify the PROCEDURE for removal of dust from parts of the INTERVENTIONAL X-RAY EQUIPMENT that are mounted above the PATIENT.

Compliance is checked by inspection.

201.11.6.5.103 * ENCLOSURES

The degree of protection without ACCESSORIES is as follows:

– Footswitches shall have a minimum degree of protection of IPX7.

– Tableside controls should have a minimum degree of protection of IPX3.

– PATIENT SUPPORT should have a minimum degree of protection of IPX2 or should be protected against spraying water at any angle up to 15° from the vertical. For the PATIENT SUPPORT test, testing may be considered sufficient by angulating the PATIENT SUPPORT 15° from the horizontal position.

– X-RAY TUBE ASSEMBLY and associated GANTRY elements should have a minimum degree of protection of IPX2, except for INTERVENTIONAL X-RAY EQUIPMENT with a FIXED over-table X-RAY SOURCE ASSEMBLY. The ACCOMPANYING DOCUMENTS shall describe the associated GANTRY elements that are included within the IPX2 classification. Testing may be considered sufficient by tilting the C-arm in the least favourable position with a maximum of 15° in any direction from the vertical position.

There shall be no ingress of water under the specified test conditions of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Subclause 201.11.8 of IEC 60601-2-54:2022 applies.

Additional subclauses:

201.11.101 Protection against excessive temperatures of BEAM LIMITING DEVICES

Subclause 201.11.101 of IEC 60601-2-54:2022 applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

NOTE In accordance with subclause 12.4.5 of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the dose related aspects of this topic are addressed in 203.6.4.3.

201.12.4 * Protection against hazardous output

201.12.4.5.2 Diagnostic X-RAY EQUIPMENT

Replacement:

INTERVENTIONAL X-RAY EQUIPMENT shall comply with IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 as modified in Clause 203.

Compliance is checked as specified in IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 as modified in Clause 203.

Additional subclauses:

201.12.4.101 Information to the OPERATOR

201.12.4.101.1 * PATIENT data

Information shall be available on the DISPLAY concerning the identity of the PATIENT and the medical procedure to which displayed images relate.

In the case of emergency interventions, this requirement is exempted.

Compliance is determined by inspection and functional tests.

201.12.4.101.2 Management of image storage capacity

In the instructions for use, the need to check regularly the available storage capacity and secure/archive important records shall be stated.

Upon completion of entry of the PATIENT data at the beginning of a new case, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate the available image storage capacity.

When the operating parameters have been entered, prior to acquiring any run, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate if there is insufficient storage space to store the run completely under the programmed conditions or shall state the number of frames possible or the IRRADIATION TIME available, at the frame rate and resolution selected.

When there is not sufficient storage space, it shall be indicated at the working position of the OPERATOR.

In the event of the INTERVENTIONAL X-RAY EQUIPMENT reaching a zero storage space condition, RADIOGRAPHY either shall not be possible or be stopped, unless data has been stored elsewhere and the INTERVENTIONAL X-RAY EQUIPMENT has a means to determine that data has been stored successfully elsewhere.

Compliance is determined by inspection and functional tests.

201.12.4.101.3 * Image DISPLAYS

During RADIOSCOPY, the live image shall always occupy the same DISPLAY location. The status of all displayed images, in particular whether they are currently live or stored and, if stored, whether they are a LIH RADIOGRAM or previously stored reference images, shall be indicated at their relevant DISPLAY locations.

Compliance is determined by inspection and functional tests.

201.12.4.101.4 Indications of emergency power supply

For PERMANENTLY INSTALLED INTERVENTIONAL X-RAY EQUIPMENT, if an emergency power supply is provided with the INTERVENTIONAL X-RAY EQUIPMENT, a visual indicator shall be displayed in the event of failure of the SUPPLY MAINS indicating that the INTERVENTIONAL X-RAY EQUIPMENT is operating on the emergency power supply.

This indicator shall be visible at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

NOTE See also 201.7.9.2.104 for requirements on ACCOMPANYING DOCUMENTS. See also 201.12.4.108 for requirements on operation of the emergency power supply.

201.12.4.102 * IMAGE DISPLAY DELAY

IMAGE DISPLAY DELAY during RADIOSCOPY shall be as short as reasonably practicable. The appropriate limit shall be determined in the RISK MANAGEMENT FILE.

The instructions for use shall state that, if the RADIOGRAPHY mode is misused on purpose by the OPERATOR for real-time imaging, the IMAGE DISPLAY DELAY can be longer than in RADIOSCOPY.

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

201.12.4.103 * Documentation of image orientation

If it is possible for the OPERATOR to change the image orientation, the INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the image orientation on both the displayed and stored images.

The INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the PATIENT orientation.

Compliance is checked by functional tests.

201.12.4.104 * Availability of RADIOSCOPY during networking activities

Networking activities shall not have an impact on the availability of RADIOSCOPY.

Compliance is checked by functional tests.

201.12.4.105 * Appropriate mask location for subtracted images

When automatic subtraction means are provided for MODES OF OPERATION where several mask images are acquired at different equipment positions, for any given image to be subtracted, the corresponding mask image shall be selected so that the difference between the position of the equipment at which this mask image was acquired and the position of the equipment for the image to be subtracted with this mask is minimized.

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

201.12.4.106 * Tableside controls

For tableside controls, as a minimum, the following user interface controls, requiring operation by touch, shall be individually and unambiguously identifiable both by touch alone and also by sight alone:

– GANTRY and PATIENT SUPPORT motions controls (not including motion controls for preselecting INTERVENTIONAL X-RAY EQUIPMENT positions);
– IRRADIATION SWITCHES (other than footswitches);
– beam limitation blade control (not including WEDGE FILTER control).

Beam limitation blade control may additionally be operated by a duplicated tableside control, such as a touchscreen user interface.

All tableside controls shall be identifiable under the lighting conditions for the INTENDED USE, and if applicable, when covered by transparent protective drapes.

Compliance is checked by inspection and by functional tests.

NOTE A tableside control is a control that can be operated adjacent to the PATIENT during a RGI PROCEDURE regardless of whether or not it is physically attached to the PATIENT SUPPORT. A footswitch is not a tableside control for the purposes of this subclause.

201.12.4.107 * Image measuring functions

The instructions for use shall describe the image measuring functions, their units and their related inaccuracies with regards to the INTENDED USE.

The errors in image measuring functions introduced by the INTERVENTIONAL X-RAY EQUIPMENT shall be as small as reasonably practicable depending on the MODE OF OPERATION and INTENDED USE.

For measurements displayed by the INTERVENTIONAL X-RAY EQUIPMENT having a measuring function, each value shall be displayed together with its unit.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and appropriate inspection and functional tests.

201.12.4.108 Provision for emergency power supply

The requirements in this subclause apply only for INTERVENTIONAL X-RAY EQUIPMENT that is PERMANENTLY INSTALLED and that is provided with an emergency power supply. For such INTERVENTIONAL X-RAY EQUIPMENT, the return to the SUPPLY MAINS in case of power failure shall be as follows:

a) If RADIOSCOPY is currently being performed,
   - in the case of automated return to SUPPLY MAINS, the SUPPLY MAINS return shall be performed without interruption of RADIOSCOPY;
   - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS, to allow for initiating the switching back to SUPPLY MAINS by the OPERATOR. This indicator shall be visible at the working positions of the OPERATOR.

b) If RADIOSCOPY is currently not being performed,
   - in the case of automated return to SUPPLY MAINS, there shall be no interruption in the availability of RADIOSCOPY;
   - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS. This indicator shall be visible at the working positions of the OPERATOR. An immediate switching back by the OPERATOR shall be possible when the SUPPLY MAINS is indicated to be available.

Compliance is checked by functional tests.

NOTE See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.7.9.3.102 for requirements on ACCOMPANYING DOCUMENTS.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Additional subclauses:

201.15.101 * Configuration for cardiopulmonary resuscitation (CPR)

In NORMAL CONDITION, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can be placed in a configuration designated for CPR within 15 s. This period is increased by 1 s for each 15° of tilt that the current working position of the PATIENT SUPPORT deviates from the CPR position.

In SINGLE FAULT CONDITIONS excluding SUPPLY MAINS failure, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can either comply with the CPR configuration time in NORMAL USE or shall be able to release or properly position the PATIENT within a time as low as reasonably practicable.

Compliance is determined by inspection of the RISK MANAGEMENT FILE and by appropriate functional tests.

In case of SUPPLY MAINS failure, the requirement for the NORMAL CONDITION applies.

Compliance is checked by disconnecting the INTERVENTIONAL X-RAY EQUIPMENT from the SUPPLY MAINS and verifying that the EQUIPMENT can be placed in CPR conditions.

201.15.102 Attachment of sterile drapes

Means shall be provided, and described in the instructions for use, for allowing sterile drapes to be attached to the INTERVENTIONAL X-RAY EQUIPMENT or its ACCESSORIES to enable RGI PROCEDURES to be conducted with an appropriate level of sterility.

Compliance is determined by inspection of the INTERVENTIONAL X-RAY EQUIPMENT and the instructions for use.

201.16 ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Replacement:

Subclause 201.16.8 of IEC 60601-2-54:2022 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Amendment of the compliance method:

Compliance is checked as specified in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, except where modified by Clause 202.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

Additional clause:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Subclause 202.101 of IEC 60601-2-54:2022 applies.

203 RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If compliance with this document is stated, the statement shall include the followings:

– MODEL OR TYPE REFERENCE;
– IEC 60601-2-43:2022.

Additional subclause:

203.4.101 Qualifying conditions for defined terms

Clause 203.4.101 of IEC 60601-2-54:2022 applies.

203.5.2.1 References in subclauses

Amendment:

In Table 2 of IEC 60601-1-3:2008, the line about Clinical protocols, Subclause 5.2.4.4, does not apply.

203.5.2.4 Instructions for use

203.5.2.4.4 Clinical protocols

Subclause 5.2.4.4 of IEC 60601-1-3:2008 does not apply.

203.5.2.4.5 Deterministic effects

Additional subclauses:

203.5.2.4.5.101 * Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY

NOTE Differences related to the same subclause in IEC 60601-2-54:2022 include: point b): item 1), item 2) and item 5); point c): the variations due to selectable ADDED FILTERS, etc. are given for all settings and not for only two settings.

a) SKIN DOSE levels

The instructions for use shall draw attention to the RISK of local SKIN DOSE levels that cause deterministic effects (tissue reactions) under the INTENDED USE in the case of repetitive or prolonged exposure. The effect of the various selectable settings available in both RADIOSCOPY and RADIOGRAPHY on the RADIATION QUALITY, the delivered REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE shall be described.

Compliance is checked by inspection of the instructions for use.

b) Available settings

In the instructions for use, information shall be provided on the available configurations delivered by the MANUFACTURER such as MODES OF OPERATION, settings of LOADING FACTORS and other operating parameters that affect the RADIATION QUALITY or the prevailing value of REFERENCE AIR KERMA (RATE) in the INTENDED USE. If applicable this information shall include:

1) the values of the REFERENCE AIR KERMA (RATE) applying to the MODES OF OPERATION in RADIOSCOPY designated normal and low in accordance with 203.6.101;
2) details of all other MODES OF OPERATION, giving the default values of the REFERENCE AIR KERMA (RATE), and the available ranges for any factor that can be varied after the MODE OF OPERATION has been selected;
3) the settings of LOADING FACTORS and other operating parameters in RADIOSCOPY delivering the highest available REFERENCE AIR KERMA RATE;
4) the settings of LOADING FACTORS and other operating parameters in RADIOGRAPHY delivering the highest available REFERENCE AIR KERMA per frame;
5) one set of REFERENCE AIR KERMA (RATE) values typical of RADIOGRAPHY for distinctive types of RGI PROCEDURES for which the INTERVENTIONAL X-RAY EQUIPMENT is intended to be used.

Compliance is checked by inspection of the instructions for use.

c) RADIATION data

In the instructions for use, for the MODES OF OPERATION and sets of values described in accordance with the settings in b) above, representative values of REFERENCE AIR KERMA (RATE) shall be given, based on measurement by the method described in 203.5.2.4.5.102.

In addition, representative values of REFERENCE AIR KERMA (RATE) based on measurement by the method described in 203.5.2.4.5.102 shall be given in the instructions for use, for respectively the MODES OF OPERATION and sets of values described in accordance with the settings in b) 1) and b) 2) of this subclause, and if they are adjustable by the OPERATOR in the MODE OF OPERATION concerned, for all settings of the following factors:

– selectable ADDED FILTERS;
– ENTRANCE FIELD SIZE;
– X-RADIATION pulse repetition frequency.

Information shall be given on the configurations of the INTERVENTIONAL X-RAY EQUIPMENT and the test geometries that can be used in the PROCEDURE described in 203.5.2.4.5.102 to verify the values given. Although it is required to provide details to enable verification by measurement in accordance with 203.5.2.4.5.102, the stated values may be determined originally by other methods, including calculation, leading to values that are in compliance, subject to the permitted tolerances, when verified by the method given in 203.5.2.4.5.102.

MEASURED VALUES shall not deviate from stated values by more than 50 %.

Compliance is checked by functional tests and inspection of the instructions for use. The stated values REFERENCE AIR KERMA (RATE) and statements concerning the variation of these values are verified by the method described in 203.5.2.4.5.102, using configurations and test geometries and settings described in the instructions for use.

d) PATIENT ENTRANCE REFERENCE POINT

In the instructions for use, the location of the PATIENT ENTRANCE REFERENCE POINT shall be described as specified for the type of INTERVENTIONAL X-RAY EQUIPMENT:

The PATIENT ENTRANCE REFERENCE POINT is located:

– 1 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT;

– 30 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT;

– 15 cm from the ISOCENTRE in the direction of the FOCAL SPOT for C-arm INTERVENTIONAL X-RAY EQUIPMENT or

  • for C-arm INTERVENTIONAL X-RAY EQUIPMENT without an ISOCENTRE, a point along the X-RAY BEAM AXIS defined by the MANUFACTURER as being representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT SURFACE. In this case, the statement in the instructions for use shall include the rationale for the choice of position made by the MANUFACTURER or

  • at the point representing the minimum FOCAL SPOT TO SKIN DISTANCE for C-arm INTERVENTIONAL X-RAY EQUIPMENT with FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm,

– for INTERVENTIONAL X-RAY EQUIPMENT not listed above the PATIENT ENTRANCE REFERENCE POINT shall be specified by the MANUFACTURER.

Compliance is checked by inspection of the instructions for use

203.5.2.4.5.102 * Test for dosimetric information

a) Relevant parameters

It is required in 203.5.2.4.5.101 to provide, in the instructions for use, a description of the configurations and test geometries applying to the stated values of REFERENCE AIR KERMA (RATE). The following are examples of factors that could be referenced, when relevant to the INTERVENTIONAL X-RAY EQUIPMENT settings concerned.

i) Equipment configuration

1) Orientation of the X-RAY BEAM

2) PATIENT SUPPORT in or out

3) ANTI-SCATTER GRID in or out

4) Appropriate ENTRANCE FIELD SIZE selected

ii) Operating settings (representative of NORMAL USE)

1) Technical details of parameters included in each MODE OF OPERATION

2) Frame rate

3) Selectable ADDED FILTERS automatically applied

4) Selectable ADDED FILTERS manually applied

iii) Test geometry

1) FOCAL SPOT TO IMAGE RECEPTOR DISTANCE

2) Distance of FOCAL SPOT to measuring detector

3) RADIATION FIELD size at the measuring detector

4) Positioning of PHANTOM (see item c) below)

5) Positioning of measuring detector (see item c) below)

b) Checking the test conditions

Before any dosimetric measurements are made, verify that the particulars of the INTERVENTIONAL X-RAY EQUIPMENT settings under test and the associated measuring arrangements given in the instructions for use are in compliance with 203.5.2.4.5.101.

c) Measurements and test conditions:

– *Use a 20 cm polymethyl-methacrylate (PMMA) PHANTOM (the PHANTOM may be fabricated from layers of material) comprising of rectangular blocks with sides equal to or exceeding 25 cm. Area density of the nominal 20 cm PHANTOM: 23,5 g/cm^2, with a relative tolerance of ± 5 %.*

– *Use a DOSIMETER with a measuring detector small enough to cover not more than 80 % of the area of the X-RAY BEAM in the plane of measurement.*

– *The PHANTOM is placed near the X-RAY IMAGE RECEPTOR, leaving as much of the available distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM.*

– *Position the measuring detector at a point that is either:*

  • *the PATIENT ENTRANCE REFERENCE POINT (only if there is at least 20 cm distance between the measuring detector and the PHANTOM)*

  or

  • *half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM. In that case, the MEASURED VALUES include scaling to the appropriate distance.*

– *Measure the AIR KERMA RATE for the RADIOSCOPY settings for which a value of REFERENCE AIR KERMA RATE is required to be stated in 203.5.2.4.5.101 c).*

– *Measure the AIR KERMA per image for RADIOGRAPHY settings as required to be stated in 203.5.2.4.5.101 c).*

– *For each setting required in 203.5.2.4.5.101, measure the AIR KERMA (RATE) using the PHANTOM described:*

  • *for all representative OPERATOR selectable ENTRANCE FIELD SIZES;*

  • *for all representative OPERATOR selectable ADDED FILTERS;*

  • *for all representative OPERATOR selectable pulse repetition frequencies.*

– *The surface of the PHANTOM shall be aligned perpendicular to the X-RAY BEAM AXIS within ±2 ° in all directions.*

Additional subclauses:

203.5.2.4.101 Instruction for use of the IRRADIATION disabling switch

The instructions for use shall mention that the IRRADIATION disabling switch be used at all times, except when a RGI PROCEDURE is in progress, to prevent the possibility of RADIATION being emitted through the inadvertent actuation of an IRRADIATION SWITCH.

203.5.2.4.102 EXAMINATION PROTOCOLS

Subclause 203.5.2.4.101 of IEC 60601-2-54:2022 applies.

NOTE The numbering of the cited subclause from IEC 60601-2-54 is different.

203.6 RADIATION management

203.6.1 General

Additional subclauses:

203.6.1.101 Management of RADIOSCOPY image storage

INTERVENTIONAL X-RAY EQUIPMENT shall provide the capability to store a RADIOSCOPY REPLAY IMAGE SEQUENCE for DISPLAY. This capability may be limited to storage of images as follows:

– at pulse rates up to 10 pulses per second, the last 30 s of RADIOSCOPY;
– for pulse rates greater than 10 pulses per second, the last 300 images;
– for continuous RADIOSCOPY, the last 10 s of RADIOSCOPY.

This requirement does not apply to MOBILE X-RAY EQUIPMENT with a maximum FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm and that is specified for extremities use only in its INTENDED USE.

NOTE The storage is not required to be a permanent storage.

Compliance is checked by functional test.

203.6.1.102 Management of EXAMINATION PROTOCOLS

Subclause 203.6.1.102 of IEC 60601-2-54:2022 applies.

203.6.2 Initiation and termination of the IRRADIATION

Subclause 203.6.2 of IEC 60601-2-54:2022 applies.

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Subclause 203.6.3.1 of IEC 60601-2-54:2022 applies except that the additional manual control without the use of the AUTOMATIC CONTROL SYSTEM in subclause 203.6.3.1 b) of IEC 60601-2-54:2022 is not possible.

203.6.3.2 Reproducibility of the RADIATION output

Subclause 203.6.3.2 of IEC 60601-2-54:2022 applies.

Additional subclauses:

203.6.3.101 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

Subclause 203.6.3.101 of IEC 60601-2-54:2022 applies.

203.6.3.102 High-level control (HLC)

Subclause 203.6.3.102 of IEC 60601-2-54:2022 applies.

203.6.3.103 * X-RADIATION pulse repetition frequency during RADIOSCOPY

If the RADIOSCOPY pulse rate is selectable, the minimum pulse rate shall be less than or equal to 4 pulses per second.

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

The LOADING STATE shall be indicated by a yellow indicator on the CONTROL PANEL.

At the initiation of IRRADIATION, a brief audible signal shall be indicated at the working position of the OPERATOR. The audible signal shall be different for RADIOSCOPY and for RADIOGRAPHY. Means shall be provided to adjust or inactivate these audible signals and shall be described in the ACCOMPANYING DOCUMENTS. All of these requirements do not apply to high-level control (HLC) RADIOSCOPY.

Compliance is checked by inspection.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Subclause 203.6.4.3 of IEC 60601-2-54:2022 applies.

203.6.4.4 Indication of automatic modes

Subclause 203.6.4.4 of IEC 60601-2-54:2022 applies.

203.6.4.5 * Dosimetric indications

Addition:

NOTE 1 Differences related to the same subclause in IEC 60601-2-54:2022 include: the 1st dash of the 3rd paragraph is applicable also to SERIAL RADIOGRAPHY; in the 4th paragraph, the minimal value is 2,5 Gy·cm^2 instead of 5 µGy·m^2, i.e. is 50 times larger; the recommended unit for displaying the DOSE AREA PRODUCT is Gy·cm^2; a requirement to have means for configuring the display unit of the DOSE AREA PRODUCT is present; additional requirements and recommendations are present after the requirement about DOSE AREA PRODUCT METERS, including additional requirement and recommendation about DOSE MAP and SKIN DOSE MAP; and also, unlike in IEC 60601-2-54, there is no specific requirement for INDIRECT RADIOGRAPHY and DIRECT RADIOGRAPHY.

The ACCOMPANYING DOCUMENTS shall provide information on the performance of the dosimetric indications and describe the operations required to maintain this performance within specification.

Means shall be provided to reset to zero the values of all the cumulative dosimetric indications prior to the commencement of a new RGI PROCEDURE.

INTERVENTIONAL X-RAY EQUIPMENT specified for either RADIOSCOPY or RADIOSCOPY and RADIOGRAPHY shall satisfy the following requirements.

– The value of the mean REFERENCE AIR KERMA RATE shall be displayed during RADIOSCOPY and during SERIAL RADIOGRAPHY in mGy/min together with this unit. This value shall be continuously displayed at the working position of the OPERATOR during the actuation of the IRRADIATION SWITCH and updated at least once every second.

– The value of the cumulative REFERENCE AIR KERMA resulting from RADIOSCOPY and RADIOGRAPHY since the last reset operation shall be
  - continuously displayed at the working position of the OPERATOR in mGy together with this unit and updated at least once every 5 s; or
  - displayed not later than 5 s after the interruption or termination of LOADING.
– The values for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be clearly distinguishable from each other.
– The REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall not deviate from their respective displayed values by more than ± 35 % over the range of 6 mGy/min and 100 mGy to the maximum values.
– The displayed values of REFERENCE AIR KERMA RATE and cumulative REFERENCE AIR KERMA may be measured or calculated.

INTERVENTIONAL X-RAY EQUIPMENT shall be provided with an indication of the cumulative DOSE AREA PRODUCT resulting from RADIOGRAPHY and from RADIOSCOPY since the last reset operation. The DOSE AREA PRODUCT may be measured or calculated. The value should be expressed in Gy·cm^2. Means shall be provided to the RESPONSIBLE ORGANIZATION to allow configuring the unit for display of DOSE AREA PRODUCT at least among all the following:

– Gy·cm^2;
– µGy·m^2 or cGy·cm^2;
– mGy·cm^2.

The instructions for use shall indicate that the unit for display of DOSE AREA PRODUCT is configurable.

The overall uncertainty of the displayed values of the cumulative DOSE AREA PRODUCT above 2,50 Gy·cm^2 shall not exceed 35 %.

NOTE 2 The DOSE AREA PRODUCT indication is not mandatory to be provided at the working position of the OPERATOR.

If part of the INTERVENTIONAL X-RAY EQUIPMENT, DOSE AREA PRODUCT METERS shall comply with IEC 60580:2019.

The indications of cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE shall be CLEARLY LEGIBLE 2,5 m from the DISPLAY in the procedure room. This DISPLAY may be included on an image monitor or it may be a separate device.

The display label for the cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT shall not be designated as SKIN DOSE and SKIN DOSE rate respectively.

When the cumulative REFERENCE AIR KERMA displayed on the INTERVENTIONAL X-RAY EQUIPMENT exceeds a threshold expected to produce skin injury, the INTERVENTIONAL X-RAY EQUIPMENT should display a visual warning to the OPERATOR. When such a DISPLAY is provided, the threshold value shall be adjustable.

The INTERVENTIONAL X-RAY EQUIPMENT should have a DOSE MAP.

NOTE 3 If a DOSE MAP is provided, it is intended for display during the RGI PROCEDURE and to be available for export at the end of the RGI PROCEDURE.

NOTE 4 A SKIN DOSE MAP is preferred over other DOSE MAPS. An example of a DOSE MAP can be obtained by cumulating the values of REFERENCE AIR KERMA over ranges of the available parameters that influence the location of the X-RAY BEAM relative to the PATIENT. When the INTERVENTIONAL X-RAY EQUIPMENT cannot determine the orientation of the X-RAY BEAM AXIS, creation of a DOSE MAP is not practical. Mapping head, chest, abdomen and pelvic anatomy is of primary value; mapping extremities is of secondary value due to smaller body part thickness and their variability in position on the PATIENT SUPPORT.

A DOSE MAP shall not be designated as a SKIN DOSE MAP, unless the RADIATION dose quantity is SKIN DOSE.

NOTE 5 Dosimetric indications apply also for operation in cone-beam CT mode. This provides a means to combine the RADIATION dose for all MODES OF OPERATIONS.

Compliance is checked by inspection and by the appropriate functional tests. The tests for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be performed with a LOADING STATE of duration longer than 3 s.

During RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, indications of one or more of the following items should be made available:

– cumulative LOADING TIME of RADIOSCOPY for the whole RGI PROCEDURE;
– cumulative LOADING TIME of RADIOSCOPY for at least one part of the RGI PROCEDURE determined by the OPERATOR;
– cumulative number of IRRADIATIONS from RADIOGRAPHY for the whole RGI PROCEDURE;
– cumulative number of IRRADIATIONS from RADIOGRAPHY for at least one part of the RGI PROCEDURE determined by the OPERATOR;
– cumulative REFERENCE AIR KERMA for at least one part of the RGI PROCEDURE determined by the OPERATOR.

Additional subclause:

203.6.4.101 Indication of READY STATE

Subclause 203.6.4.101 of IEC 60601-2-54:2022 applies.

203.6.5 AUTOMATIC CONTROL SYSTEM

Subclause 203.6.5 of IEC 60601-2-54:2022 applies.

203.6.6 SCATTERED RADIATION reduction

Subclause 203.6.6 of IEC 60601-2-54:2022 applies, except as follows:

Addition:

INTERVENTIONAL X-RAY EQUIPMENT specified for paediatric applications shall have means to easily remove the ANTI-SCATTER GRID without the use of TOOLS.

Compliance is determined by inspection and functional tests.

203.6.7 Imaging performance

Additional subclause:

203.6.7.101 * Display of LAST IMAGE HOLD RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE

INTERVENTIONAL X-RAY EQUIPMENT shall be equipped with means to display either a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE following termination of the radioscopic IRRADIATION and shall comply with the following.

1) When the LIH RADIOGRAM is displayed, it shall be displayed following termination of the radioscopic IRRADIATION and shall remain visible either until an action by the OPERATOR or until display of the RADIOSCOPY REPLAY IMAGE SEQUENCE.

2) Means shall be provided to clearly indicate to the OPERATOR whether a displayed image is
   – a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE, or
   – from ongoing RADIOSCOPY.
3) DISPLAY of the LIH RADIOGRAM or the RADIOSCOPY REPLAY IMAGE SEQUENCE shall be replaced by the RADIOSCOPY image concurrently with reinitiation of radioscopic IRRADIATION, unless a separate DISPLAY is provided for the RADIOSCOPY images.
4) For a LIH RADIOGRAM obtained by retaining pre-termination RADIOSCOPY images, if the number of images and method of combining images are selectable by the OPERATOR, the selection shall be indicated prior to the initiation of the radioscopic IRRADIATION.

Compliance is checked by inspection and functional tests.

Additional subclauses:

203.6.101 Range of AIR KERMA RATES in RADIOSCOPY

For RADIOSCOPY the MODES OF OPERATION provided for NORMAL USE shall include two modes, designated normal and low respectively, producing different REFERENCE AIR KERMA RATES, such that the value for the low mode does not exceed 50 % of the value for the normal mode. Additional MODES OF OPERATION may be provided, with REFERENCE AIR KERMA RATES less or greater than the values for the normal and low modes.

A control for the selection of any of these MODES OF OPERATION shall not also perform the function of an IRRADIATION SWITCH.

An indication of the selected MODE OF OPERATION shall be provided at the working position of the OPERATOR.

The INTERVENTIONAL X-RAY EQUIPMENT shall not default to a setting with a REFERENCE AIR KERMA RATE higher than that of the normal setting, when the INTERVENTIONAL X-RAY EQUIPMENT is being prepared for the commencement of a RGI PROCEDURE.

Compliance is determined by inspection and functional tests and also by the test PROCEDURE given in 203.5.2.4.5.102 using the 20 cm polymethyl-methacrylate (PMMA) PHANTOM in order to verify the ratio of the REFERENCE AIR KERMA RATES at the designated normal and low MODES OF OPERATION.

203.6.102 * Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

Means to switch between RADIOSCOPY and RADIOGRAPHY shall be provided at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

203.6.103 IRRADIATION disabling switch

A switch shall be provided to disable/enable the LOADING STATE without affecting any other functions of the INTERVENTIONAL X-RAY EQUIPMENT. The operation of this switch shall not, in itself, be capable of initiating the LOADING STATE.

The state of the IRRADIATION disabling switch shall be displayed at the working position of the OPERATOR. The switch should be configured to minimize the likelihood of accidental operation.

Compliance is determined by inspection and functional tests.

203.6.104 * Last-image-hold (LIH)

For RADIOSCOPY sequences that have not been stored, the INTERVENTIONAL X-RAY EQUIPMENT shall be equipped with means to store the LIH RADIOGRAM with other stored images.

NOTE 1 Storage of the LIH RADIOGRAM is subject to 201.12.4.101.2.

NOTE 2 The requirement for having a last-image-hold can be found in 203.6.7.101 of IEC 60601-2-54:2022.

Compliance is determined by inspection and functional tests.

203.6.105 Limitation of RADIATION output

In the case of SINGLE FAULT CONDITIONS, there shall be no unwanted IRRADIATIONS.

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

203.7 RADIATION QUALITY

Subclause 203.7 of IEC 60601-2-54:2022 applies.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Subclause 203.8.4 of IEC 60601-2-54:2022 applies.

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 * Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Subclause 203.8.5.3 of IEC 60601-2-54:2022 applies, except as follows:

Addition:

Regardless of the shape of the IMAGE RECEPTION AREA (circular and non-circular shape), when the X-RAY BEAM is perpendicular to the IMAGE RECEPTION PLANE, the maximum area of the X-RAY FIELD shall conform to the following requirements:

a) at least 80 % of the area of the X-RAY FIELD shall overlie the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION AREAS smaller than 10 cm in diameter or less than 10 cm in length on any side are exempted;

b) the X-RAY FIELD measured from the centre of the IMAGE RECEPTION AREA in the direction of greatest misalignment with the IMAGE RECEPTION AREA shall not extend beyond the boundary of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm.

The additional requirement is applicable for all magnification steps and for minimum and maximum positions of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and for horizontal and vertical positions of the GANTRY.

Compliance is checked by inspection and testing of the equipment by measurement of the X-RAY FIELDS. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, in order for the automatic mechanism to complete any adjustment occurring during the tests (see Annex AA).

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Subclause 203.8.5.4 of IEC 60601-2-54:2022 applies.

Additional subclauses:

203.8.101 Boundary and dimensions of the X-RAY FIELD

Subclause 203.8.101 of IEC 60601-2-54:2022 applies.

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

203.8.102.1 General

Subclause 203.8.102.1 of IEC 60601-2-54:2022 applies.

203.8.102.2 Indication on the X-RAY EQUIPMENT

INTERVENTIONAL X-RAY EQUIPMENT shall provide a graphical representation of the boundaries of the X-RAY FIELD on the image DISPLAY while the BEAM LIMITING DEVICE is adjusted when no IRRADIATION SWITCH is actuated. This representation shall be

– provided at the working position of the OPERATOR, and
– updated during BEAM LIMITING DEVICE adjustment.

203.8.102.3 Indication in the instructions for use

Subclause 203.8.102.3 of IEC 60601-2-54:2022 applies.

203.8.102.4 Accuracy of marked and written indications

Subclause 203.8.102.4 of IEC 60601-2-54:2022 applies.

203.8.103 Interception of the X-RAY BEAM in RADIOSCOPY

Subclause 203.8.103 of IEC 60601-2-54:2022 applies.

203.8.104 Positioning of the X-RAY BEAM AXIS

Subclause 203.8.104 of IEC 60601-2-54:2022 applies.

203.9 FOCAL SPOT TO SKIN DISTANCE

Subclause 203.9 of IEC 60601-2-54:2022 applies.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Subclause 203.10 of IEC 60601-2-54:2022 applies.

203.11 Protection against RESIDUAL RADIATION

Subclause 203.11 of IEC 60601-2-54:2022 applies.

203.12 Protection against LEAKAGE RADIATION

Subclause 203.12 of IEC 60601-2-54:2022 applies.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Subclause 203.13.2 of IEC 60601-2-54:2022 applies.

203.13.3 Protection by distance

Subclause 203.13.3 of IEC 60601-2-54:2022 applies.

203.13.4 Designated SIGNIFICANT ZONES OF OCCUPANCY

Subclause 13.4 of IEC 60601-1-3:2008 applies, except as follows:

Replacement of the third dashed item in the third paragraph in 13.4 of IEC 60601-1-3:2008:

– Isokerma maps shall be provided in the ACCOMPANYING DOCUMENTS, describing the distribution of STRAY RADIATION around the INTERVENTIONAL X-RAY EQUIPMENT. These maps shall apply to typical configurations of the INTERVENTIONAL X-RAY EQUIPMENT when operated at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and shall satisfy the following conditions:

- information shall be given for at least one typical configuration with the X-RAY BEAM horizontal and one with the X-RAY BEAM vertical;
- the isokerma maps shall be presented as isokerma curves normalised to a DOSE AREA PRODUCT of 1 Gy·cm^2;
- the isokerma maps shall be given at heights of 1,0 m and 1,5 m above the floor and may be given additionally for other planes;
- the values of adjacent curves of the isokerma map shall not differ by more than a factor of 2;
- the measurement geometry on which the data are based shall be compatible with the arrangements used for verification as described in Annex BB;
- the data presented shall be accurate within ±50 % at all points more than 15 cm from the INTERVENTIONAL X-RAY EQUIPMENT or PHANTOM and within 3 m of the PATIENT ENTRANCE REFERENCE POINT or down to 0,1 μGy/(Gy·cm^2).

The information shall also include, for each configuration, a scaled schematic representation of the arrangement of the INTERVENTIONAL X-RAY EQUIPMENT showing the projection of the FOCAL SPOT on to the plane of the drawing. Details shall also be given of the applicable measurement geometry, FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, X-RAY TUBE VOLTAGE and ENTRANCE FIELD SIZE.

NOTE Examples of the presentation of isokerma maps are given in Figure BB.1 and Figure BB.2.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS. The isokerma maps are checked by the PROCEDURE described in Annex BB.

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT, means to switch into and out of the LOADING STATE shall be available for use by an OPERATOR located in the following positions:

a) In any of the designated SIGNIFICANT ZONES OF OCCUPANCY, with the INTERVENTIONAL X-RAY EQUIPMENT appropriately configured; a single footswitch with a sufficiently long cable may be used for several SIGNIFICANT ZONES OF OCCUPANCY near the PATIENT;

b) At least 2 m from the irradiated region of the PATIENT, or within a PROTECTED AREA if provided in the installation.

For INTERVENTIONAL X-RAY EQUIPMENT, all visual and audible signals required by 203.6.4.2 shall be provided in such a way that they are perceptible to the OPERATOR in all the locations of items a) and b) above. The presence of an image on the monitor shall not be considered as satisfying this requirement.

Additional subclauses:

203.13.4.101 SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION

Subclause 203.13.4.101 of IEC 60601-2-54:2022 applies.

203.13.4.102 Control from a designated SIGNIFICANT ZONE OF OCCUPANCY

Subclause 203.13.4.102 of IEC 60601-2-54:2022 applies.

203.13.5 Handgrips and control devices

Subclause 203.13.5 of IEC 60601-2-54:2022 applies.

203.13.6 Test for STRAY RADIATION

For testing 203.13.4, subclause 13.6 of IEC 60601-1-3:2008 does not apply and Annex BB applies.

For testing 203.13.4.101 and 203.13.5, subclause 203.13.6 of IEC 60601-2-54:2022 applies.

Additional subclause:

203.101 DIRECT RADIOSCOPY

DIRECT RADIOSCOPY shall not be permitted on INTERVENTIONAL X-RAY EQUIPMENT.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of this document. Its purpose is to promote effective application of this document by explaining the reasons for the requirements and provide additional guidance where appropriate.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

Indications for the need to use INTERVENTIONAL X-RAY EQUIPMENT complying with this document

Since the early 1980s, there has been a substantial increase in the use of RADIOSCOPY for visualisation in a wide range of diagnostic procedures and RGI PROCEDURES. All indications are that this increase will continue in the near future. These RGI PROCEDURES sometimes require long periods of RADIOSCOPY operation with, in some cases, an unchanged position of the RADIATION FIELD on the PATIENT SURFACE. It should be noted that these RGI PROCEDURES usually provide significant advantages over alternative therapies in terms of overall clinical outcome for the PATIENT. Table AA.1 provides examples of RGI PROCEDURES which can involve prolonged RADIOSCOPY IRRADIATION TIMES. In addition, these RGI PROCEDURES are performed by a variety of clinicians with different degrees of training in RADIOLOGICAL PROTECTION. Because of these characteristics, these RGI PROCEDURES are different from procedures in medical diagnostic RADIOLOGY in that the possibility of deterministic effects such as RADIATION-induced skin injury cannot be excluded.

Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible

Radio-frequency cardiac catheter ablations
Transjugular intrahepatic portosystemic shunt (TIPS)
Embolizations
Cardiac and non-cardiac vascular reconstructions

The concern over confirmed RADIATION-induced skin injuries as a result of some RGI PROCEDURES has prompted some countries to issue special advice on the avoidance of injuries during RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES [8], [9]. This special advice has included a recommendation for INTERVENTIONAL X-RAY EQUIPMENT features that permit estimation of the ABSORBED DOSE to the skin. The purpose of this recommendation is to encourage identification of those areas of the skin which are irradiated to levels of ABSORBED DOSE that approach or exceed the threshold for deterministic injury. Such identification would be important for communication and PATIENT care upon the onset of symptoms of RADIATION injury or where additional IRRADIATION in the same skin area is being considered. In addition, the information can assist medical practitioners and health-care organisations in improving RGI PROCEDURES, thereby reducing the potential for injury in the future.

There are also a number of RGI PROCEDURES in which these particular radiations RISKS do not arise by the nature of the RGI PROCEDURE but for which a part or all of other interventional RISKS apply, such as bleeding, infection, blood vessel damage. Some examples of these RGI PROCEDURES are given in Table AA.2.

Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely

IVC filter placement
Venous access
Biopsy
Dialysis access maintenance

The decision to offer equipment complying with this document rests with the MANUFACTURER. The decision to use interventionally labelled EQUIPMENT rests with the RESPONSIBLE ORGANIZATION and OPERATOR of the INTERVENTIONAL X-RAY EQUIPMENT.

See also references [10], [11].

Subclause 201.3.203 – IMAGE DISPLAY DELAY

The IMAGE DISPLAY DELAY relates to the latency between the physical production of any X-ray pulse and the appearance of the corresponding image.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 state that the term ESSENTIAL PERFORMANCE is directly related to the performance of a clinical function (definition 3.27 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012). Table 201.101 provides a list of requirements that can be correlated with the performance of a clinical function and that could therefore be ESSENTIAL PERFORMANCE. The decision on whether any of these requirements constitutes ESSENTIAL PERFORMANCE is subject to a RISK EVALUATION that considers the INTENDED USE of the X-RAY EQUIPMENT.

The identification of potential ESSENTIAL PERFORMANCE requirements is justified because the RISK associated with ionizing X-RADIATION is overweighed by the benefits expected from the examination.

The intent of the requirements in this document is to support MANUFACTURERS in providing state-of-the-art X-RAY EQUIPMENT that is safe under NORMAL CONDITIONS.

Requirements under SINGLE FAULT CONDITIONS are either stipulated in this document or determined by the RISK EVALUATION. There can be cases in which simply detection of SINGLE FAULT CONDITIONS during regular checks within a maintenance or a QUALITY CONTROL PROCEDURE is considered sufficient. In some other cases, a RISK which occurs under SINGLE FAULT CONDITIONS is considered acceptable due to its low probability or low SEVERITY. However, SINGLE FAULT CONDITIONS that result in an unacceptable RISK due to the probability of HARM or the SEVERITY of HARM require additional RISK CONTROL measures. These RISK CONTROL measures are selected according to ISO 14971 and can include frequent functional self-monitoring, installation of redundant parts, or appropriate protective measures.

Subclause 201.4.101 – Recovery management

A failure recoverable by the OPERATOR (for example a reset of the equipment) is a failure for which a series of practical actions can be made by the OPERATOR with the means available with the equipment and described in the instructions for use.

A failure that would not be recoverable by the OPERATOR would require external help such as a service intervention or means that are not provided with the equipment.

Returning to the MODE OF OPERATION which was used at the time of the recoverable equipment failure is important in the sense that some RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES require the use of magnification and high RADIATION doses in order to visualize devices such as small stents, catheters, etc. These devices can be minimally radiopaque. In order to ensure that these devices can be safely placed or safely removed, it is necessary to return to the previous mode of RADIOSCOPY used by the OPERATOR to visualize them.

The normal operation of many controls as mentioned in the requirement is important. Because recoverable equipment failure should be uncommon, when it does occur there will be confusion on the part of the OPERATOR. Emergency functions should be operated using the same controls and in the same way as during non-emergency operation, in order to minimize this confusion.

Subclause 201.4.102 – RADIATION dose documentation

Recording manually the displayed dose values is not considered as being robust enough to provide freedom from the RISK arising from the lack of dose information.

There are two reasons why the ability to export dose data is a potential ESSENTIAL PERFORMANCE. The first is the need to know the PATIENT's RADIATION dose from previous RGI PROCEDURES. The second is the need to know the PATIENT's RADIATION dose from the current RGI PROCEDURE.

In the first case, the HAZARD to the PATIENT is the absence of information regarding the PATIENT's RADIATION dose from previous RGI PROCEDURES. Previous RADIATION to the skin sensitizes it and lowers the threshold for deterministic effects with subsequent IRRADIATION. Without knowledge of the amount of RADIATION previously delivered to the skin, the OPERATOR cannot judge the likelihood of causing HARM and will have difficulty performing the RGI PROCEDURE so as to minimize the RISK of causing HARM. The RISK due to this HAZARD is therefore the increased likelihood of HARM due to RADIATION; specifically, deterministic injury to the skin. The SEVERITY of this HARM can be extreme: a skin lesion that is painful, disfiguring, causes inability to work and loss of income, requires surgery to treat and can take years to heal. ([12], [13])

In the second case, the HAZARD to a PATIENT who has undergone a RGI PROCEDURE and has received a dose high enough to cause deterministic effects is the absence of information regarding RADIATION dose from that RGI PROCEDURE. The HARM is the inability to provide the PATIENT with a diagnosis and prognosis for the deterministic injury unless the physician who performed the RGI PROCEDURE has separately recorded the dose data. The SEVERITY of the deterministic injury is directly proportional to the SKIN DOSE, and appropriate management depends on knowledge of the dose.

The RISK is high for the RGI PROCEDURES that are the INTENDED USE of equipment subject to this document. ([14],[15],[16],[17], [20], [23]) The importance of recording and preserving dose data for PATIENTS undergoing RGI PROCEDURES is so great that in some countries recording these data is mandatory.([18])

The performance required to reduce the RISK is the ability to export dose data, with or without image data, in a publicly available form. A publicly available form is necessary so that a physician reviewing previous RGI PROCEDURES will have these dose data available. One cannot assume that the physician will be able to access dose data recorded in a proprietary format.

For EQUIPMENT intended for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, dose data export capability as described in subclause 201.4.102 is needed – dose data are recorded in public fields, the output is DICOM compatible, and the data recorded are sufficient to permit a medical physicist to reconstruct actual SKIN DOSE from overlapping RADIATION FIELDS. SKIN DOSE reconstructions are more accurate than the crude estimates of SKIN DOSE that are provided by measurements of overall dose, such as cumulative dose and DAP. ([14], [19], [21], [22])

Subclause 201.7.2.102 – PATIENT SUPPORT load

Removing the CPR loading from the SAFE WORKING LOAD in the marked value is to allow for CPR provision.

Subclause 201.7.2.105 – Protection against ingress of liquids

Ingress of body fluids can create HAZARDOUS SITUATIONS for person working/servicing the INTERVENTIONAL X-RAY EQUIPMENT. When attached protective covers are used, although they contribute to this protection, they are not taken into account for the IPXY markings in accordance with definition 3.1 of IEC 60529:1989.

It is desirable that the location "in the PATIENT vicinity (or around the PATIENT)" means locations within 1,5 m from the PATIENT SUPPORT.

Subclause 201.7.9.2.12 – Cleaning, disinfection and sterilization

The need for the development of this document in this area arises from the nature of RGI PROCEDURES and the heightened awareness of the RISK of transmission of potentially lethal organisms. Whilst incisions made during RGI PROCEDURES are small, large blood vessels and collections of body fluids (for example, abscesses) are frequently directly accessed with catheters or tubes. Arising from this, blood and body fluids can spill on to or contaminate the work environment and the INTERVENTIONAL X-RAY EQUIPMENT. Some RGI PROCEDURES also involve copious quantities of fluids being used to wash or flush away debris during RGI PROCEDURES. These fluids have been known to enter and lodge in cavities and crevices in the INTERVENTIONAL X-RAY EQUIPMENT, thereby producing both electrical and infection control HAZARDS. The latter can be a serious problem for maintenance technicians who can have to approach INTERVENTIONAL X-RAY EQUIPMENT containing up to several litres of saline and miscellaneous body fluids of unknown origin. The possibility of such occurrences can be greatly reduced or even eliminated at the design stage of the INTERVENTIONAL X-RAY EQUIPMENT, by giving careful thought to the issues involved.

The possibility that INTERVENTIONAL X-RAY EQUIPMENT can become contaminated or have fluids or deposits lodge in cracks and crevices, gives rise to the need for cleaning and disinfection. This, in turn, gives rise to the use of cleaning and disinfection agents which can achieve their own aims admirably but, in doing so, can give rise to electrical HAZARDS or damage the INTERVENTIONAL X-RAY EQUIPMENT surfaces to which they are applied. Again, such problems can be greatly reduced at the design stage, and by giving explicit instructions on cleaning and disinfection.

Subclause 201.7.9.2.102 – Provisions for cardiopulmonary resuscitation (CPR)

The INTERVENTIONAL X-RAY EQUIPMENT is not designed primarily to perform CPR and does not need to provide all the necessary ACCESSORIES to perform CPR. However, it is important that the INTERVENTIONAL X-RAY EQUIPMENT be designed so that CPR can be given to the PATIENT when the INTERVENTIONAL X-RAY EQUIPMENT is properly configured. If, in order to configure the system for the performance of CPR, it is necessary to use or to remove specific ACCESSORIES that are part of the INTERVENTIONAL X-RAY EQUIPMENT, then the instructions for use have to describe this.

Subclause 201.7.9.2.103 – Emergency instructions

It is intended that the emergency instructions be immediately available, and they are therefore exposed and susceptible to damage and fluids. The resistance to manipulation, water damage and cleaning is related to the durability of the emergency instructions. A plasticized set of sheets is an example of durable emergency instructions.

Limiting the content of emergency instructions to include only key material will be important for their effective use during an emergency when there is no time to consult a long version of the instructions for use or when it is not possible to consult an electronic version due to loss of power. The intention is that these emergency instructions be brief.

Subclause 201.9.2.4 – Emergency stopping devices

In INTERVENTIONAL X-RAY EQUIPMENT, HAZARDS can arise if functionality is unnecessarily affected by the operation of safety devices such as anti-collision devices.

Subclause 201.11.1.1 – Maximum temperature during NORMAL USE

A part of the INTERVENTIONAL X-RAY EQUIPMENT that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT.

Subclause 201.11.6.1 – General (within subclause 201.11.6 "Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the me equipment")

In RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, there can be relatively large quantities of body and other fluids which can, directly or through deposits left behind, give rise to damage to the INTERVENTIONAL X-RAY EQUIPMENT, or cause electrical, toxic or infectious HAZARDS to PATIENTS, OPERATORS and service personnel.

Subclause 201.11.6.5.102 – Sources of dust and other particles

To avoid inadvertent PATIENT infection, sources of dust and other particles that can reach the PATIENT shall be avoided. Sources of dust and other particles comprise e.g., fan directed towards the PATIENT, fall of dust from devices/ACCESSORIES above the PATIENT, etc.

It is desirable to have no sources of dust and other particles in the volume defined horizontally by a distance from the PATIENT SUPPORT of at least 2 m and vertically from floor to ceiling.

Subclause 201.11.6.5.103 – ENCLOSURES

For convenience, here is a brief description of the degree of protection from Table 3 of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013:

– IPX0: non-protected
– IPX2: protected against vertically falling water drops when ENCLOSURE tilted up to 15°
– IPX3: protected against spraying water
– IPX7: protected against the effects of temporary immersion in water

Image monitor can be IPX0 with optional marking.

Subclause 201.12.4 – Protection against hazardous output

The provisions in the additional subclauses recognize that protection against hazardous output from INTERVENTIONAL X-RAY EQUIPMENT requires flexibility in the delivery of the intended RADIATION and the avoidance of confusion in the presentation of image data to the OPERATOR during the course of a RGI PROCEDURE.

Subclause 201.12.4.101.1 – PATIENT data

Information about the identity of the PATIENT and the medical procedure will typically include at least the name and date of birth of the PATIENT, and the date and time of the RGI PROCEDURE.

Subclause 201.12.4.101.3 – Image DISPLAYS

A DISPLAY location can be one of several separate monitor screens or a logical subdivision of the area of an individual monitor screen.

These requirements arise from the extreme danger that occurs if an OPERATOR undertakes a RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE on the mistaken assumption that a currently displayed image is, for example, a live one.

Subclause 201.12.4.102 – IMAGE DISPLAY DELAY

IMAGE DISPLAY DELAY is linked to the hand-eye coordination when performing interventions.

Subclause 201.12.4.103 – Documentation of image orientation

This requirement is meant to avoid RISKS associated with potential OPERATOR misinterpretation of the PATIENT orientation on the image, e.g., mirror effect: left/right, top/bottom.

Subclause 201.12.4.104 – Availability of RADIOSCOPY during networking activities

Examples of networking activities include the sending of an examination sequence to a workstation, etc.

Subclause 201.12.4.105 – Appropriate mask location for subtracted images

In subtracted imaging modes with rotational GANTRY motion (e.g., subtracted 3D) or longitudinal table motion, etc., it is important to select the most appropriate mask in order to minimize subtraction artifacts.

Subclause 201.12.4.106 – Tableside controls

For the other tableside controls (other than GANTRY and PATIENT SUPPORT motions controls, IRRADIATION SWITCHES, and beam limitation blade control), the identification could be made by light indicator, by touch or something else. This requirement is necessary because this type of INTERVENTIONAL X-RAY EQUIPMENT is typically used in a darkened room, and these controls are otherwise difficult for the OPERATOR to see and identify, even with a fully transparent means for protection against non-sterile conditions.

Subclause 201.12.4.107 – Image measuring functions

There are several sources of inaccuracy such as initial calibration, geometric distortion, marker position, etc.

Examples of image measuring function are vessel sizing, ventricular ejection fraction estimation, etc.

Subclause 201.15.101 – Configuration for cardiopulmonary resuscitation (CPR)

The time period to place the INTERVENTIONAL X-RAY EQUIPMENT during NORMAL USE in a configuration for CPR includes not only the possible table motion but all necessary GANTRY motion and removal of ACCESSORIES.

Subclause 203.5.2.4.5.101 – Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY

For b) available settings, item 5): This would, for example, include a typical vascular setting and a typical cardiac setting for INTERVENTIONAL X-RAY EQUIPMENT intended to be used for both applications.

For c) RADIATION data: the relatively large tolerance reflects the circumstances that MEASURED VALUES are being compared with stated values given in the instruction for use.

For d) PATIENT ENTRANCE REFERENCE POINT: For lateral positioning of a C-arm, the definition of PATIENT ENTRANCE REFERENCE POINT relative to the ISOCENTRE is the same as described for C-arms.

Subclause 203.5.2.4.5.102 – Test for dosimetric information

In this document, the required statements of AIR KERMA and AIR KERMA RATE are expressed as values of REFERENCE AIR KERMA (RATE), at the applicable position of the PATIENT ENTRANCE REFERENCE POINT. This position generally approximates to the position of the PATIENT SURFACE, but does not necessarily coincide with it under all conditions. The concept, supported by the measuring PROCEDURE described here, is intended to provide a uniform method for stating the AIR KERMA (RATE) produced by INTERVENTIONAL X-RAY EQUIPMENT in NORMAL USE. This test method is based on the use of specific polymethyl-methacrylate (PMMA) PHANTOMS under particular conditions. The compliance criteria stated in this PROCEDURE allow for manufacturing tolerances in the stated values, when these values are verified against the MEASURED VALUES resulting from the test. For this reason and also because of factors such as PATIENT variability and the actual clinical configuration of the INTERVENTIONAL X-RAY EQUIPMENT, the stated values are not regarded as accurate measures of RADIATION actually incident upon the skin of the PATIENT.

In addition to its purpose of verifying the compliance of statements made in accordance with this document, the method can be adapted for use in other situations, such as those where it is required to determine or verify levels of AIR KERMA (RATE) applying at any time to examples of INTERVENTIONAL X-RAY EQUIPMENT under conditions of NORMAL USE, or to investigate the dependence of the REFERENCE AIR KERMA (RATE) on selected MODES OF OPERATION or on the settings of variable operating parameters. Such additional uses, however, are not within the normative intent of this subclause.

About the measurements and test conditions:

Placing the PHANTOM near the X-RAY IMAGE RECEPTOR while leaving as much distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM, will minimize the effect of SCATTERED RADIATION on the measurements. Additionally, placing the measuring detector half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM will minimize the contribution of STRAY RADIATION to the readings; see also Figure 5 of reference [24].

Aligning the surface of the PHANTOM within ±2° allows, in the case of several rotational positions being contained within this limit, use of any of these rotational positions.

Subclause 203.6.3.103 – X-RADIATION pulse repetition frequency during RADIOSCOPY

RADIATION usage is optimised when the amount of RADIATION used to produce an image or an image series is the least possible that permits adequate visualization of the structures of interest. International and national guidelines from radiation protection organizations [25], [26] and medical professional societies [28], [29], [30] recommend that in interventional RADIOSCOPY, dose rate is reduced to the extent possible. Clinical circumstances can require a high or low dose per pulse independent of pulse rate. In these situations, the ability to select a low pulse rate independently of dose per pulse is essential for optimisation.

Subclause 203.6.101 already requires a minimum of two MODES OF OPERATION for NORMAL USE in RADIOSCOPY – "normal" and "low" REFERENCE AIR KERMA RATES – with the "low" MODE OF OPERATION providing a REFERENCE AIR KERMA RATE that does not exceed 50 % of the value for the normal mode. This permits the OPERATOR to select a low dose rate when clinically appropriate. When a selectable RADIOSCOPY pulse rate is available, the new requirement extends the OPERATOR'S ability to optimise RADIATION usage by specifying that at least one low pulse rate is available. This will permit the OPERATOR to select the lowest clinically acceptable pulse rate independently of dose rate.

Subclause 203.6.4.5 – Dosimetric indications

Provisions for fine-tuning the dosimetric indications by a qualified end-user are not included in this document since these indications shall comply with accuracy requirements as described in this document. Thus, further fine-tuning does not meet a need for avoiding unacceptable RISK and can in contrast create problems in cases of uncontrolled fine-tuning.

The new value of accuracy is believed to represent the current state-of-the-art for dose indications that can be either measured or computed from technique factors. Refer also to [7].

In relation to DOSE AREA PRODUCT:

– Reference [25]mentions in its subsection D.3 that DAP can be useful for stochastic effects to PATIENTS and OPERATORS, but not for deterministic effects. See also reference [18].

– A single dosimetric indication unit is recommended, since allowing a free choice of displayed RADIATION units could be confusing to OPERATOR, particularly if OPERATORS use equipment from several MANUFACTURERS.

– The DOSE AREA PRODUCT, DOSE AREA PRODUCT RATE or related values can be indicated, particularly in training situations. However, the DOSE AREA PRODUCT is primarily used as an indicator for stochastic effects and is not useful for predicting deterministic effects. It can be useful to momentarily indicate the DOSE AREA PRODUCT RATE and the cumulative DOSE AREA PRODUCT at the position of the OPERATOR, by means of a toggle.

In relation to the display label not referring to skin: The PATIENT ENTRANCE REFERENCE POINT seldom corresponds to the actual position of the PATIENT's skin.

In relation to the threshold visual warning: A suggested default threshold is 2 Gy. Refer to ICRP-85 ([25]) for a description of other appropriate threshold values. See reference [13] also.

In relation to the cumulative number or IRRADIATIONS from RADIOGRAPHY: It is understood that all X-ray pulses performed during RADIOGRAPHY are to be counted and included in the cumulative number of IRRADIATIONS from RADIOGRAPHY.

In relation to notations:

REFERENCE AIR KERMA is sometimes written differently in the bibliography (e.g. in [26] and[27]) and denoted as $K_{a,r}$.

DOSE AREA PRODUCT is sometimes written differently in the bibliography (e.g. in [26] and[27]) and denoted as air kerma area product P_{KA}.

In relation to SKIN DOSE MAP:

Introduction:

The application of any form of RADIATION to a PATIENT is part of the practice of medicine. The practitioner has the responsibility of balancing the expected benefits of a RGI PROCEDURE against associated RISKS. To meet this goal, the practitioner needs to have timely access to appropriate information.

X-RAY EQUIPMENT that meets IEC 60601-2-43 or IEC 60601-2-54, or for example U.S. performance standards (21 CFR 1020[7]) includes dosimetric displays. Depending on the applicable standard, this includes real time displays of cumulative REFERENCE AIR KERMA at the PATIENT ENTRANCE REFERENCE POINT, DOSE AREA PRODUCT, or both. The cumulative REFERENCE AIR KERMA is required to be visible at the OPERATOR's working position. SKIN DOSE MAPS were foreseen as a logical extension of these real time displays and were recommended in NCRP Report 168 [26] and ICRP Publication 120 [27]. However, when IEC 60601-2-43:2010 was published, the technology was not sufficiently developed to include a normative requirement for SKIN DOSE MAPS.

The distribution of IRRADIATION on the PATIENT has been intermittently available from various MANUFACTURERS since the late 1990's in various real-time or post-procedure modes. IEC 61910-1:2014 defines a RADIATION DOSE STRUCTURED REPORT (RDSR) with sufficient information ("extended dose documentation") to construct a SKIN DOSE MAP using additional geometric and anatomical information supplied externally to the imaging equipment. Depending on the use of IEC 61910-1:2014 and the supporting equipment, this might be either real-time or post-procedure. Some models of INTERVENTIONAL X-RAY EQUIPMENT already provide integrated SKIN DOSE MAPS using the equipment's own resources.

The clinical goal of these efforts is to provide the OPERATOR with sufficient real-time information to avoid unnecessary tissue reactions. Reducing the frequency and SEVERITY of tissue reactions is a requirement for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES above the requirements for general procedures (X-RAY EQUIPMENT within the scope of IEC 60601-2-54).

Real-time dosimetric displays:

RADIATION is one of many factors affecting the practitioner's ability to safely and effectively complete a RGI PROCEDURE. Automatic notifications of any kind can result in poorer overall clinical results if they unnecessarily distract the OPERATOR's attention. Many non-RADIATION events that occur during a RGI PROCEDURE also require the OPERATOR's attention. Unless OPERATOR action is urgent, such notifications can be given to the OPERATOR by a knowledgeable participant in the RGI PROCEDURE (located either in the control room or the procedure room) as soon as it is safe to do so.

Continuous, real-time display provides immediate access to accumulated dosimetric information without requiring an action or distracting the OPERATOR's concentration. NCRP Report 168 [26], ICRP Publication 120 [27] and guidelines from interventional radiology [28] and interventional cardiology [29] societies recommend OPERATOR notification when specified dosimetric levels, including peak SKIN DOSE, are exceeded. RADIATION injuries do not have a binary dose-response function. Exceeding any nominal RADIATION threshold by a few tens of percent is highly unlikely to substantially affect the frequency or nature of any RADIATION injury.

Some equipment currently has the capability of non-distractively indicating when the cumulative REFERENCE AIR KERMA exceeds a threshold using means such as reversing the colours of a display and its background.

DOSE MAPS:

The simplest DOSE MAP is a display of the REFERENCE AIR KERMA as a function of GANTRY angle. Such maps typically display a single value for all of the IRRADIATION occurring in a range of angles (e.g. 30° x 30°). Their construction does not require any information about the PATIENT or the PATIENT's position relative to the beam. Nevertheless, these AIR KERMA maps can be sufficient for certain aspects of operational RADIATION management.

During a RGI PROCEDURE, the availability of a current SKIN DOSE MAP displayed on a surface that reasonably represents the actual PATIENT is clinically important. This map is useful to indicate the size, shape, and location of the current X-RAY FIELD(S). Such a DISPLAY provides the OPERATOR with immediate information regarding the RISKS of continuing IRRADIATION and provides the information necessary to manage the RADIATION FIELDS so as to control the likelihood and SEVERITY of a cutaneous tissue reaction [32].

The skin surface of the PATIENT can be represented by a model. In that case, the PATIENT surface model can be a stylized representation of the skin surface of a human. The PATIENT surface model can be adaptable to the PATIENT under examination. The PATIENT surface model can exclude PATIENT extremities. For example, the PATIENT surface model could be based on the PATIENT's height and weight.

Isodose boundaries and colour codes:

OPERATORS can work in one or more locations with different MANUFACTURERS' equipment. A consistent use of isodose boundaries and colour codes is useful to avoid confusion amongst OPERATORS when working between systems from different MANUFACTURERS.

Table AA.3 presents examples of colour and grayscale code with isodose boundaries. Isodose boundaries are derived from Table 2.5 from NCRP Report 168 [26]. Colour and grayscale codes are expressed in RGB space (see e.g., reference [33] for RGB space description). Lower isodose boundaries for AIR KERMA maps could be used to keep meaningful biological RISK indications. These could be 75 % of the SKIN DOSE MAP ones since AIR KERMA does not account for effects like backscatter.

Table AA.3 – Examples of isodose boundaries and colour codes for SKIN DOSE MAP and AIR KERMA map

SKIN DOSE MAP isodose boundaries	Air kerma map isodose boundaries	RGB colour	RGB grayscale
A. Example 1			
Base surface to < 0,1 Gy	Base surface to < 0,075 Gy	220,220,220	220,220,220
0,1 Gy	0,075 Gy	0,0,0	0,0,0
1,0 Gy	0,75 Gy	0,0,255	70,70,70
2,0 Gy	1,5 Gy	0,255,0	105,105,105
5,0 Gy	3,75 Gy	255,255,0	145,145,145
8,0 Gy	6,0 Gy	255,128,0	190,190,190
11,0 Gy	8,25 Gy	255,0,0	235,235,235
≥ 15,0 Gy	≥ 11,25 Gy	255,255,255	255,255,255
B. Example 2			
0,1 Gy	0,075 Gy	0,0,255	0,0,0
1,0 Gy	0,75 Gy	0,255,0	70,70,70
2,0 Gy	1,5 Gy	255,255,0	105,105,105
3,0 Gy	2,25 Gy	255,128,0	145,145,145
5,0 Gy	3,75 Gy	255,0,0	190,190,190
10,0 Gy	7,5 Gy	240,160,160	235,235,235
≥ 15,0 Gy	≥ 11,25 Gy	255,255,255	255,255,255

NOTE Except for the first and last table entry, the colours used to represent doses between isodose boundaries could be displayed as either a continuous transition between the values or as the lower dose value.

The following considerations are relevant as part of the design PROCESS for a SKIN DOSE MAP.

– The SKIN DOSE MAP is configurable by the OPERATOR to be displayed at least at the position of the RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE when LOADING in RADIOSCOPY or RADIOGRAPHY is not active. A second DISPLAY of the SKIN DOSE MAP in the control room is a helpful option for OPERATOR notification. The SKIN DOSE MAP includes at least the relevant anatomical region of the body.

– The PATIENT orientation is apparent on the SKIN DOSE MAP.

– An indication of the current location of the X-RAY FIELD(S) is displayed on the SKIN DOSE MAP.

– The SKIN DOSE MAP can be displayed as a grayscale or colour-coded image. A colour-coded map is preferred. When the SKIN DOSE MAP is intended to be displayed without colour, a dedicated grayscale scheme is necessary.

– Providing a mean to use colour or grayscale schemes different from those shown in Table AA.3 or provided by the MANUFACTURER is desirable because it promotes future standardization of the SKIN DOSE MAP display, and therefore could provide additional PATIENT safety.

– For clinically important values of SKIN DOSE, displayed values of SKIN DOSE are close to actual SKIN DOSE. The minimum value stated as part of the criterion for accuracy concerns only the accuracy of the displayed SKIN DOSE. It is not intended to be used to determine which values of SKIN DOSE are displayed.

– The current value of the highest SKIN DOSE within the current X-RAY FIELD(S) and the highest SKIN DOSE at any point on the SKIN DOSE MAP (peak SKIN DOSE) are displayed in conjunction with the SKIN DOSE MAP. These displayed values are CLEARLY LEGIBLE at 1,5 m from the DISPLAY, when configured by the OPERATOR.

– Use of tissue equivalent anthropomorphic PHANTOMS for quantifying accuracy.

The following information is relevant for inclusion in the ACCOMPANYING DOCUMENTS:

– description of the PATIENT surface model;
– description of the PHANTOM(S) for quantifying accuracy;
– test conditions and accuracy.

Subclause 203.6.7.101 – Display of LAST IMAGE HOLD RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE

INTERVENTIONAL X-RAY EQUIPMENT differs from non-interventional X-RAY EQUIPMENT with respect to display of a LIH RADIOGRAM. There are specific RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES (e.g. a coronary artery chronic total occlusion procedure) for which the OPERATOR can prefer having a DISPLAY of a reference acquisition image instead of a LIH display.

While the requirements for display of a LIH RADIOGRAM differ from 203.6.7.101 of IEC 60601-2-54:2022, the LIH RADIOGRAM definition is the same as in 201.3.212 of IEC 60601-2-54:2022.

Subclause 203.6.102 – Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

This requirement is intended to ensure that switching can be achieved by a sole OPERATOR without change of location and without the intervention of a second member of the operating staff.

Subclause 203.6.104 – Last-image-hold (LIH)

Storage of the LIH RADIOGRAM is particularly important for paediatrics applications. INTERVENTIONAL X-RAY EQUIPMENT equipped with means for auto-replay of an optionally stored RADIOSCOPY sequence (whether fully or partially) which would replace the last-image-hold is not in contradiction with these requirements, as long as the LIH RADIOGRAM is displayable and storable when the RADIOSCOPY sequence has not been stored.

Subclause 203.8.5.3 – Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

The additional requirement implies higher precision for small X-RAY FIELDS in INTERVENTIONAL X-RAY EQUIPMENT as compared with the corresponding subclause in IEC 60601-2-54, reflecting the working conditions applicable for such equipment and the current state of the technology.

Annex BB
(normative)

Distribution maps of STRAY RADIATION

BB.1 General

This document contains requirements in 203.13.4 for isokerma maps of STRAY RADIATION to be provided with INTERVENTIONAL X-RAY EQUIPMENT. The purpose is to provide information on the distribution of the STRAY RADIATION for guidance in the RADIOLOGICAL PROTECTION of staff. This annex describes the PROCEDURE for verifying compliance. Since dosimetric information of this kind depends considerably on the operating conditions and measuring methods employed, the annex is also intended for the guidance of MANUFACTURERS in meeting the requirements.

The measurements obtained shall not be used for determining RADIATION shielding for a specific procedure room.

NOTE The measurements obtained are representative of the test situation only; they do not represent all clinical situations.

BB.2 Equipment configuration

The ACCOMPANYING DOCUMENTS are examined in relation to the configuration of the INTERVENTIONAL X-RAY EQUIPMENT and other data applying to the isokerma curves. For compliance:

– *the information shall be complete, as listed in 203.13.4;*
– *configurations shall be typical of the NORMAL USE of the INTERVENTIONAL X-RAY EQUIPMENT;*
– *the measuring arrangements described shall be compatible with those specified in this annex for verification of the values.*

If the information is compliant, the isokerma maps are verified as in BB.3 and BB.4, with the INTERVENTIONAL X-RAY EQUIPMENT configured and operated as described in the ACCOMPANYING DOCUMENTS.

BB.3 PHANTOM

The PHANTOM consists of a 25 cm cube of polymethyl-methacrylate (PMMA), which may be assembled from 25 cm square slabs.

BB.4 Measurement set-up

The X-RAY BEAM is aligned so that the centre of the ENTRANCE SURFACE of the PHANTOM is at the PATIENT ENTRANCE REFERENCE POINT. The X-RAY BEAM shall not be aligned in such a way that its axis lies in the plane between adjacent slabs of PMMA. The RADIATION FIELD size shall be 100 cm^2 at the entrance of the PHANTOM.

Measurements are performed at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY.

Measurements are made at all locations within 3 m of the PATIENT ENTRANCE REFERENCE POINT or down to 0,1 µGy/(Gy·cm^2), except that measurements may be omitted:

– *within 15 cm of the PATIENT ENTRANCE REFERENCE POINT when placement of the measuring device is impractical, and*
– *at locations vertically over the INTERVENTIONAL X-RAY EQUIPMENT.*

Measurements are made for two orientations of the X-RAY BEAM, one horizontal and one vertical. When the X-RAY BEAM is vertical, the X-RAY SOURCE ASSEMBLY is oriented to the beam direction corresponding to the most frequent use of the INTERVENTIONAL X-RAY EQUIPMENT.

EXAMPLE For an isocentric system, the beam is directed vertically upward.

BB.5 Criteria for compliance

The MEASURED VALUES are normalised to a DOSE AREA PRODUCT of 1 Gy·cm^2. For compliance, all values of AIR KERMA represented by the curves in the ACCOMPANYING DOCUMENTS shall be within ±50 % of the normalised MEASURED VALUES determined by the test.

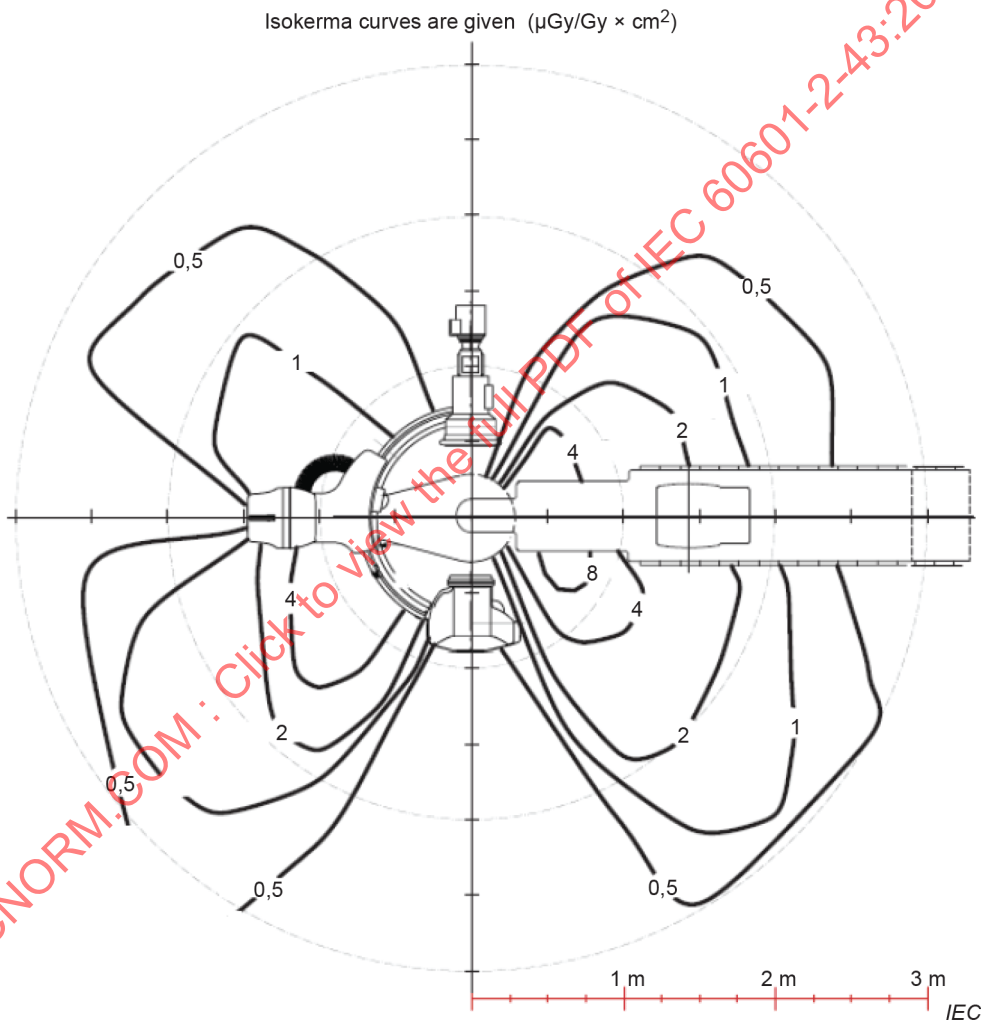

Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration

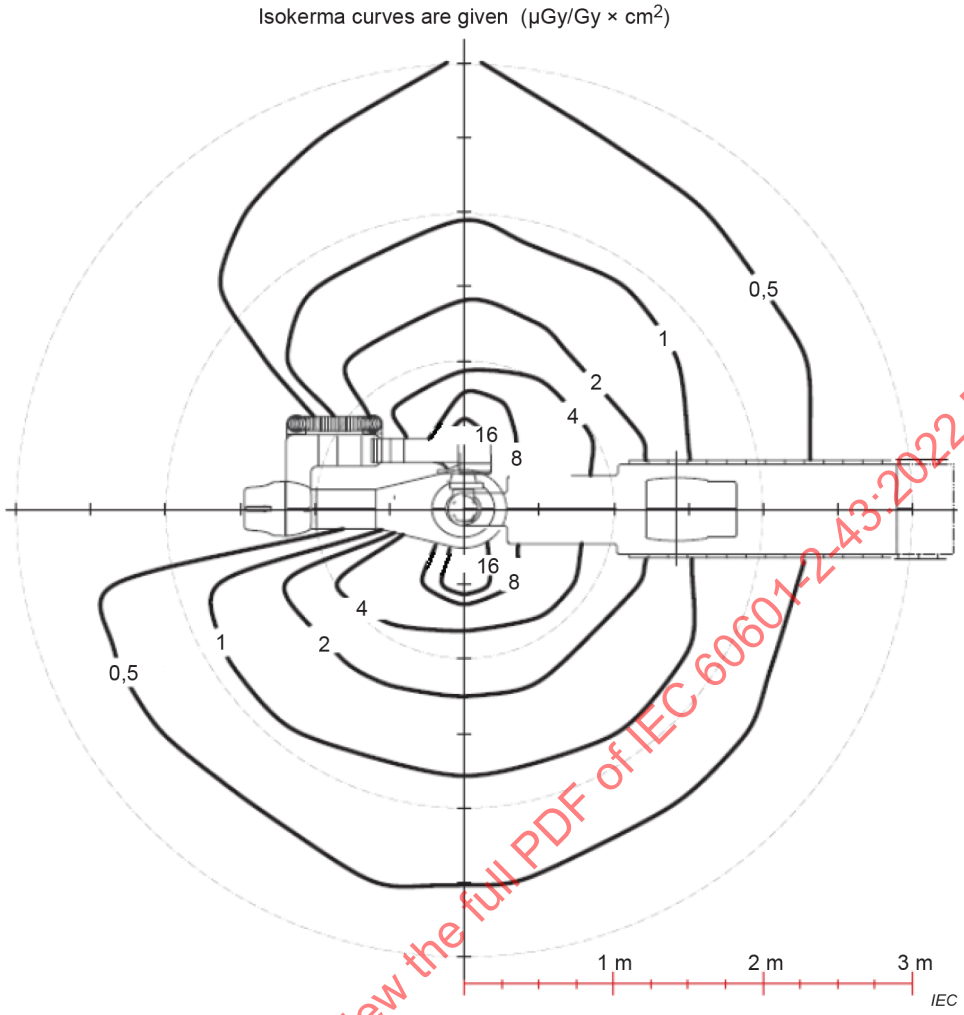

Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration

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Index of defined terms

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.
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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*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, l'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021, l'IEC 60601-2-54:2022, l'IEC TR 60788:2004, l'IEC 61910-1:2014, l'IEC 62220-1-1:2015 ainsi que les suivants s'appliquent.

NOTE Une liste de termes définis est donnée dans l'Index des termes définis.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

Addition:

201.3.201
CARTE DE DOSE
représentation de la distribution spatiale d'une quantité de dose de RAYONNEMENT

201.3.202
RADIOSCOPIE D'URGENCE
RADIOSCOPIE mettant à disposition un ensemble limité de fonctions (fonctions d'urgence), destinée à être utilisée lors de la reprise après une défaillance de l'APPAREIL A RAYONNEMENT X D'INTERVENTION pouvant être traitée

201.3.203
*** DELAI D'AFFICHAGE DE L'IMAGE**
au cours d'un acte de RADIOSCOPIE ou de RADIOGRAPHIE, intervalle de temps qui s'écoule entre un évènement capturé pendant l'APPLICATION D'UNE CHARGE DE RAYONNEMENT X utilisée pour créer une image et l'AFFICHAGE de cet évènement sur l'image

201.3.204
APPAREIL A RAYONNEMENT X D'INTERVENTION
APPAREIL A RAYONNEMENT X pour INTERVENTIONS GUIDEES PAR RADIOSCOPIE

201.3.205
INTERVENTION GUIDEE PAR RADIOSCOPIE
INTERVENTION RGI
intervention invasive (impliquant l'introduction d'un dispositif, par exemple une aiguille ou un cathéter dans le corps du PATIENT) utilisant LA RADIOSCOPIE comme principal moyen de guidage à des fins de traitement ou de diagnostic médical du PATIENT

Note 1 à l'article: L'abréviation "RGI" est dérivée du terme anglais développé correspondant "radioscopically guided interventional".

201.3.206
DOSE SUR LA PEAU
DOSE ABSORBEE estimée au niveau de la peau en un point spécifique

201.3.207
CARTE DE DOSE SUR LA PEAU
CARTE DE DOSE de la DOSE SUR LA PEAU

201.4 Exigences générales

L'Article 4 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:

201.4.3 * PERFORMANCES ESSENTIELLES

Le paragraphe 201.4.3 de l'IEC 60601-2-54:2022 s'applique, avec les exceptions suivantes:

Addition:

NOTE Le paragraphe 203.6.4.3.104.2 (Précision des PARAMETRES DE CHARGE en mode de commande automatique) de l'IEC 60601-2-54:2022 précise une limitation pour l'application des paragraphes 203.6.4.3.104.3 (Précision de la HAUTE TENSION RADIOGENE) et 203.6.4.3.104.4 (Précision du COURANT DANS LE TUBE RADIOGENE) de l'IEC 60601-2-54:2022. Cette limitation est aussi valable pour la liste des PERFORMANCES ESSENTIELLES.

Des exigences supplémentaires de PERFORMANCES ESSENTIELLES possibles sont données dans les paragraphes énumérés dans le Tableau 201.101.

Tableau 201.101 – Liste supplémentaire de PERFORMANCES ESSENTIELLES possibles à prendre en considération par le FABRICANT dans l'analyse de GESTION DES RISQUES

Exigence	Paragraphe
Gestion de la reprise	201.4.101
Documentation sur la dose de RAYONNEMENT	201.4.102

201.4.10.2 RESEAU D'ALIMENTATION POUR APPAREILS EM et SYSTEMES EM

Le paragraphe 201.4.10.2 de l'IEC 60601-2-54:2022 s'applique.

Paragraphes supplémentaires:

201.4.101 * Gestion de reprise

Le temps de reprise de toutes les fonctions nécessaires pour réaliser une RADIOSCOPIE D'URGENCE après une défaillance pouvant être traitée automatiquement ou par l'OPERATEUR doit être aussi court que raisonnablement possible en pratique. La GESTION DES RISQUES doit tenir compte de la disponibilité d'une alimentation de secours pour la détermination du temps de reprise.

Lorsque la reprise est complète, une relance de l'IRRADIATION doit être exigée pour continuer à produire des IRRADIATIONS.

Le temps nécessaire à la reprise de toutes les fonctions, après une défaillance pouvant être traitée automatiquement ou par l'OPERATEUR, doit être aussi court que raisonnablement possible en pratique.

Dans le cas d'une défaillance pouvant être traitée manuellement, le temps nécessaire à la reprise de toutes les fonctions ne doit pas dépasser 10 min entre le déclenchement de la reprise par l'OPERATEUR et la reprise de toutes ses fonctions par l'APPAREIL A RAYONNEMENT *X* D'INTERVENTION.

Dans le cas d'une défaillance pouvant être détectée et traitée automatiquement, le temps de reprise de toutes les fonctions ne doit pas dépasser 10 min entre la défaillance de l'APPAREIL A RAYONNEMENT X et la reprise de toutes ses fonctions par l'APPAREIL A RAYONNEMENT X.

L'APPAREIL A RAYONNEMENT X D'INTERVENTION peut comporter ces deux modes de reprise.

NOTE Il est souhaitable que toutes les fonctions permettant une RADIOSCOPIE D'URGENCE. Il est souhaitable que toutes les fonctions soient reprises en moins de 3 min.

Les instructions d'utilisation doivent indiquer:

– le temps nécessaire pour obtenir toutes les fonctions de la RADIOSCOPIE D'URGENCE;
– le temps nécessaire pour retrouver toutes les fonctions de l'APPAREIL A RAYONNEMENT X D'INTERVENTION;
– pour les défaillances pouvant être traitées par l'OPERATEUR, la PROCEDURE exigée, qui peut être suivie par l'OPERATEUR pour effectuer cette reprise.

Lorsque le système est en mode RADIOSCOPIE D'URGENCE, ce mode doit être indiqué au poste de travail de l'OPERATEUR.

Les fonctions nécessaires pour réaliser la RADIOSCOPIE D'URGENCE doivent comporter, au minimum:

– le MODE DE FONCTIONNEMENT DE RADIOSCOPIE, par ordre de priorité:
  - RADIOSCOPIE dans le MODE DE FONCTIONNEMENT qui a été utilisé au moment de la défaillance de l'équipement pouvant être traitée;
  - ou, si cela est impossible, RADIOSCOPIE dans un MODE DE FONCTIONNEMENT aussi proche que possible de celui utilisé au moment de la défaillance de l'équipement pouvant être traitée;
– le fonctionnement normal du SUPPORT PATIENT;
– le fonctionnement normal des PORTIQUES;
– le fonctionnement normal des commandes côté table pour toutes les fonctions décrites ci-dessus;
– le fonctionnement normal de l'interrupteur d'arrêt de l'IRRADIATION (voir 203.6.103);
– le fonctionnement normal de l'interrupteur d'arrêt des commandes de mouvement (voir 201.9.2.3.1 de l'IEC 60601-2-54:2022);
– le fonctionnement normal des fonctions anticollision (voir 201.9.2.4).

La conformité est vérifiée par l'examen des instructions d'utilisation et du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.4.102 * Document sur la dose de RAYONNEMENT

L'APPAREIL A RAYONNEMENT X D'INTERVENTION doit créer des RAPPORTS STRUCTURES SUR LA DOSE DE RAYONNEMENT (RDSR - radiation dose structured report) et doit pouvoir réaliser une TRANSMISSION DE FIN DE PROCEDURE du RDSR.

Le RDSR doit comporter les éléments de données exigés ("doit") en 5.1.2 et 5.1.3 de l'IEC 61910-1:2014.

Il convient que le RDSR comporte les éléments de données recommandés ("il convient") en 5.1.2 et 5.1.3 de l'IEC 61910-1:2014.

NOTE Les indications conditionnelles associées aux éléments de données de l'IEC 61910-1:2014 sont considérées comme faisant partie intégrante de ces éléments de données.

Si l'APPAREIL A RAYONNEMENT X D'INTERVENTION n'est pas en mesure de déterminer les angulations des PORTIQUES, il n'est pas nécessaire que le RDSR comporte les éléments de données relatifs aux angles du positionneur.

Les éléments de données doivent comporter les données spécifiées.

La conformité est vérifiée par un examen approprié et un essai fonctionnel.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 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:

201.5.7 Préconditionnement humide

Addition:

Pour les APPAREILS A RAYONNEMENT X D'INTERVENTION qui sont utilisés exclusivement dans des environnements contrôlés, comme cela est spécifié dans les DOCUMENTS D'ACCOMPAGNEMENT, aucun traitement de préconditionnement à l'humidité n'est exigé. Les DOCUMENTS D'ACCOMPAGNEMENT doivent inclure la durée de maintien des conditions ambiantes de fonctionnement avant la mise sous tension du système.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 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:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.7 Puissance absorbée du RESEAU D'ALIMENTATION

Le paragraphe 201.7.2.7 de l'IEC 60601-2-54:2022 s'applique.

201.7.2.15 Conditions de refroidissement

Le paragraphe 201.7.2.15 de l'IEC 60601-2-54:2022 s'applique.

Paragraphes supplémentaires:

201.7.2.101 LIMITEUR DE FAISCEAU

Le paragraphe 201.7.2.101 de l'IEC 60601-2-54:2022 s'applique.

201.7.2.102 * Charge du SUPPORT PATIENT

Le SUPPORT PATIENT doit être marqué avec la masse maximale admissible en kilogrammes pour une UTILISATION NORMALE, en excluant l'utilisation pour la réanimation cardio-pulmonaire (RCP).

Cette masse maximale admissible doit correspondre à la CHARGE DE FONCTIONNEMENT EN SECURITE moins la charge de réanimation cardio-pulmonaire (voir 201.9.8.3.1 pour la valeur de cette charge RCP).

201.7.2.103 Réanimation cardio-pulmonaire (RCP)

Le SUPPORT PATIENT doit être marqué avec des instructions abrégées concernant la configuration de l'APPAREIL A RAYONNEMENT X D'INTERVENTION pour la RCP.

201.7.2.104 Marquage de conformité

Lorsque la conformité au présent document est marquée sur l'extérieur de l'APPAREIL A RAYONNEMENT X D'INTERVENTION, un tel marquage doit être réalisé en combinaison avec la REFERENCE DU MODELE OU DU TYPE comme suit:

APPAREIL A RAYONNEMENT X D'INTERVENTION [référence du modèle ou du type] IEC 60601-2-43:2022.

201.7.2.105 * Protection contre la pénétration de liquides

Les ENVELOPPES des APPAREILS A RAYONNEMENT X D'INTERVENTION, qui sont situées à proximité du PATIENT (ou autour de lui), doivent porter le marquage du degré de protection défini dans l'IEC 60529:1989, l'IEC 60529:1989/AMD1:1999 et l'IEC 60529:1989/AMD2:2013. Lorsqu'un ACCESSOIRE est exigé pour assurer la protection contre la pénétration des liquides, ceci doit être indiqué dans les instructions d'utilisation.

NOTE 1 Voir aussi 201.11.6.5.103.

NOTE 2 Le marquage des parties qui sont IPX0 est facultatif.

201.7.8.1 Couleurs des voyants lumineux

Le paragraphe 201.7.8.1 de l'IEC 60601-2-54:2022 s'applique.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.1 Généralités

Le paragraphe 201.7.9.1 de l'IEC 60601-2-54:2022 s'applique.

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Le paragraphe 201.7.9.2.1 de l'IEC 60601-2-54:2022 s'applique.

201.7.9.2.12 * Nettoyage, désinfection et stérilisation

Addition:

NOTE Pour satisfaire aux exigences du 11.6.6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, les informations fournies excluent de préférence les substances fréquemment utilisées mais potentiellement corrosives, comme l'hypochlorite de sodium, lorsque l'utilisation de ces dernières présente un RISQUE d'endommagement de pièces de l'APPAREIL A RAYONNEMENT X D'INTERVENTION concerné.

201.7.9.2.17 APPAREIL EM émettant des rayonnements

Le paragraphe 201.7.9.2.17 de l'IEC 60601-2-54:2022 s'applique.

NOTE Les exigences correspondantes du 203.5 citées dans le paragraphe 201.7.9.2.17 de l'IEC 60601-2-54:2022 figurent en 203.5 du présent document et non dans le paragraphe 203.5 de l'IEC 60601-2-54:2022.

Paragraphes supplémentaires:

201.7.9.2.101 DISPOSITIFS DE PROTECTION et ACCESSOIRES

Une liste des DISPOSITIFS DE PROTECTION et des ACCESSOIRES recommandés doit être fournie lorsque les APPAREILS A RAYONNEMENT X D'INTERVENTION sont utilisés pour des INTERVENTIONS GUIDEES PAR RADIOSCOPIE. Il peut exister différentes listes pour différents types d'INTERVENTIONS RGI. La liste peut inclure des DISPOSITIFS DE PROTECTION comme les VETEMENTS DE PROTECTION, recommandés pour l'utilisation mais ne faisant pas partie de l'APPAREIL A RAYONNEMENT X D'INTERVENTION.

201.7.9.2.102 * Dispositions pour la réanimation cardio-pulmonaire (RCP)

Les instructions d'utilisation doivent inclure des instructions pour au moins une méthode de configuration des APPAREILS A RAYONNEMENT X D'INTERVENTION pour la réalisation des RCP incluant l'utilisation de tout ACCESSOIRE nécessaire fourni avec l'APPAREIL A RAYONNEMENT X D'INTERVENTION. Ces instructions ne doivent pas demander d'utiliser des ACCESSOIRES qui ne sont pas fournis avec les APPAREILS A RAYONNEMENT X D'INTERVENTION.

Dans le cas où les instructions sont différentes pour l'UTILISATION NORMALE et pour les CONDITIONS DE PREMIER DEFAUT, elles doivent être données pour tous les cas appropriés.

201.7.9.2.103 * Instructions pour situations d'urgence

Des instructions pour situations d'urgence doivent être fournies sous forme non électronique, et elles doivent résister aux manipulations, aux dommages provoqués par l'eau et aux nettoyages.

Il convient de reproduire le contenu des instructions pour situations d'urgence en un emplacement unique dans les instructions d'utilisation complètes.

Les instructions pour situations d'urgence ne doivent contenir que des instructions liées à des fonctions et des situations d'urgence.

Les instructions pour situations d'urgence doivent comprendre au moins des instructions pour les cas suivants:

- la configuration des APPAREILS A RAYONNEMENT X D'INTERVENTION pour la RCP (uniquement pour les APPAREILS A RAYONNEMENT X D'INTERVENTION équipés d'un SUPPORT PATIENT) (voir 201.7.9.2.102);
- la PROCEDURE de redémarrage en cas de défaillance pouvant être traitée par l'OPERATEUR (voir 201.4.101);
- la PROCEDURE de redémarrage pour l'APPAREIL A RAYONNEMENT X D'INTERVENTION en cas de défaillance du RESEAU D'ALIMENTATION (voir 201.7.9.2.104);
- la PROCEDURE de redémarrage pour l'APPAREIL A RAYONNEMENT X D'INTERVENTION en cas d'utilisation d'une alimentation de secours exigeant de telles actions (voir 201.7.9.2.104);
- l'emplacement, le fonctionnement et la manœuvre de l'interrupteur d'arrêt de l'IRRADIATION (voir 203.5.2.4.101);
- l'emplacement, le fonctionnement et la manœuvre de l'interrupteur d'arrêt des commandes de mouvement (voir 201.9.2.3.1 de l'IEC 60601-2-54:2022);
- la liste des fonctions d'urgence, comme cela est défini en 201.4.101;
- si les instructions d'utilisation complètes sont seulement disponibles sous format électronique, les instructions pour accéder aux instructions d'utilisation complètes.

La conformité est déterminée par examen et par les essais fonctionnels appropriés.

201.7.9.2.104 Coupure du RESEAU D'ALIMENTATION

Les instructions d'utilisation doivent décrire la réponse fonctionnelle et la PROCEDURE de redémarrage pour l'APPAREIL A RAYONNEMENT X D'INTERVENTION en cas de coupure du RESEAU D'ALIMENTATION.

La conformité est déterminée par examen des instructions d'utilisation.

201.7.9.2.105 Description de la protection contre la pénétration des liquides

Les instructions d'utilisation doivent expliquer le marquage IPXY utilisé sur l'APPAREIL A RAYONNEMENT X D'INTERVENTION.

NOTE Voir aussi 201.7.2.105.

201.7.9.3 Description technique

Paragraphes supplémentaires:

201.7.9.3.101 ENSEMBLE RADIOGENE

Le paragraphe 201.7.9.3.101 de l'IEC 60601-2-54:2022 s'applique.

201.7.9.3.102 Installation

Pour les APPAREILS A RAYONNEMENT X D'INTERVENTION INSTALLES DE FAÇON PERMANENTE, la description technique doit contenir les recommandations suivantes concernant l'installation des APPAREILS A RAYONNEMENT X D'INTERVENTION:

– il ne doit pas y avoir de VERROUILLAGE sur les portes de la salle contenant l'APPAREIL A RAYONNEMENT X D'INTERVENTION. Il convient qu'aucune autre mesure, employée ou non pour la RADIOPROTECTION, ne soit capable de provoquer l'interruption de l'IRRADIATION ou toute autre perturbation d'une INTERVENTION RGI en cours, sauf si l'OPERATEUR est en mesure d'empêcher qu'une telle action se produise pendant l'INTERVENTION RGI;
– toutes les commandes d'arrêt d'urgence du système doivent être protégées contre une manœuvre accidentelle;
– un espace suffisant doit être disponible autour du SUPPORT PATIENT pour pouvoir réaliser une RCP sans difficulté;
– un ou plusieurs voyants d'alarme doivent être présents pour indiquer l'ETAT EN CHARGE aux personnes à tous les emplacements de la salle contenant l'APPAREIL A RAYONNEMENT X D'INTERVENTION (voir aussi l'exigence du 203.13.4);
– des voyants d'alarme appropriés doivent être présents pour indiquer l'ETAT EN CHARGE à proximité des portes qui ouvrent sur la salle d'intervention lorsque les voyants d'alarme qui sont à l'intérieur de la salle ne sont pas visibles.

NOTE 1 Cette liste est un ensemble d'informations pour l'ORGANISME RESPONSABLE, c'est la raison pour laquelle le verbe "devoir" est utilisé pour bien faire la distinction avec les exigences applicables à l'APPAREIL A RAYONNEMENT X D'INTERVENTION lui-même.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent indiquer les possibilités de dispositions pour l'installation d'une alimentation de secours dans les cas suivants:

– pour la préservation des images stockées uniquement;
– pour la RADIOSCOPIE D'URGENCE (comme cela est décrit en 201.4.101);
– pour les déplacements minimaux de l'appareil (déplacement limité de PORTIQUE, de table et de source-à-image tels qu'ils sont déterminés par le FABRICANT);
– pour toutes les fonctions pour RADIOSCOPIE et RADIOGRAPHIE;

– pour placer l'APPAREIL A RAYONNEMENT X D'INTERVENTION en position RCP en cas de coupure du RESEAU D'ALIMENTATION, si cette opération consistant à placer l'APPAREIL A RAYONNEMENT X D'INTERVENTION en configuration RCP exige du courant électrique.

NOTE 2 Cette information est nécessaire afin que l'ORGANISME RESPONSABLE soit capable de décider du niveau approprié de protection à fournir contre de telles coupures.

NOTE 3 Voir 201.12.4.101.4 pour les exigences sur les indications de mode d'alimentation de secours. Voir aussi 201.12.4.108 pour les exigences de fonctionnement de l'alimentation de secours.

La conformité est déterminée par examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.101 Déclarations supplémentaires dans les DOCUMENTS D'ACCOMPAGNEMENT

Des exigences supplémentaires pour les indications dans les DOCUMENTS D'ACCOMPAGNEMENT (qui incluent les instructions d'utilisation et la description technique) sont données dans les paragraphes énumérés dans le Tableau 201.C.102 de l'IEC 60601-2-54:2022 et dans le Tableau 201.102.

Tableau 201.102 – Autres paragraphes exigeant des indications dans les DOCUMENTS D'ACCOMPAGNEMENT

Paragraphe	Intitulé
201.4.101	Gestion de la reprise
201.7.2.105	Protection contre la pénétration de liquides
201.9.8.3.1	Résistance des SUPPORTS PATIENT ou OPERATEUR, ou des systèmes de suspension – Généralités
201.11.6.1	Débordement, renversement, etc. – Généralités
201.11.6.5.102	Sources de poussières et d'autres particules
201.12.4.101.2	Gestion de la capacité de stockage des images
201.12.4.102	DELAI D'AFFICHAGE DE L'IMAGE
201.12.4.107	Fonctions de mesure
201.15.102	Fixation des champs opératoires stériles
203.5.2.4.5	Effets déterministes
203.5.2.4.101	Interrupteur d'arrêt de l'IRRADIATION
203.6.4.2	Indication de l'ETAT EN CHARGE
203.13.4	ZONES SIGNIFICATIVES D'OCCUPATION désignées
201.5.7	Préconditionnement humide
201.11.6.5.103	ENVELOPPES
203.5.2.4.102	PROTOCOLES D'EXAMEN
203.6.4.5	Indications dosimétriques
NOTE Alors que le Tableau 201.C.102 de l'IEC 60601-2-54:2022 répertorie les paragraphes suivants "203.6.4.5 Indications dosimétriques" et "203.5.2.4.5.101 Informations dosimétriques relatives aux APPAREILS A RAYONNEMENT X spécifiés pour la RADIOSCOPIE et/ou la SERIOGRAPHIE", les exigences correspondantes relatives aux indications données dans les DOCUMENTS D'ACCOMPAGNEMENT figurent dans le présent document et non dans l'IEC 60601-2-54:2022.	

201.8 Protection contre les DANGERS d'origine électrique des APPAREILS EM

Remplacement:

L'Article 201.8 de l'IEC 60601-2-54:2022 s'applique.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 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:

201.9.2 DANGERS MECANIQUES associés aux parties en mouvement

201.9.2.2 ZONE DE PIEGEAGE

201.9.2.2.4 BARRIERES et autres mesures de MAITRISE DU RISQUE

Le paragraphe 201.9.2.2.4.4 de l'IEC 60601-2-54:2022 s'applique.

201.9.2.2.5 Activation continue

Le paragraphe 201.9.2.2.5 de l'IEC 60601-2-54:2022 s'applique.

201.9.2.2.6 Vitesse du ou des mouvements

Le paragraphe 201.9.2.2.6 de l'IEC 60601-2-54:2022 s'applique.

201.9.2.3 Autres DANGERS MECANIQUES associés aux parties en mouvement

Le paragraphe 201.9.2.3 de l'IEC 60601-2-54:2022 s'applique.

201.9.2.4 * Dispositifs d'arrêt d'urgence

Addition:

aa) De manière à empêcher les DANGERS provenant d'une interruption involontaire d'INTERVENTIONS GUIDEES PAR RADIOSCOPIE, le fonctionnement des dispositifs anticollision dans les APPAREILS A RAYONNEMENT X D'INTERVENTION ne doit pas couper automatiquement l'IRRADIATION et ne doit pas affecter les autres fonctions de l'APPAREIL A RAYONNEMENT X D'INTERVENTION, à l'exception des mouvements liés à la collision potentielle. Des moyens doivent être prévus pour que tout mouvement désactivé par la manœuvre d'un dispositif anticollision se reprenne de la collision en l'espace de 5 s après une action positive prise au poste de travail de l'OPERATEUR.

Paragraphe supplémentaire:

201.9.2.4.101 Commandes

Le paragraphe 201.9.2.4.101 de l'IEC 60601-2-54:2022 s'applique.

201.9.8 DANGERS MECANIQUES associés aux systèmes de support

201.9.8.3 Résistance des SUPPORTS PATIENT ou OPERATEUR ou des systèmes de suspension

201.9.8.3.1 Généralités

Addition:

Dans les APPAREILS A RAYONNEMENT X D'INTERVENTION, la charge pour laquelle le SUPPORT PATIENT est conçu doit être la charge normale imposée par le PATIENT (comme cela est spécifié et marqué ou, dans le cas contraire, comme cela est exigé dans le présent paragraphe), avec l'ajout d'une charge d'au moins 50 kg pour tenir compte des charges supplémentaires imposées par la réalisation d'une RCP. Cette charge supplémentaire doit être considérée par hypothèse comme étant appliquée de manière uniforme sur une longueur de 1 500 mm à partir de l'extrémité de tête du SUPPORT PATIENT ou sur toute la longueur si celle-ci est inférieure à 1 500 mm, lorsque l'APPAREIL A RAYONNEMENT X D'INTERVENTION est configuré pour la RCP conformément aux instructions d'utilisation, y compris la fixation de tout ACCESSOIRE spécifié pour utilisation dans la RCP.

Ajout à la description de l'essai de conformité:

Pour les APPAREILS A RAYONNEMENT X D'INTERVENTION, l'essai doit être réalisé dans la position la moins favorable lorsqu'ils ne sont pas configurés pour la RCP et aussi dans la position la moins favorable en configuration RCP. En configuration RCP, l'essai doit inclure l'application d'un poids supplémentaire réparti sur la portion du SUPPORT PATIENT qui va de l'extrémité de tête jusqu'à 1 500 mm ou la longueur maximale disponible si elle est inférieure. Ce poids supplémentaire doit être appliqué après 1 min ou plus après l'application du poids d'essai représentant la charge normale.

Pour un essai d'APPAREIL A RAYONNEMENT X D'INTERVENTION en configuration RCP, le système doit être exempt d'effets de flexion ou de résonance qui empêchent la réalisation de la RCP.

201.9.8.3.3 Forces dynamiques dues à la charge des personnes

Le paragraphe 201.9.8.3.3 de l'IEC 60601-2-54:2022 s'applique.

201.9.8.4 Systèmes avec DISPOSITIFS DE PROTECTION MECANIQUE

Le paragraphe 201.9.8.4 de l'IEC 60601-2-54:2022 s'applique.

Paragraphe supplémentaire:

201.9.8.101 Dispositifs d'absorption des chocs

Le paragraphe 201.9.8.101 de l'IEC 60601-2-54:2022 s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires et excessifs

L'Article 201.10 de l'IEC 60601-2-54:2022 s'applique.

NOTE Voir l'Article 203.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 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:

201.11.1 Températures excessives dans les APPAREILS EM

201.11.1.1 * Température maximale en UTILISATION NORMALE

Addition:

Le Tableau 24 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 doit être utilisé pour les parties des APPAREILS A RAYONNEMENT X D'INTERVENTION qui peuvent, en UTILISATION NORMALE, être en contact prolongé avec le PATIENT.

201.11.6 Débordement, renversement, fuites, pénétration d'eau ou de particules, nettoyage, désinfection, stérilisation et compatibilité avec des substances utilisées avec des APPAREILS EM

201.11.6.1 * Généralités

Addition:

Tous les composants qui peuvent entrer en contact avec les sécrétions, les excrétions ou autres fluides corporels des PATIENTS ou avec d'autres liquides doivent être construits de telle manière que:

– les caches ou les champs opératoires puissent être utilisés pour dévier ces liquides de l'APPAREIL A RAYONNEMENT X D'INTERVENTION, et

– les surfaces des APPAREILS A RAYONNEMENT X D'INTERVENTION sur lesquelles les liquides peuvent s'écouler soient adaptées au nettoyage et à la désinfection.

Des recommandations doivent être fournies pour l'utilisation des agents de nettoyage et des désinfectants énumérés dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les surfaces des APPAREILS A RAYONNEMENT X D'INTERVENTION susceptibles d'être exposées aux agents de nettoyage et aux désinfectants spécifiés doivent être conçues de manière à être protégées contre ou à tolérer les produits en question.

Il convient de partir du principe que toutes les surfaces externes de l'ENSEMBLE RADIOGENE, du PORTIQUE, de l'ensemble RECEPTEUR D'IMAGE RADIOLOGIQUE, du SUPPORT PATIENT et des commandes côté table peuvent être contaminées par les fluides corporels des PATIENTS en UTILISATION NORMALE.

NOTE L'attention est attirée sur les exigences supplémentaires du 201.7.9.2.12 concernant le nettoyage et la désinfection.

201.11.6.5 Pénétration d'eau ou de corps solides dans les APPAREILS EM et les SYSTEMES EM

Paragraphes supplémentaires:

201.11.6.5.101 Interrupteurs au pied

Les interrupteurs au pied des APPAREILS A RAYONNEMENT X D'INTERVENTION, qui sont situés à côté de la table, doivent pouvoir être actionnés même si le sol est recouvert d'une solution saline de 25 mm.

NOTE L'attention est attirée sur la limitation des tensions de fonctionnement imposées par 8.10.4 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020.

La conformité est déterminée en actionnant et en relâchant l'interrupteur au pied (sans connexion à une source de courant électrique) 900 fois dans 25 mm d'une solution saline à au moins 0,9 % en poids/volume de chlorure de sodium dans l'eau pendant 1 h, puis en vérifiant son fonctionnement et sa sécurité électrique conformément à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020. En outre, il ne doit y avoir aucun signe prouvant qu'un liquide a touché des pièces mécaniques qui peuvent se détériorer si elles restent humides indéfiniment.

Il convient que les connexions côté table du câble de l'interrupteur au pied soient à au moins 25 mm au-dessus du niveau du sol.

La conformité est déterminée par examen.

201.11.6.5.102 * Sources de poussières et d'autres particules

Les sources de poussières ou d'autres particules dues aux APPAREILS A RAYONNEMENT X D'INTERVENTION ne doivent pas être dirigées vers le PATIENT.

Les parties des APPAREILS A RAYONNEMENT X D'INTERVENTION montées au-dessus du PATIENT doivent être conçues pour réduire le plus possible l'accumulation de poussières, qui peut entraîner la chute de ces poussières sur le PATIENT.

Les instructions d'utilisation doivent spécifier la PROCEDURE à utiliser pour éliminer les poussières des parties des APPAREILS A RAYONNEMENT X D'INTERVENTION qui sont montées au-dessus du PATIENT.

La conformité est vérifiée par examen.

201.11.6.5.103 * ENVELOPPES

Le degré de protection sans ACCESSOIRES est le suivant:

– les interrupteurs au pied doivent avoir un degré minimal de protection de IPX7;
– il convient que les commandes côté table aient un degré minimal de protection de IPX3;
– il convient que le SUPPORT PATIENT ait un degré minimal de protection de IPX2 ou qu'il soit protégé contre la pulvérisation d'eau jusqu'à 15° par rapport à la verticale. Concernant l'essai du SUPPORT PATIENT, l'essai peut être considéré comme suffisant en orientant le SUPPORT PATIENT de 15° par rapport à l'horizontale;
– il convient que la GAINE EQUIPEE et les éléments de PORTIQUE associés aient un degré minimal de protection de IPX2, sauf pour les APPAREILS A RAYONNEMENT X D'INTERVENTION équipés d'un ENSEMBLE RADIOGENE FIXE placé au-dessus de la table. Les DOCUMENTS D'ACCOMPAGNEMENT doivent décrire les éléments de PORTIQUE associés, inclus dans la classification IPX2. Les essais peuvent être considérés comme suffisants si le bras C est incliné dans la position la plus défavorable avec un angle maximal de 15° dans toute direction par rapport à la verticale.

Il ne doit pas y avoir de pénétration d'eau dans les conditions d'essai spécifiées de l'IEC 60529:1989, l'IEC 60529:1989/AMD1:1999 et l'IEC 60529:1989/AMD2:2013.

201.11.8 Coupure de l'alimentation/du RESEAU D'ALIMENTATION vers l'APPAREIL EM

Le paragraphe 201.11.8 de l'IEC 60601-2-54:2022 s'applique.

Paragraphes supplémentaires:

201.11.101 Protection contre les températures excessives des LIMITEURS DE FAISCEAU

Le paragraphe 201.11.101 de l'IEC 60601-2-54:2022 s'applique.

201.12 Précision des commandes et des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 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 Conformément au paragraphe 12.4.5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, les aspects de dose concernant cette question sont traités en 203.6.4.3.

201.12.4 * Protection contre les caractéristiques de sortie présentant des risques

201.12.4.5.2 APPAREILS A RAYONNEMENT X de diagnostic

Remplacement:

Les APPAREILS A RAYONNEMENT X D'INTERVENTION doivent satisfaire à l'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021 telles qu'elles sont modifiées à l'Article 203.

La conformité est vérifiée comme cela est spécifié dans l'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021, telles qu'elles sont modifiées à l'Article 203.

Paragraphes supplémentaires:

201.12.4.101 Informations destinées à l'OPERATEUR

201.12.4.101.1 * Données PATIENT

Des informations doivent être disponibles sur l'AFFICHAGE concernant l'identité du PATIENT et l'intervention à laquelle correspondent les images affichées.

Cette exigence ne s'applique pas dans les cas des interventions d'urgence.

La conformité est déterminée par examen et par des essais fonctionnels.

201.12.4.101.2 Gestion de la capacité de stockage des images

Les instructions d'utilisation doivent indiquer qu'il y a besoin de vérifier régulièrement la capacité de stockage disponible et de sécuriser/archiver les enregistrements importants.

Après la saisie des données correspondant au PATIENT à l'arrivée d'un nouveau cas, l'APPAREIL A RAYONNEMENT X D'INTERVENTION doit indiquer la capacité de stockage d'images disponible.

Après avoir entré les paramètres de fonctionnement, avant de démarrer une session, l'APPAREIL A RAYONNEMENT X D'INTERVENTION doit indiquer s'il y a un espace de stockage suffisant pour conserver toute la session dans les conditions programmées ou il doit indiquer le nombre de vues possible ou le TEMPS D'IRRADIATION disponible, à la cadence de prise de vue et avec la résolution choisies.

Lorsque l'espace de stockage n'est pas suffisant, ceci doit être indiqué au poste de travail de l'OPERATEUR.

Lorsque l'APPAREIL A RAYONNEMENT X D'INTERVENTION arrive en fin de capacité de stockage, la RADIOGRAPHIE ne doit pas être possible ou doit être stoppée, sauf si les données ont été stockées à un autre endroit et que l'APPAREIL A RAYONNEMENT X D'INTERVENTION est en mesure de déterminer que les données ont été stockées ailleurs avec succès.

La conformité est déterminée par examen et par des essais fonctionnels.

201.12.4.101.3 * AFFICHAGES d'images

Au cours d'une RADIOSCOPIE, l'image en direct doit toujours occuper le même emplacement d'AFFICHAGE. Le statut de toutes les images affichées, en particulier le fait de savoir si ce sont des images en direct ou stockées et, dans le cas d'images stockées, le fait de savoir si ce sont des RADIOGRAMMES LIH ou des images de référence stockées auparavant, doit être indiqué à leurs emplacements d'AFFICHAGE.

La conformité est déterminée par examen et par des essais fonctionnels.

201.12.4.101.4 Indications de l'alimentation de secours

Pour les APPAREILS A RAYONNEMENT X D'INTERVENTION INSTALLES DE FAÇON PERMANENTE équipés d'une alimentation de secours, un voyant doit s'activer en cas de coupure du RESEAU D'ALIMENTATION, indiquant que l'APPAREIL A RAYONNEMENT X D'INTERVENTION est en train de fonctionner sur l'alimentation de secours.

Ce voyant doit être visible depuis les postes de travail de l'OPERATEUR.

La conformité est déterminée par examen et par des essais fonctionnels.

NOTE Voir aussi 201.7.9.2.104 pour les exigences concernant les DOCUMENTS D'ACCOMPAGNEMENT. Voir aussi 201.12.4.108 pour les exigences de fonctionnement de l'alimentation de secours.

201.12.4.102 * DELAI D'AFFICHAGE DE L'IMAGE

Le DELAI D'AFFICHAGE DE L'IMAGE au cours d'une RADIOSCOPIE doit être aussi court que raisonnablement possible en pratique. La limite appropriée doit être déterminée dans le DOSSIER DE GESTION DES RISQUES.

Les instructions d'utilisation doivent indiquer que, lorsque le mode RADIOGRAPHIE est volontairement utilisé par l'OPERATEUR pour de l'imagerie en temps réel, ce qui est contraire à la pratique normale, le DELAI D'AFFICHAGE DE L'IMAGE peut être plus long qu'en RADIOSCOPIE.

La conformité est vérifiée par l'examen de l'inspection des instructions d'utilisation, DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels appropriés.

201.12.4.103 * Documentation de l'orientation d'image

S'il est possible que l'OPERATEUR change l'orientation de l'image, l'APPAREIL A RAYONNEMENT X D'INTERVENTION doit être en mesure de documenter l'orientation d'image à la fois sur les images affichées et sur les images stockées.

L'APPAREIL A RAYONNEMENT X D'INTERVENTION doit être en mesure de documenter l'orientation du PATIENT.

La conformité est vérifiée par des essais fonctionnels.

201.12.4.104 * Disponibilité de la RADIOSCOPIE au cours des activités de réseau

Les activités de réseau ne doivent pas affecter la disponibilité de la RADIOSCOPIE.

La conformité est vérifiée par des essais fonctionnels.

201.12.4.105 * Emplacement de masque approprié pour des images soustraites

Lorsqu'il existe des moyens de soustraction automatiques pour les MODES DE FONCTIONNEMENT dans lesquels plusieurs images masques sont acquises à différentes positions de l'appareil, pour toute image à soustraire, l'image masque correspondante doit être choisie de manière à réduire le plus possible la différence entre la position de l'appareil à laquelle cette image masque a été acquise et la position de l'appareil pour l'image à déduire avec ce masque.

La conformité est vérifiée par l'examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.12.4.106 * Commandes côté table

Pour les commandes côté table, au minimum, les commandes d'interface utilisateur suivantes (qui exigent d'être touchées pour être enclenchées) doivent être identifiables individuellement et sans risque d'erreur uniquement au toucher mais aussi uniquement visuellement:

– commandes de mouvement des PORTIQUES et des SUPPORTS PATIENT (à l'exclusion des commandes de mouvement pour présélectionner les positions de l'APPAREIL A RAYONNEMENT X D'INTERVENTION);
– COMMANDES D'IRRADIATION (autres que les interrupteurs au pied);
– commande de lame de limitation du faisceau (n'inclut pas de commande de FILTRE EN COIN).

La commande de lame de limitation du faisceau peut, en outre, être actionnée par une commande côté table dupliquée, telle qu'une interface utilisateur à écran tactile.

Toutes les commandes côté table doivent être identifiables dans les conditions d'éclairage pour l'UTILISATION PREVUE, et le cas échéant, lorsqu'elles sont recouvertes de draps de protection transparents.

La conformité est vérifiée par examen et par des essais fonctionnels.

NOTE Une commande côté table est une commande qui peut être actionnée à côté du PATIENT durant une INTERVENTION RGI, qu'elle soit ou non fixée physiquement au SUPPORT PATIENT. Pour les besoins du présent paragraphe, un interrupteur au pied n'est pas une commande côté table.

201.12.4.107 ** Fonctions de mesure d'images*

Les instructions d'utilisation doivent décrire les fonctions de mesure d'image, leurs unités et leurs imprécisions liées par rapport à l'UTILISATION PREVUE.

Les erreurs dans les fonctions de mesure d'images introduites par l'APPAREIL A RAYONNEMENT X D'INTERVENTION doivent être aussi faibles que raisonnablement possible en pratique en fonction du MODE DE FONCTIONNEMENT et de l'UTILISATION PREVUE.

Pour les mesures affichées par l'APPAREIL A RAYONNEMENT X D'INTERVENTION ayant une fonction de mesure, chaque valeur doit être affichée avec son unité.

La conformité est vérifiée par l'examen du DOSSIER DE GESTION DES RISQUES et par un examen et des essais fonctionnels appropriés.

201.12.4.108 Disposition pour l'alimentation de secours

Les exigences du présent paragraphe s'appliquent seulement aux APPAREILS A RAYONNEMENT X D'INTERVENTION qui sont INSTALLES DE FAÇON PERMANENTE et qui sont équipés d'une alimentation de secours. Pour de tels APPAREILS A RAYONNEMENT X D'INTERVENTION, le retour vers le RESEAU D'ALIMENTATION en cas de coupure de courant doit se faire comme suit:

a) en cours de RADIOSCOPIE,
   - en cas de retour automatique vers le RESEAU D'ALIMENTATION, ce retour doit être réalisé sans interrompre la RADIOSCOPIE;
   - en cas de retour manuel vers le RESEAU D'ALIMENTATION, il doit y avoir une indication de l'état du RESEAU D'ALIMENTATION, pour permettre de lancer la permutation retour vers le RESEAU D'ALIMENTATION de la part de l'OPERATEUR. Ce voyant doit être visible depuis les postes de travail de l'OPERATEUR.

b) si aucune RADIOSCOPIE n'est en cours,
   - en cas de retour automatique vers le RESEAU D'ALIMENTATION, la RADIOSCOPIE doit rester disponible en permanence;
   - dans le cas d'un retour manuel vers le RESEAU D'ALIMENTATION, il doit y avoir une indication de l'état du RESEAU D'ALIMENTATION. Ce voyant doit être visible depuis les postes de travail de l'OPERATEUR. Un retour immédiat réalisé par l'OPERATEUR doit être possible lorsque le RESEAU D'ALIMENTATION est indiqué comme disponible.

La conformité est vérifiée par des essais fonctionnels.

NOTE Voir 201.12.4.101.4 pour les exigences sur les indications de mode d'alimentation de secours. Voir aussi 201.7.9.3.102 pour les exigences concernant les DOCUMENTS D'ACCOMPAGNEMENT.

201.13 SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM

L'Article 13 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

L'Article 14 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.15 Construction de l'APPAREIL EM

L'Article 15 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:

Paragraphes supplémentaires:

201.15.101 * Configuration pour réanimation cardio-pulmonaire (RCP)

En CONDITION NORMALE, l'APPAREIL A RAYONNEMENT X D'INTERVENTION doit être construit de telle manière qu'il puisse être placé dans une configuration désignée pour la RCP en l'espace de 15 s. Ce délai est augmenté de 1 s pour chaque différence d'inclinaison de 15° de la position de travail en cours du SUPPORT PATIENT par rapport à la position RCP.

Dans les CONDITIONS DE PREMIER DEFAUT, hors cas de coupure du RESEAU D'ALIMENTATION, l'APPAREIL A RAYONNEMENT X D'INTERVENTION doit être construit de telle manière qu'il puisse être conforme à la durée de configuration RCP en UTILISATION NORMALE ou qu'il soit capable de relâcher ou de positionner correctement le PATIENT dans un délai aussi bref que raisonnablement possible en pratique.

La conformité est déterminée par l'examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels appropriés.

En cas de coupure du RESEAU D'ALIMENTATION, l'exigence de la CONDITION NORMALE s'applique.

La conformité est vérifiée en déconnectant l'APPAREIL A RAYONNEMENT X D'INTERVENTION du RESEAU D'ALIMENTATION et en vérifiant que l'APPAREIL peut être placé dans les conditions RCP.

201.15.102 Fixation des champs opératoires stériles

Des dispositifs doivent être fournis et décrits dans les instructions d'utilisation, pour permettre la fixation des champs opératoires stériles aux APPAREILS A RAYONNEMENT X D'INTERVENTION ou à leurs ACCESSOIRES pour permettre la réalisation des INTERVENTIONS RGI avec un niveau approprié de stérilité.

La conformité est déterminée par l'examen de l'APPAREIL A RAYONNEMENT X D'INTERVENTION et par l'examen des instructions d'utilisation.

201.16 SYSTEMES EM

L'Article 16 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec l'exception suivante:

201.16.8 Interruption de l'alimentation électrique de parties d'un SYSTEME EM

Remplacement:

Le paragraphe 201.16.8 de l'IEC 60601-2-54:2022 s'applique.

201.17 Compatibilité électromagnétique des APPAREILS EM et des SYSTEMES EM

L'Article 17 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec l'exception suivante:

Amendement de la méthode de conformité:

La conformité est vérifiée comme cela est spécifié dans l'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, à l'exception des modifications apportées par l'Article 202.

202 Perturbations électromagnétiques – Exigences et essais

L'IEC 60601-1-2:2014 et IEC 60601-1-2:2014/AMD1:2020 s'appliquent, avec l'exception suivante:

Article supplémentaire:

202.101 Essais d'immunité des PERFORMANCES ESSENTIELLES

Le paragraphe 202,101 de l'IEC 60601-2-54:2022 s'applique.