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Edition 2.0 2022-09
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 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 60601-2-54 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 second edition cancels and replaces the first edition published in 2009, Amendment 1:2015 and Amendment 2:2018. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the IEC 60601-1:2005/AMD2:2020. 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;

b) terms and definitions taken exclusively from IEC TR 60788:2004 and which are specifically applicable in this document have been moved to 201.3;

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 subclause 201.11.101 “Protection against excessive temperatures of X-ray tube assemblies” has been removed from this document as its requirements are sufficiently and clearly covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017;

e) to adopt changes which are introduced with respect to indicator lights in 7.8.1 of the IEC 60601-1:2005/AMD2:2020 clarification of requirements is provided to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT;

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

The text of this document is based on the following documents:

Draft	Report on voting
62B/1285/FDIS	62B/1293/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

This document has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. The purpose of this second edition is to introduce changes to reference the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. Moreover, in Annex AA a clarification of the term for ESSENTIAL PERFORMANCE is provided. ~~While the previously existing standards for such equipment were dedicated to components and subsystems,~~ This document addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-54:2009 is to introduce changes to reference the first amendment (2012) to IEC 60601-1:2005. As neither IEC 60601-2-54:2009 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed. In addition, a number of technical errors have been corrected.

INTRODUCTION TO AMENDMENT 2

The purpose of this second amendment to IEC 60601-2-54:2009 is to introduce changes which take the current state of the art into account. Therefore, X-RAY EQUIPMENT specified for DIRECT RADIOSCOPY is no longer in the scope of this document. The normative references were also updated in this amendment, and editorial clarifications and new terms and definitions were added. Provisions for QUALITY CONTROL PROCEDURES to be recommended by the MANUFACTURER are emphasized. Specific attention is paid to EXAMINATION PROTOCOLS in a new subclause which differentiate between adult and paediatric applications, in particular for X-RAY EQUIPMENT without an AUTOMATIC CONTROL SYSTEM. In addition, fixed periods for termination of LOADING after release of the RADIATION control by the OPERATOR are stipulated for RADIOSCOPY.

A new subclause on electronic documentation of EXAMINATION PROTOCOLS is introduced. It recommends providing access to electronic documentation containing relevant parameters of the PRE-PROGRAMMED EXAMINATION PROTOCOL. In another new subclause, the creation of basic documentation of the RADIATION DOSE STRUCTURED REPORT (RDSR) according to IEC 61910-1 is recommended. Furthermore, the subclause describing the LAST IMAGE HOLD RADIOGRAM has been revised and requires that the last image in RADIOSCOPY be displayed rather than provide just a means to display it.

This amendment recommends providing a graphical DISPLAY of the position of the BEAM LIMITING DEVICE blades on the IMAGE DISPLAY DEVICE in the subclause "Indication on the X-RAY EQUIPMENT".

Finally, the requirement for providing means to limit the FOCAL SPOT TO SKIN DISTANCES for radioscopic X-RAY EQUIPMENT differentiates between MOBILE and FIXED EQUIPMENT and extends, in the latter case, the minimum distance in possible clinical applications.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this document.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental or radiotherapy applications are excluded from the scope of this document. The scope of this document also excludes radiotherapy simulators.

If a clause or subclause is specifically intended to be applicable to ME 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 ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

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 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply, as modified in Clauses 202 and 203 respectively. If the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in a HOME HEALTHCARE ENVIRONMENT, then IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply and if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in an EMERGENCY MEDICAL SERVICES ENVIRONMENT, then IEC 60601-1-12:2014 and IEC 60601-1-12:2015/AMD1:2020 apply. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10~~, IEC 60601-1-11 and IEC 60601-1-12~~ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 1 OPERATORS of X-RAY EQUIPMENT are used to audible signals as ~~required~~ specified in this document rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, 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 document, 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, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC

60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – ~~Characteristics of focal spots~~ Focal spot dimensions and related characteristics*

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

IEC 60806, *Determination of the maximum symmetrical radiation field ~~from a rotating anode~~ of X-ray tube assemblies and X-ray source assemblies for medical diagnosis*

~~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*~~

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

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

Amendment:

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

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, ~~applicable collateral standards~~ and IEC 60601-1:2005/AMD2:2020, IEC TR 60788:2004 and the following apply~~, except as follows~~.

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

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

NOTE An Index of defined terms is found in the last part of this document.

Addition:

201.3.201
APPARENT RESISTANCE OF SUPPLY MAINS
for diagnostic X-RAY GENERATOR, resistance of the SUPPLY MAINS determined under specific load conditions

201.3.202
AUTOMATIC INTENSITY CONTROL
in an X-RAY GENERATOR, mode of operation in which one or more LOADING FACTORS are controlled automatically in order to obtain at a pre-selected location a desired rate of a RADIATION QUANTITY

201.3.203
DIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected at an IMAGE RECEPTION AREA

Example: Film-screen or film RADIOGRAPHY.

201.3.204
DIRECT RADIOSCOPY
RADIOSCOPY in which the visible images are presented at the IMAGE RECEPTION AREA, or close to it, in the RADIATION BEAM

201.3.205
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$)

Note 1 to entry: This definition is equivalent to AIR KERMA area product.

201.3.206
DOSIMETER
EQUIPMENT which uses ionization chambers or semiconductor detectors for the measurement of AIR KERMA or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for diagnostic medical RADIOLOGICAL examinations

201.3.207
ENTRANCE FIELD SIZE
dimensions of the field in the entrance plane of an X-RAY IMAGE RECEPTOR that can be used for the transmission of an X-RAY PATTERN under specific conditions

201.3.208
EXAMINATION PROTOCOL
full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and DISPLAY

201.3.209
EXAMINATION PROTOCOL SELECTION CONTROL
control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.210
HIGH-VOLTAGE GENERATOR
in an X-RAY GENERATOR, combination of all components for control and production of the electrical energy to be supplied to an X-RAY TUBE, usually consisting of a high-voltage transformer assembly and a control assembly

201.3.211
IMAGE RECEPTION PLANE
plane containing the greatest dimensions of the IMAGE RECEPTION AREA

201.3.212
INDIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected after TRANSFER of the information obtained at an IMAGE RECEPTION AREA

Examples: CR systems, digital detector systems, image intensifier systems.

201.3.213
INDIRECT RADIOSCOPY
RADIOSCOPY in which the images are presented at a location outside the RADIATION BEAM after TRANSFER of the information

201.3.214
INTERLOCK
means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

201.3.215
ISOCENTRE
in RADIOLOGICAL equipment with several modes of movement of the REFERENCE AXIS around a common centre, centre of the smallest sphere through which the X-RAY BEAM AXIS passes

201.3.216
LAST IMAGE HOLD RADIOGRAM
LIH RADIOGRAM
single image obtained by sampling or temporal processing of one or more images from the end of a radioscopic IRRADIATION

Note 1 to entry: This note applies to the French language only.

201.3.217
NOMINAL ELECTRIC POWER
for a HIGH-VOLTAGE GENERATOR, highest constant electric power which can be delivered for a single X-RAY TUBE load in a specific LOADING TIME

201.3.218
NOMINAL SHORTEST IRRADIATION TIME
shortest LOADING TIME for which a required constancy of the controlled radiation quantity is maintained

Note 1 to entry: The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

201.3.219
PRE-PROGRAMMED EXAMINATION PROTOCOL
single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.220
QUALITY CONTROL
operational techniques and activities that are used to fulfil requirements for quality

201.3.221
RADIATION OUTPUT
AIR KERMA per CURRENT TIME PRODUCT (mGy/mAs) at a given distance from the FOCAL SPOT in the primary X-RAY BEAM

201.3.222
RADIOSCOPY REPLAY IMAGE SEQUENCE
series of the most recent images of the most recent RADIOSCOPY IRRADIATION-EVENT

201.3.223
REGION OF INTEREST
localized part of an image, which is of particular interest at a given time

201.3.224
SERIAL RADIOGRAPHY
RADIOGRAPHY in which the information is obtained and recorded in a regular or irregular series of LOADINGS with equal or unequal LOADING FACTORS

201.3.225
SIX-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a three-phase supply that delivers a rectified output voltage with six peaks during each cycle of the supply

201.3.226
TIMING DEVICE
device integrating and/or presenting time elapsed during an equipment function and optionally changing the state of operation at the end of a predetermined time interval

201.3.227
TWELVE-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a three-phase supply that delivers a rectified output voltage with twelve peaks during each cycle of the supply

201.3.228
X-RAY BEAM AXIS
for a symmetrical RADIATION BEAM, line through the centre of the RADIATION SOURCE and half way between the effective edges of the BEAM LIMITING DEVICE

Note 1 to entry: Usually, the X-RAY BEAM AXIS coincides within required tolerances with the REFERENCE AXIS of the RADIATION SOURCE.

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

Additional subclause:

201.4.3.101 * Additional potential ESSENTIAL PERFORMANCE requirements

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

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.104
Reproducibility of the RADIATION output	203.6.3.2
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS ~~is to~~ shall be considered sufficiently low for the operation of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this document are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems ~~may~~ can be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

X-RAY EQUIPMENT is considered to comply with the requirements of this document only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the accompanying documents.

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.

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

Addition:

For ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

b) the number of phases; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

c) the frequency, in hertz; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;

e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

~~NOTE These requirements are adapted from 6.1j) of IEC 60601-2-7:1998.~~

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENT, including as appropriate:

– the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;

– the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;

– the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

~~NOTE These requirements are adapted from 6.1t) of IEC 60601-2-7:1998.~~

Additional subclause:

201.7.2.101 Beam limiting device

BEAM LIMITING DEVICES shall be provided with the following markings:

– those required in 7.2.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;

– serial designation or individual identification;

– QUALITY EQUIVALENT FILTRATION of all materials together that are permanently fixed and intercept the X-RAY BEAM.

~~NOTE These requirements are adapted from 6.1 of IEC 60601-2-28:1993.~~

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-RAY related states shall be excluded from 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. Subclauses 203.6.4.2 and

203.6.4.101 shall apply instead. Yellow and green colors of lights which are listed in Table 2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 should only be used if they are clearly distinguishable from the indication of the X-ray related states as required in these subclauses.

If applicable, conflicts which can arise from using same or similar colors for indication of X-RAY related states and other functions of the ME EQUIPMENT shall be evaluated by using the USABILITY ENGINEERING process.

Colors of indicator lights and alarm indicator lights for ME EQUIPMENT which are designated as HIGH PRIORITY, MEDIUM PRIORITY, and LOW PRIORITY ALARM CONDITION listed in Table 2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 do not apply to X-RAY EQUIPMENT.

NOTE Even though 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 mentions the collateral standard IEC 60601-1-8 which application is excluded in 201.1.3 of this document, the selected specified references therein are considered informative and help to understand the requirements of 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall contain instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria for each test and frequency for each test.

NOTE The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

Additionally for X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

– an identification of adjustable or selectable image processing applied to ORIGINAL DATA including the version number or how to determine it;
– a description of the file transfer format of the images acquired with this unit and of any data associated with these images.

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Additional subclauses:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

a) The corresponding NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE CURRENT obtainable from the ME EQUIPMENT when operated at that X-RAY TUBE VOLTAGE.

b) The corresponding highest X-RAY TUBE CURRENT for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE VOLTAGE obtainable from the ME EQUIPMENT when operating at that X-RAY TUBE CURRENT.

c) The corresponding combination of X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY, and X-RAY TUBE CURRENT which results in the highest electric power in the high-voltage circuit (see 203.4.101).

d) The NOMINAL ELECTRIC POWER given as the highest constant electric power in kilowatts which the ME EQUIPMENT can produce/generate, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with nearest parameters (see 203.4.101).

   The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

e) For ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

   If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, it is possible that the lowest CURRENT TIME PRODUCT ~~may~~ be given as a table or curve showing the dependence.

f) The NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT.

   If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

   The maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATIONS, controlled with the AUTOMATIC EXPOSURE CONTROL SYSTEMS, shall be stated in the instructions for use.

~~NOTE These requirements are adapted from 6.8.2 a) of IEC 60601-2-7:1998.~~

201.7.9.2.1.102 X-ray source assembly

The instructions for use shall state the maximum symmetrical RADIATION FIELD of the integrated X-RAY SOURCE ASSEMBLY determined according to IEC 60806.

~~NOTE This requirement is adapted from 6.8.2 (dd) of IEC 60601-2-28:1993.~~

201.7.9.2.1.103 Integrated X-RAY IMAGE RECEPTOR

For X-RAY EQUIPMENT provided with an integrated X-RAY IMAGE RECEPTOR, the instructions for use shall contain a description of the particular handling and maintenance of the X-RAY IMAGE RECEPTOR.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Replacement:

For X-RAY EQUIPMENT the instructions for use shall provide information as required in 203.5.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 X-ray source assembly

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following, in addition to the data required to be marked according to 7.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020:

~~a) specification of the REFERENCE AXIS to which the TARGET ANGLE(s) and the FOCAL SPOT characteristics of the X-RAY SOURCE ASSEMBLY refer;~~

~~b) TARGET ANGLE(s) with respect to the specified REFERENCE AXIS;~~

~~c) position of the FOCAL SPOT and its tolerances on the REFERENCE AXIS;~~

~~d) NOMINAL FOCAL SPOT VALUE(s) determined according to IEC 60336 for the specified REFERENCE AXIS.~~

a) REFERENCE AXIS;

b) TARGET ANGLE(s);

c) position and tolerances of the FOCAL SPOT(s);

d) FOCAL SPOT size(s):
If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then state the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.

NOTE These requirements are adapted from ~~6.8.3 dd)~~ 201.7.9.3.101 of IEC 60601-2-28:~~1998~~2017.

~~*Additional subclause:*~~

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.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.4 Limitation of voltage, current or energy

201.8.4.3 ME EQUIPMENT intended to be connected to a power source by a plug

Additional subclauses:

201.8.4.3.101 High-voltage cable connections

Detachable high-voltage cable connections shall either be designed so that the use of TOOLS is required to disconnect them or they shall be provided with INTERLOCKS so that at all times when protective covers or high-voltage connections are removed:

– the ME EQUIPMENT is disconnected from its power supply, and

– capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and

– the discharged state is maintained.

Compliance is checked by inspection and by measurement.

~~NOTE These requirements are adapted from Clause 15, item aa) of IEC 60601-2-7:1998.~~

~~*Additional subclause:*~~

201.8.4.101 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

~~NOTE This requirement is adapted from 3.1 of IEC 60601-2-7:1998.~~

201.8.5 Separation of parts

201.8.5.1 Means of protection (mop)

Additional subclause:

201.8.5.1.101 Additional limitation of voltage, current or energy

Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This ~~may~~ can be achieved for example

– by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;

– by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

~~NOTE These requirements are adapted from 15bb) of IEC 60601-2-7:1998.~~

201.8.5.4 WORKING VOLTAGE

Additional subclause:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE ~~is to~~ shall be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

~~NOTE This requirement is adapted from 20.4 l) of IEC 60601-2-7:1998.~~

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

201.8.6.4 Impedance and current-carrying capability

Addition:

The flexible conductive screen ~~is~~ shall not ~~to~~ be recognized as satisfying a requirement for a PROTECTIVE EARTH CONNECTION between the devices connected by the cable.

Additional subclause:

201.8.6.101 X-RAY TUBE ASSEMBLY

a) Accessible high-voltage cables connecting X-RAY TUBE ASSEMBLIES to their associated HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding 1 $\Omega\ m^{-1}$, and covered with a non-conductive material capable of

protecting the screen against mechanical damage. The screen shall be connected to the conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item aa) of IEC 60601-2-28:1993.

b) In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the ACCESSIBLE METAL PARTS of its receptacle on the X-RAY TUBE ASSEMBLY.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item cc) of IEC 60601-2-28:1993.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 * Allowable values

Item c) is amended as follows:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the TOUCH CURRENT under SINGLE FAULT CONDITION shall not exceed 2 mA.

Item d) is replaced with:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the allowable values of the EARTH LEAKAGE CURRENT are 2,5 mA in NORMAL CONDITION and 5 mA in SINGLE FAULT CONDITIONS. For PERMANENTLY INSTALLED ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 10 mA in NORMAL CONDITION and in SINGLE FAULT CONDITIONS.

Item e) is amended as follows:

For PERMANENTLY INSTALLED ME EQUIPMENT including HIGH-VOLTAGE GENERATORS, the allowable value of EARTH LEAKAGE CURRENT is 20 mA in NORMAL CONDITION and SINGLE FAULT CONDITION.

NOTE These requirements are adapted from 19.3 of IEC 60601-2-7:1998.

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of the ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min in RADIOGRAPHY and 15 min in RADIOSCOPY.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE ASSEMBLY connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE ASSEMBLY connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X- RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

For ME EQUIPMENT in which the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY does not exceed 80 % of that for RADIOGRAPHY, the test voltage for the high-voltage circuit shall be referred to the value for RADIOGRAPHY, and the test shall be carried out in that mode only.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit ~~are to~~ shall be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Additions:

aa) *HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY ~~are to~~ shall be tested with an appropriately loaded X-RAY TUBE;*

bb) *If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test ~~is to~~ shall be reduced to such an extent that the allowable X-RAY TUBE LOAD at the increased X-RAY TUBE VOLTAGE will not be exceeded.*

cc) *If the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures should be taken to ensure that the values are kept as close as possible to 100 %, and ~~is~~ are not ~~to be~~ outside the range of 100 % and 105 % of the value required.*

~~NOTE These requirements are adapted from 20.3 and 20.4 of IEC 60601-2-7:1998.~~

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**~~

201.9.2.2.4.4 Other RISK CONTROL measures

Additional subclause:

201.9.2.2.4.4.101 Collision protection

If anti-collision features are provided with the X-RAY EQUIPMENT, the instructions for use shall describe the anti-collision features. In addition, the measures provided to prevent unnecessary interruption and to allow continuation of ~~a procedure~~ an examination shall be described.

Means shall be provided or warnings given in the ACCOMPANYING DOCUMENTS, to prevent injuries that could result from collision of power-driven ME EQUIPMENT parts with other moving or stationary items likely to be in proximity.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.5 Continuous activation

Amendment:

The movement of ME EQUIPMENT or ME EQUIPMENT parts which could cause physical injury to the PATIENT or OPERATOR in NORMAL USE shall require the continuous control of the OPERATOR.

The motorized movement of ME EQUIPMENT or ME EQUIPMENT parts which could crush or otherwise cause physical injury to the PATIENT or OPERATOR, and for which the response of the

OPERATOR to actuate an emergency stop cannot be relied on to prevent an injury, shall be operated only by continuous actuation of two switches by the OPERATOR. Each switch shall be capable of interrupting independently the movement.

The two switches may be designed into a single control, and one switch may be in a circuit which is common to all motions.

These switches shall be in a location such that possible injury to the PATIENT can be observed by the OPERATOR. At least one set of switches shall be so located as to require the presence of the OPERATOR close to the PATIENT, to observe the moving parts of the ME EQUIPMENT.

The motorized movement of ME EQUIPMENT parts which could indirectly cause physical injury, such as a table angulation which could cause a PATIENT to fall, is not required to be controlled by two switches.

For ME EQUIPMENT designed to be set up or pre-positioned automatically, a control requiring continuous actuation which stops the mechanical motions on release shall be located at the position where movements can be visually observed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, continuous actuation is not required.

The MANUFACTURER shall identify by RISK MANAGEMENT the motorized movements which could cause the HAZARD.

Compliance is checked by inspection of the risk management file and by functional test.

201.9.2.2.6 Speed of movement(s)

Addition:

The overtravel of such movement, occurring after actuation of a control to stop the motion, shall not exceed 10 mm in NORMAL USE. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, overtravel may exceed 10 mm.

Except for MOBILE ME EQUIPMENT, when movement of power-driven ME EQUIPMENT towards the PATIENT is within 300 mm of the PATIENT table top, or 100 mm of the table side, the speed should be limited to half the maximum speed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, the speed limitation is not required.

Compliance is checked by inspection of the risk management file and by functional test and measurement.

~~NOTE These requirements are adapted from 22.4.4 of IEC 60601-2-32:1994.~~

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

Means shall be provided to minimize the possibility of unintended motion, which could result in physical injury to the PATIENT or OPERATOR, in NORMAL USE and SINGLE FAULT CONDITION. The following shall apply:

a) Where failure, such as welded relay contacts, would result in uncontrolled motion, redundant control or other such protection shall be provided. A failure of one of the redundant controls shall be indicated to the OPERATOR, either directly or by a test according to the instructions for use.

b) Switching elements shall not be connected on the earthed side of a motion controlling circuit.

Compliance is checked by inspection of the circuit diagram, visual inspection and functional test.

~~NOTE These requirements are adapted from 22.4.2 of IEC 60601-2-32:1994.~~

For PERMANENTLY INSTALLED ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT parts, the following shall apply:

When placement or movement of an object or PATIENT against any motion control can actuate both switches, there shall be a motion disabling switch that permits disabling of the motion controls.

NOTE This switch can be located in the ~~procedure~~ examination room and not necessarily at the table side. It ~~may~~ can be helpful to the OPERATOR to have the motion disabling switch located near the IRRADIATION disabling switch.

The operation of the motion disabling switch shall not, in itself, be capable of initiating motions.

There shall be an indication of the motion disabling switch state at the working position of the OPERATOR.

The location, function and operation of the motion disabling switch shall be described in the instructions for use.

The motion disabling switch shall be separate from the IRRADIATION disabling switch.

The switch should be readily accessible to the OPERATOR and configured to minimize the likelihood of accidental operation.

The configurations shall be considered in the USABILITY ENGINEERING PROCESS.

Compliance is checked by functional tests and by inspection of the instructions for use and the USABILITY ENGINEERING FILE.

Additional subclauses:

201.9.2.3.1.101 Unintended movement during PATIENT loading/unloading

Means shall be provided to prevent unintended movement of ME EQUIPMENT or ME EQUIPMENT parts during PATIENT loading and unloading that could cause injury to the PATIENT or OPERATOR.

Compliance is checked by functional test taking into account the maximum NOMINAL PATIENT weight.

~~*Additional subclause:*~~

201.9.2.3.101 Pressure and force limitation

The pressure or force allowed to be applied to the PATIENT for diagnostic purposes shall be analysed with respect to the body part which ~~may~~ can come in contact with the ME EQUIPMENT, to application requirements and the potential for injury. As a general guideline, the pressure on the PATIENT should be limited to 70 kPa maximum and the force to 200 N.

NOTE Higher limits of COMPRESSION DEVICE ~~may~~ can be allowed by different local regulations.

For motorized compression movements, means shall be provided which limit the force applied to the PATIENT, according to the values given in the instructions for use.

Compliance is checked by visual inspection, functional test, measurement and inspection of the instructions for use.

~~NOTE These requirements are adapted from 22.4.3 of IEC 60601-2-32:1994.~~

201.9.2.3.102 Motion INTERLOCK for compression devices

When a compression force is applied to the PATIENT and the movements are not directly controlled by an OPERATOR in the vicinity of the PATIENT, movements which could be hazardous to the PATIENT and are not needed for the examination shall be interlocked. In case override of this INTERLOCK is necessary for the ongoing ~~procedure~~ examination, provision may be given to override this INTERLOCK through a dedicated control. Visual indication shall be given to the OPERATOR as long as the INTERLOCK override is active.

Information shall be given in the instructions for use warning the OPERATOR against possible RISK resulting from the use of this INTERLOCK override.

Compliance is checked by functional test and by inspection of the ACCOMPANYING DOCUMENTS.

201.9.2.4 Emergency stopping devices

Additional subclause:

201.9.2.4.101 Controls

All power-driven motions which could cause physical injury shall be provided with an emergency stop control. In the event of an emergency stop, means shall be provided for PATIENT access and removal while the ME EQUIPMENT is disabled. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, an emergency stop control is not required.

If in NORMAL USE a power-driven ME EQUIPMENT part is intended or likely to contact the PATIENT, and when appropriate for the designed application, means shall be provided to detect PATIENT contact and stop the motion if the contact could cause physical injury to the PATIENT.

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

~~NOTE These requirements are adapted from 22.4.1 of IEC 60601-2-32:1994.~~

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

NOTE The mass is accelerated for 150 mm, and then decelerates during compression of the 60 mm of foam, resulting in a force equivalent from 2 to 3 times the SAFE WORKING LOAD.

Where mechanical analysis proves that the following alternate static load test is more severe than the dynamic load test specified in IEC 60601-1, it is possible to waive the dynamic load test based on RISK MANAGEMENT. If the dynamic load test is passed, the static test ~~may~~ is not ~~be~~ necessary.

Prior to performing this test, a PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

For the area of support/suspension where a PATIENT or OPERATOR can sit, adequate multiples of mass (as defined in Figure 33 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) equivalent to SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in instructions for use is applied to the area for at least 1 min. Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Additional subclauses:

201.9.8.4.101 Mechanical protective device

Ropes, chains or bands running parallel to other rope, chains or bands may be regarded as a MECHANICAL PROTECTIVE DEVICE if they are not loaded during NORMAL USE.

Ropes, chains or bands used as a MECHANICAL PROTECTIVE DEVICE shall be accessible for inspection and the ACCOMPANYING DOCUMENTS shall give appropriate instructions for inspection.

Compliance is checked by functional test and inspection of ACCOMPANYING DOCUMENTS.

~~NOTE These requirements are adopted from 28.105 of IEC 60601-2-32:1994.~~

~~*Additional subclause:*~~

201.9.8.101 Shock absorbing means

Appropriate damping means shall be provided in cases where in NORMAL USE high dynamic loads occur, for example as a result of rapid acceleration or deceleration.

Compliance is checked by functional test.

~~NOTE This requirement is adapted from 28.103 of IEC 60601-2-32:1994~~

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except Subclause 10.3 (Microwave radiation), which does not apply.

NOTE The collateral standard IEC 60601-1-3 is referenced in IEC 60601-1 and is covered under Clause 203 of this document.

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:

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

NOTE Restrictions on allowable maximum temperature in Table 22 of IEC 60601-1:2005 for parts in contact with oil ~~shall~~ do not apply to parts wholly immersed in oil.

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

Replacement of the first paragraph modified by IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012:

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.

Additional subclause:

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

~~Where certain unguarded ACCESSIBLE SURFACES of X-RAY TUBE ASSEMBLIES can attain high temperatures, means shall be provided to make it impossible to contact such surfaces for any purposes connected with NORMAL USE.~~

~~NOTE Examples of such means are covers, handles for operation etc.~~

~~Measures should be taken to avoid all unintentional contact. In such cases the instructions for use shall state information about temperatures of ACCESSIBLE SURFACES to be expected in NORMAL USE; see Tables 22 to 24 of the general standard.~~

~~*Compliance is checked by functional test and inspection of instructions for use.*~~

201.11.101 Protection against excessive temperatures of BEAM LIMITING DEVICES

BEAM LIMITING DEVICES incorporating a LIGHT FIELD-INDICATOR shall be provided with one of the following means to reduce the possible temperature rise occurring if the lamp remains energized while the BEAM LIMITING DEVICE is covered with drapes or other material, reducing the normal heat dissipation:

a) a THERMAL CUT-OUT preventing the lamp being energized if the allowable maximum temperature, according to subclause 11.1.1 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, of any ACCESSIBLE SURFACE of the BEAM LIMITING DEVICE has been exceeded;

b) a time-limiting device preventing the lamp from remaining energized for a period exceeding 2 min after the most recent action by the OPERATOR to energize it;

c) a statement in the ACCOMPANYING DOCUMENTS giving details of the time-limiting switch to be externally connected to perform the function described in the item b) above.

Compliance is checked by functional test and inspection of ACCOMPANYING DOCUMENTS.

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:

Addition:

NOTE According to subclause 12.4.5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the dose related aspects of this question are addressed under 203.6.4.3 of this document.

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.

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, excepts as follows.

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

Replacement of the first paragraph modified by IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012:

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.

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.

~~NOTE The third edition of IEC 60601-1-2 has been slightly modified to resolve the deficiencies of the second edition with respect to imaging equipment.~~

202 Electromagnetic ~~compatibility~~ 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

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER ~~needs to~~ shall take into account the sensitivity to the EMC environment, probability of EMC condition and SEVERITY, and probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Only non-invasive measurements shall be performed.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

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 ME EQUIPMENT, or a sub-assembly, compliance with this document is to be stated, the statement shall be made in the following form:

X-RAY EQUIPMENT for RADIOGRAPHY and/or RADIOSCOPY ... ++) IEC 60601-2-54:~~2009~~2022

++) MODEL OR TYPE REFERENCE

Additional subclauses:

203.4.101 Qualifying conditions for defined terms

203.4.101.1 Electric power

The electric power in the high-voltage circuit, mentioned in this document in subclause 201.7.9.2.1.101, items c) and d), is calculated according to the formula:

$$P = f\,U\,I$$

where

– P is the electric power;

– f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

  a) 0,95 for ME EQUIPMENT including a SIX-PEAK HIGH-VOLTAGE GENERATOR, or

  b) 1,00 for ME EQUIPMENT including a TWELVE-PEAK HIGH-VOLTAGE GENERATOR or a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR; or

  c) for other ME EQUIPMENT the most appropriate value, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

– U is the X-RAY TUBE VOLTAGE;

– I is the X-RAY TUBE CURRENT.

203.4.101.2 PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS

The PERCENTAGE RIPPLE of the output voltage for ME EQUIPMENT with a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR shall not exceed 4 %.

NOTE ~~1~~ See also 7.2 of IEC 60601-1-3:2008.

~~NOTE 2 This requirement is adapted from 2.101.2 of IEC 60601-2-7:1998.~~

203.4.101.3 LOADING TIME

The LOADING TIME is measured as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

For ME EQUIPMENT in which LOADING is controlled by electronic switching of the HIGH VOLTAGE, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME may be determined as the time interval between the instant when the TIMING DEVICE generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For ME EQUIPMENT in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

NOTE ~~1~~ See also definition 3.37 of IEC 60601-1-3:2008.

~~NOTE 2 These requirements are adapted from 2.101.4 of IEC 60601-2-7:1998.~~

203.4.101.4 NOMINAL SHORTEST IRRADIATION TIME

The NOMINAL SHORTEST IRRADIATION TIME is determined according to 203.6.5.101 as the shortest LOADING TIME:

– for a LOADING during which the average AIR KERMA attained does not differ by more than 20 % from the average AIR KERMA attained for a LOADING TIME at least 50 times greater, when measured in accordance with 203.6.3.2.103, and

– which is no shorter than the shortest LOADING TIME for which the requirements for consistency are met in accordance with 203.6.3.2.102 c) 2) and reproducibility in accordance with 203.6.3.2.102 d).

~~NOTE These requirements are adapted from 50.104.3 of IEC 60601-2-7:1998.~~

203.5 ME EQUIPMENT identification, marking and documents

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.

~~*Additional subclause:*~~

~~**203.5.2.4.101 EXAMINATION PROTOCOLS**~~

~~When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the instructions for use shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the RESPONSIBLE ORGANIZATION.~~

~~*Compliance is checked by inspection of the instructions for use.*~~

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

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 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 MODES OF OPERATION in RADIOSCOPY designated e.g. as normal, low or high resolution, or normal, low or high dose mode;
2) the settings in a typical MODE OF OPERATION, as described in item 1), giving the default values, and the available ranges of factors 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) the settings of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, corresponding to minimal and typical values of REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE.

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 of item 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 of b) 1) and b) 2) of this subclause, and if they are adjustable by the OPERATOR in the MODE OF OPERATION concerned, for two 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 ME 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.

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

NOTE 1 The measured values are ~~to be~~ compared with stated values in the instruction for use, therefore a deviation of 50 % is appropriate.

Compliance is checked by functional tests and inspection of the instructions for use. The stated values of 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 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 RADIOSCOPY EQUIPMENT:

The PATIENT ENTRANCE REFERENCE POINT is located:

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

– 30 cm above the PATIENT SUPPORT for 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 X-RAY EQUIPMENT or

  • for C-arm 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 X-RAY EQUIPMENT with FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm,

  NOTE 2 For lateral positioning of C-arm the same definition of PATIENT ENTRANCE REFERENCE POINT is ~~to be~~ used in relationship to the ISOCENTRE as described for C-arms above.

– for 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

Use the following test PROCEDURE to determine dosimetric information:

– *As the PHANTOM, use a 20 cm thick polymethyl-methacrylate (PMMA) rectangular block with sides equal to or exceeding 25 cm. (The PHANTOM may be fabricated from layers of material.)*

– *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 area of the DETECTOR surface perpendicular to the source-detector axis shall not exceed 30 cm^2~~.*

– *Adjust the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to its minimum value. Place the PHANTOM as close as possible to the X-RAY IMAGE RECEPTOR, leaving as much of the available distance as possible between X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM. (This will minimize the effect of SCATTERED RADIATION on the measurements.)*

– *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 ~~are to be corrected~~ includes scaling to the appropriate geometrical distance.*

  NOTE 1 This positioning will minimize the contribution of STRAY RADIATION to the reading.

– *Measure the AIR KERMA RATE for the radioscopic 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 radiographic settings as required to be stated in 203.5.2.4.5.101 c).*

  NOTE 2 If measurements are involving AUTOMATIC EXPOSURE CONTROLS, verify the LOADING FACTORS that would prevail without the measuring detector and then perform the dose measurements by setting these LOADING FACTORS in the manual mode.

– *For each setting, the AIR KERMA (RATE) shall be measured, using the described PHANTOM, for two settings of the following factors:*
  - *selectable ADDED FILTERS*,
  - *representative OPERATOR selectable ENTRANCE FIELD SIZES*,
  - X-*RADIATION pulse repetition frequency*.

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the instructions for use shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the instructions for use.

203.6 RADIATION management

203.6.1 General

Additional subclauses:

203.6.1.101 Management of RADIOSCOPY image storage

X-RAY EQUIPMENT specified for RADIOSCOPY should 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 seconds of RADIOSCOPY;
- for pulse rates greater than 10 pulses per second, the last 300 images;
- for continuous RADIOSCOPY, the last 10 seconds of RADIOSCOPY.

Compliance is checked by functional test.

203.6.1.102 Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and if the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For equipment without an AUTOMATIC CONTROL SYSTEM:

– at least three PATIENT size choices should be selectable by the OPERATOR for adult PATIENTS;
– if the INTENDED USE includes paediatric applications, at least three PATIENT size choices should be selectable by the OPERATOR for paediatric PATIENTS.

Compliance is checked by inspection or by the appropriate functional tests.

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Addition:

a) It shall not be possible to initiate any subsequent IRRADIATION or, in SERIAL RADIOGRAPHY, any subsequent series without releasing the control by which the previous IRRADIATION was initiated.

b) Means shall be provided for the OPERATOR to terminate each LOADING at any time before its intended completion, except during SERIAL RADIOGRAPHY or for single LOADINGS with a LOADING TIME of 0,5 s or less.

During SERIAL RADIOGRAPHY, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to permit completion of any single LOADING of the series in progress.

c) For operation in RADIOSCOPY, when the duration of IRRADIATION is determined by the OPERATOR while it is in progress, a TIMING DEVICE shall be provided to give an audible warning signal to the OPERATOR of the completion of accumulated periods of LOADING. The TIMING DEVICE shall have the following characteristics:

1) it shall be possible to set the timing period of the device so as to permit LOADINGS with a maximum cumulative duration of 5 min without any warning being given. Provision may also be made for periods shorter than 5 min to be set. Any LOADING made without the device having been set and any LOADING made subsequently to the expiry of its most recently set period shall cause an audible warning signal to be given continuously while such LOADING is taking place;

2) it shall be possible to reset the device, without prevention or interruption of LOADING, in order to stop the warning and to permit further periods of LOADING, each not exceeding 5 min, to be accumulated, during which no warning is given;

3) any control for setting or resetting the time period shall be separate from any IRRADIATION SWITCH.

d) In addition to the TIMING DEVICE required in item c) above, means shall be provided to ensure automatic termination in the event of LOADING in RADIOSCOPY having continued without interruption for a period exceeding 10 min. In the event of termination being effected by these means in NORMAL CONDITION, it shall be possible to resume LOADING by releasing and re-actuating the IRRADIATION SWITCH.

e) * For a RADIOSCOPY IRRADIATION-EVENT of more than 0,5 s, the X-RAY EQUIPMENT shall terminate the LOADING within 0,1 s from the time the OPERATOR releases the control (e.g., by releasing pressure on a foot pedal). The shortest possible time is desirable.

For a RADIOSCOPY IRRADIATION-EVENT of 0,5 s or less, the X-RAY EQUIPMENT shall terminate the LOADING within 0,5 s from the time the OPERATOR releases the control (e.g., by releasing pressure on a foot pedal).

The instructions for use shall indicate the RADIOSCOPY IRRADIATION-EVENT times for which RADIOSCOPY can continue after the control is released, as described in 203.6.2.1 e), and the maximum amount of time that RADIOSCOPY can continue in each of the described cases.

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

Additional subclauses:

203.6.2.1.101 Charging mode INTERLOCK

Every MOBILE X-RAY EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorized persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present but battery charging is also possible in the absence of the key.

Compliance is checked by inspection.

203.6.2.1.102 Connections of external INTERLOCKS

X-RAY EQUIPMENT, except MOBILE X-RAY EQUIPMENT, shall be provided with connections for external electrical devices separate from the ME EQUIPMENT that either

– can prevent the X-RAY GENERATOR from starting to emit X-RADIATION,
– can cause the X-RAY GENERATOR to stop emitting X-RADIATION,
– or both.

If the state of the signals from these external electrical devices is not displayed on the CONTROL PANEL, the ACCOMPANYING DOCUMENTS shall contain information for the RESPONSIBLE ORGANISATION that this state should be indicated by visual means in the installation.

NOTE An example of the use of this facility would be to ensure the presence of PROTECTIVE SHIELDING during RADIOSCOPY.

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

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Addition:

If the normal termination depends upon a RADIATION measurement

– the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination, and
– either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and LOADING TIME shall be limited to not more than 60 kWs per IRRADIATION, or the CURRENT TIME PRODUCT shall be limited to not more than 600 mAs per IRRADIATION.

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

203.6.3 RADIATION dose and RADIATION quality

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Addition:

a) Systems for automatic control of LOADING FACTORS shall provide an adequate range of combinations of preselectable LOADING FACTORS, so that the automatic control is applied in ranges enabling the requirement of the collateral standard to be met.
b) In systems for automatic control of LOADING FACTORS and/or automatically controlled ADDITIONAL FILTRATION in RADIOSCOPY, the requirement of the collateral standard shall be considered to be met if
   – at least two appropriately differentiated levels of the controlled quantity can be selected, or
   – at least two appropriately differentiated levels of one characteristic LOADING FACTOR and/or automatically controlled ADDITIONAL FILTRATION, or appropriately differentiated functions of interdependent LOADING FACTORS and/or automatically controlled ADDITIONAL FILTRATION can be selected, or
   – additionally, manual control without the use of the AUTOMATIC CONTROL SYSTEM is possible.

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

203.6.3.2 Reproducibility of the RADIATION output

Additional subclauses:

203.6.3.2.101 Reproducibility of the RADIATION output in RADIOGRAPHY

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS.

Compliance is checked by the following test PROCEDURE:

Make 10 measurements of air kerma in 1 h under the test conditions according to subclause 203.6.3.2.103, at each of the test settings A, B, C and D according to Table 203.101.

Calculate the coefficient of variation for each of the measurement series and the average AIR KERMA for test settings C and D, to verify compliance.

203.6.3.2.102 Linearity and constancy in RADIOGRAPHY

a) Linearity of AIR KERMA over limited intervals of LOADING FACTORS

For operation in RADIOGRAPHY the quotients of the average of the MEASURED VALUES of AIR KERMA divided by the preselected values or the indicated values of CURRENT TIME PRODUCT, or the product of the values of X-RAY TUBE CURRENT and LOADING TIME, obtained

– at either two consecutive settings of LOADING TIME or X-RAY TUBE CURRENT or CURRENT TIME PRODUCT,

– or at any two settings of the above LOADING FACTORS when preselection is continuous and the preselected values differ by a factor as close as possible to but not exceeding 2,

shall not differ by more than 0,2 times the mean value of these quotients:

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{I_1 t_1} + \frac{\overline{K}_2}{I_2 t_2}}{2}$$

where

$\overline{K}_1$, $\overline{K}_2$ are the averages of the MEASURED VALUES of AIR KERMA;

Q_1 and Q_2 are the indicated CURRENT TIME PRODUCTS;

I_1 and I_2 are the indicated X-RAY TUBE CURRENTS;

t_1 and t_2 are the indicated LOADING TIMES.

Compliance is checked by the following test PROCEDURE:

Make 10 measurements of AIR KERMA in 1 h under the test conditions according to 203.6.3.2.103, at each of the test settings E and F according to Table 203.101.

Calculate the average value of AIR KERMA for the two measurements series. Use these average values and those for test settings C and D to verify compliance according to the formula.

Table 203.101 – Tests for verifying reproducibility and linearity

Test setting	A	B	C	D	E	F
X-RAY TUBE VOLTAGE	Lowest	Highest	50 % of highest	80 % of highest	50 % of highest	80 % of highest
X-RAY TUBE CURRENT *or* CURRENT TIME PRODUCT [a]	Highest	Lowest	Giving 1 µGy to 5 µGy [b]		Adjacent to setting for C and D	
LOADING TIME	Between 0,01 s and 0,32 s for all settings					

[a] As available with the settings defined in previous rows.

[b] DOSE values correspond to the air kerma in the IMAGE ~~RECEPTOR~~ RECEPTION PLANE.

b) Reproducibility of automatic exposure controls for direct radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for DIRECT RADIOGRAPHY, the reproducibility shall comply with the following requirements, either:

– the coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05; or

– the variation of optical density in the resultant RADIOGRAMS shall not exceed a value of 0,10 for unchanged X-RAY TUBE VOLTAGE and constant thickness of the irradiated object.

Compliance is checked by the following test PROCEDURES:

i) *Compliance of coefficient of variation of MEASURED VALUES OF AIR KERMA:*

– *Test conditions*

Use the test conditions according to 203.6.3.2.103 with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Make 10 measurements of AIR KERMA in 1 h. Calculate the coefficient of variation of AIR KERMA.

ii) *Compliance of variation of optical density, see test PROCEDURE in item c).*

c) Consistency of automatic exposure controls for direct radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for DIRECT RADIOGRAPHY, the variation of optical density in the resultant RADIOGRAMS shall not exceed a value of

1) 0,15 arising from changes of the X-RAY TUBE VOLTAGE, the thickness of the irradiated object being constant,

2) 0,20 arising from changes in the thickness of the irradiated object, the X-RAY TUBE VOLTAGE being constant,

3) 0,20 arising from changes in both the X-RAY TUBE VOLTAGE and the thickness of the irradiated object.

Compliance is checked by the following test PROCEDURE:

i) *Method*

Measure the optical density of RADIOGRAMS of PHANTOMS made of water or other tissue equivalent material, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations of density for different PHANTOM thicknesses and for different X-RAY TUBE VOLTAGES.

ii) *Test arrangement*

Use a test arrangement with the following characteristics:

1) a FOCAL SPOT TO IMAGE RECEPTOR DISTANCE of 1 m or corresponding to the INTENDED USE, remaining unchanged for all tests in a series;

2) an 18 cm x 24 cm RADIOGRAPHIC CASSETTE as X-RAY IMAGE RECEPTOR, the same cassette being used for all tests in a series;

3) *an X-RAY SOURCE ASSEMBLY of a type specified for use with the HIGH-VOLTAGE GENERATOR under test. The X-RAY FIELD is aligned and adjusted to 18 cm x 24 cm at the ENTRANCE SURFACE of the cassette and remains unchanged for all tests in a series;*

4) *provision for mounting the measuring chamber of the AUTOMATIC EXPOSURE CONTROL in a manner and position corresponding to the INTENDED USE;*

5) *provision of PHANTOMS of three different thicknesses, 10 cm, 15 cm and 20 cm, each of a size to cover the cassette fully, the PHANTOM in use for a particular test being mounted as close as possible to the ENTRANCE SURFACE of the cassette;*

6) *provision of a focused grid having the appropriate application limits;*

7) *provision for accurate and reproducible film processing and for measuring the optical density of the processed films.*

iii) *Radiographic film and intensifying screen*

Use a combination of RADIOGRAPHIC FILM and INTENSIFYING SCREEN of a type specified to be suitable for the INTENDED USE of the AUTOMATIC EXPOSURE CONTROL.

For any one series of tests, select pieces of film from the same batch, for which consistency of characteristics has been verified.

iv) *Setting the automatic exposure control*

1) *Select the central field of the measuring chamber of the AUTOMATIC EXPOSURE CONTROL.*

2) *Make any adjustments required in accordance with the instructions for use to apply the density correction for the type of film-screen combination in use and to produce a measured optical density in the processed film of 1,1 to 1,3, when operating at an X-RAY TUBE VOLTAGE of 80 kV, using the 15 cm PHANTOM.*

v) *Selecting the X-RAY TUBE CURRENT*

Except when testing an AUTOMATIC EXPOSURE CONTROL that operates with a fixed LOADING TIME, select a value of X-RAY TUBE CURRENT that will result in LOADING TIMES during the tests exceeding three times the shortest specified LOADING TIME but not exceeding 1 s. Record any selected value.

If no suitable value of X-RAY TUBE CURRENT can be selected, use a different FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to enable the stated range of LOADING TIMES to be achieved with the available setting of X-RAY TUBE CURRENT closest to the determined suitable value.

vi) *Test LOADINGS*

Make eight test LOADINGS, using the combinations of X-RAY TUBE VOLTAGE and PHANTOM thickness indicated in Table 203.102 and four additional LOADINGS at 80 kV with 15 cm PHANTOM thickness. Process the films; measure and record the optical density of each image.

Table 203.102 – LOADINGS for testing automatic exposure controls

X-RAY TUBE VOLTAGE [a] kV	PHANTOM thicknesses cm
60 [b]	10 and 15
80	15 and 20
100	15 and 20
120 [b]	10 and 15

[a] If any of these values are not selectable, use the nearest selectable value.

[b] If this value is outside the specified range, use the nearest value within the specified range and select other values as evenly spaced as possible in the reduced range.

vii) *Compliance criteria*

Compliance is achieved if

1) *for the four LOADINGS made with the 15 cm PHANTOM with different X-RAY TUBE VOLTAGES, no MEASURED VALUE of optical density differs by more than 0,15 from the mean of the four values and no value differs by more than 0,15 from the value for an adjacent step of X-RAY TUBE VOLTAGE,*

2) *for each of the four pairs of LOADINGS made at the same X-RAY TUBE VOLTAGE (with PHANTOMS of different thickness), no MEASURED VALUE of optical density differs by more than 0,2 from the other value in the pair,*

3) *for the whole series of eight LOADINGS, no MEASURED VALUE of optical density differs by more than 0,2 from the mean of the eight values,*

4) *for five LOADINGS at constant test parameters, 80 kV with 15 cm PHANTOM thickness, no MEASURED VALUE of optical density differs by more than 0,1 from the mean value of the five values.*

d) Reproducibility of automatic exposure controls for indirect radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for INDIRECT RADIOGRAPHY with DIGITAL X-RAY IMAGING DEVICES, the reproducibility shall comply with one of the following requirements:

– either the ratio between the highest and the lowest MEASURED VALUES of AIR KERMA shall be less than 1,2; or

– with integrated DIGITAL X-RAY IMAGING DEVICES the ratio between the highest and the lowest mean LINEARIZED DATA on a constant REGION OF INTEREST shall be less than 1,2 for constant X-RAY TUBE VOLTAGE and constant thickness of the irradiated object; or

– with integrated DIGITAL X-RAY IMAGING DEVICES and if the EXPOSURE INDEX according to IEC 62494-1:2008 is displayed the ratio between the highest and the lowest EXPOSURE INDEX in the RELEVANT IMAGE REGION shall be less than 1,2 for constant X-RAY TUBE VOLTAGE and constant thickness of the irradiated object.

Compliance is checked by the following test PROCEDURES:

i) *Compliance of ratio of MEASURED VALUES of AIR KERMA:*

– *Test conditions*

Use the test conditions according to 203.6.3.2.103 with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Make 10 measurements of AIR KERMA in 1 h. Calculate the ratio between the highest and the lowest MEASURED VALUES of AIR KERMA.

ii) *Compliance of ratio in the mean LINEARIZED DATA or EXPOSURE INDEX:*

– *Test conditions*

Use the X-RAY EQUIPMENT in conditions representative of the specified INTENDED USE, in terms of geometric settings and selection of MODE OF OPERATION, the PATIENT being replaced by a PHANTOM made of PMMA, the section and thickness of which match this INTENDED USE.

As a minimum, a PHANTOM with a thickness of 20 cm and a square area of 25 cm × 25 cm shall be used, with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Acquire 10 images per set of conditions. Calculate the ratio between the highest and the lowest mean LINEARIZED DATA or EXPOSURE INDEX.

203.6.3.2.103 Conditions for measuring AIR KERMA

203.6.3.2.103.1 Measuring arrangements

Arrange the HIGH-VOLTAGE GENERATOR or subassembly under test in a suitable combination with an X-RAY SOURCE ASSEMBLY (and, if applicable, with other subassemblies needed to constitute

an X-RAY GENERATOR) specified in the ACCOMPANYING DOCUMENTS of the unit under test as suitable for this purpose.

Align the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR under NARROW BEAM CONDITION.

Arrange the attenuating material needed near the X-RAY SOURCE ASSEMBLY or select the attenuating material specified in 203.6.3.2.103.2 b). Verify the RADIATION QUALITY according to 203.6.3.2.103.2 a).

203.6.3.2.103.2 ATTENUATION and RADIATION QUALITY for measurement of AIR KERMA

a) *Radiation quality*

Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with the HALF-VALUE LAYER requirements in IEC 60601-1-3:2008, Table 3, as applicable.

b) *Attenuation*

To simulate the presence of a PATIENT during the measurement of AIR KERMA, add a layer of aluminium with a thickness related to the selected X-RAY TUBE VOLTAGE in accordance with Table 203.103 and of sufficient size to intercept the whole of the X-RAY BEAM.

Table 203.103 – ATTENUATION for the measurement of AIR KERMA

X-RAY TUBE VOLTAGE up to and including kV	Thickness of aluminium mm
40	4
50	10
60	16
70	21
80	26
90	30
100	34
120	40
150	45
NOTE RADIATION QUALITIES RQA 2 to RQA 10, IEC 61267:2005. [2] [1)]	

~~*Additional subclause:*~~

203.6.3.101 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

ME EQUIPMENT designed for RADIOSCOPY shall be provided with means for the available combinations of LOADING FACTORS in RADIOSCOPY to be restricted to correspond, in particular installations, to any limit on the maximum AIR KERMA RATE that is necessary to comply with local regulations.

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

1) Figures in square brackets refer to the bibliography.

203.6.3.102 * High-level control (HLC)

If X-RAY EQUIPMENT specified for RADIOSCOPY include MODES OF OPERATION designed to produce REFERENCE AIR KERMA RATES greater than 88 mGy/min or than those REFERENCE AIR KERMA RATES specified in 203.6.3.101, these MODES OF OPERATION, described as high-level controls, shall be operable only when the OPERATOR provides continuous manual activation. When a high-level control is provided, a continuous signal audible to the OPERATOR shall indicate that the high-level control is being activated. When high-level controls are activated, the X-RAY EQUIPMENT shall not be operable at any combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT that will result in a REFERENCE AIR KERMA RATE in excess of 176 mGy/min.

For the application of this requirement to C-arm X-RAY EQUIPMENT, the REFERENCE AIR KERMA RATE shall be replaced by the AIR KERMA RATE measured at 30 cm from the ACCESSIBLE SURFACE of the X-RAY IMAGE RECEPTOR.

NOTE Lower limits ~~may~~ can be ~~required by~~ applicable according to different local regulations.

Compliance is checked by inspection and tests. Tests shall be performed by measurement of the maximum entrance REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT for non-C-arm X-RAY EQUIPMENT, and, for C-arm X-RAY EQUIPMENT, at the point specified above.

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.

Compliance is checked by inspection.

203.6.4.3 Indication of loading factors and modes of operation

Additional subclauses:

203.6.4.3.101 General requirements for the indication of LOADING FACTORS

The units of indication shall be as follows:

– for X-RAY TUBE VOLTAGE, kilovolts;
– for X-RAY TUBE CURRENT, milliamperes;
– for LOADING TIME, seconds and/or milliseconds;
– for CURRENT TIME PRODUCT, milliampereseconds;
– in RADIOSCOPY, the LOADING TIME may be indicated in minutes and seconds or decimally in minutes.

If pulse rate or pulse width in pulsed RADIOSCOPY is selectable, then the units of indication shall be as follows:

– for duration of X-RADIATION pulse, milliseconds;
– for X-RADIATION pulse repetition frequency, number of pulses per second.

Compliance is checked by inspection.

203.6.4.3.102 Shortened indication of LOADING FACTORS

a) For HIGH-VOLTAGE GENERATORS operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of

the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

In this case, the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the instructions for use.

In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

b) For HIGH-VOLTAGE GENERATORS operating with fixed combinations of semi-permanently preselectable (such as anatomic programmable) LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination.

In this case, provisions shall be made to enable

– the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the instructions for use, and in addition to enable

– the values to be listed in a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.

Compliance is checked by inspection.

203.6.4.3.103 Indication of varying LOADING FACTORS

For HIGH-VOLTAGE GENERATORS operating with AUTOMATIC INTENSITY CONTROL in RADIOSCOPY, continuous indication of the LOADING FACTORS that vary shall be given at the CONTROL PANEL.

Compliance is checked by inspection.

203.6.4.3.104 Accuracy of LOADING FACTORS

203.6.4.3.104.1 General aspects for the accuracy of LOADING FACTORS

In HIGH-VOLTAGE GENERATORS the requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is checked by inspection and tests.

203.6.4.3.104.2 Accuracy of LOADING FACTORS in automatic control mode

In X-RAY EQUIPMENT with AUTOMATIC CONTROL SYSTEMS when the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT, or both, is intended to vary during the IRRADIATION, the accuracy of the intentionally varied LOADING FACTOR required in 203.6.4.3.104.3 and 203.6.4.3.104.4, shall be disregarded.

203.6.4.3.104.3 Accuracy of X-RAY TUBE VOLTAGE

For operation of a HIGH-VOLTAGE GENERATOR in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE VOLTAGE, in any combination of LOADING FACTORS, shall be not greater than 8 %.

The increment or decrement of the X-RAY TUBE VOLTAGE between any two indicated settings shall be within 50 % and 150 % of the indicated change.

Compliance is checked by the following test PROCEDURE, using a test instrument with appropriate uncertainty:

a) *RADIOGRAPHY*

One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and the shortest indicated value of LOADING TIME.

One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

One measurement shall be made at the highest indicated value of X-RAY TUBE VOLTAGE and the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

b) *RADIOSCOPY*

One measurement shall be made at 90 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

One measurement shall be made at 60 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

203.6.4.3.104.4 Accuracy of X-RAY TUBE CURRENT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE CURRENT, in any combination of LOADING FACTORS, shall be not greater than 20 %.

Compliance is checked by the following test PROCEDURE:

a) RADIOGRAPHY

One measurement shall be made at the lowest indicated value of X-RAY TUBE CURRENT, the highest indicated value of X-RAY TUBE VOLTAGE and the shortest indicated value of LOADING TIME.

One measurement shall be made at the lowest indicated value of X-RAY TUBE CURRENT, the highest indicated value of X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

One measurement shall be made at the highest indicated value of X-RAY TUBE CURRENT, the highest available X-RAY TUBE VOLTAGE for the tested X-RAY TUBE CURRENT and a LOADING TIME of approximately 0,1 s.

b) RADIOSCOPY

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the lowest available X-RAY TUBE VOLTAGE.

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the highest available X-RAY TUBE VOLTAGE.

203.6.4.3.104.5 Accuracy of LOADING TIME

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE LOADING TIME, in any combination of LOADING FACTORS, shall be not greater than ± (10 % + 1 ms).

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest indicated value of LOADING TIME, the highest indicated value of X-RAY TUBE VOLTAGE and any indicated value of X-RAY TUBE CURRENT.

One measurement shall be made at the lowest indicated value of LOADING TIME and the highest available electric power, P.

203.6.4.3.104.6 Accuracy of CURRENT TIME PRODUCT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.105 Indication of ADDED FILTERS

If the X-RAY EQUIPMENT has provisions to select ADDED FILTERS by remote control or through an automatic system, the selected ADDED FILTER shall be indicated to the OPERATOR at a location appropriate for the INTENDED USE. If the FILTER change is automatic, it may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and functional tests.

203.6.4.3.106 * Electronic documentation of EXAMINATION PROTOCOLS

X-RAY EQUIPMENT that includes EXAMINATION PROTOCOL SELECTION CONTROL should provide access to the electronic documentation of those parameters invoked by each available PRE-PROGRAMMED EXAMINATION PROTOCOL in a defined format file (e.g., xml format, comma-separated format, space-separated format) and export to an output device. This electronic documentation should include the selected settings for each adjustable or selectable parameter in each PRE-PROGRAMMED EXAMINATION PROTOCOL.

Data elements incorporated in the electronic documentation should also include the date of configuration of the set of PRE-PROGRAMMED EXAMINATION PROTOCOLS.

If access to modify the PRE-PROGRAMMED EXAMINATION PROTOCOLS is provided, means shall be provided to track the date of the last change, and means shall be provided to enter an identifier for the agent responsible for the change.

X-RAY EQUIPMENT that provides electronic documentation of EXAMINATION PROTOCOLS shall provide either:

– access to a media output device; or

– access to a networked output device to transmit the electronic documentation through.

NOTE Additional equipment ~~may~~ can be ~~required~~ applicable (e.g., PC, CD/DVD drive, approved USB device, laptop wired by Ethernet connection, etc.) to enable export.

If a PRE-PROGRAMMED EXAMINATION PROTOCOL contains adjustable or selectable parameters, the MANUFACTURERS default value of each such parameter shall be provided.

Means should be recommended or provided to allow flagging differences between two or more PRE-PROGRAMMED EXAMINATION PROTOCOLS to assist in the local review and clinical audit process.

The means may be external to the X-RAY EQUIPMENT and, if so, it does not need to be considered a medical device.

Compliance is checked by inspection and appropriate functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For X-RAY EQUIPMENT operating in RADIOGRAPHY in which AUTOMATIC EXPOSURE CONTROL is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

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

203.6.4.5 * Dosimetric indications

Addition:

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

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

- The value of the REFERENCE AIR KERMA RATE shall be displayed during RADIOSCOPY 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.

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY and/or SERIAL RADIOGRAPHY shall be provided with an indication of the cumulative DOSE AREA PRODUCT resulting from RADIOGRAPHY and, when applicable, from RADIOSCOPY since the last reset operation. The DOSE AREA PRODUCT may be measured or calculated. The value shall be expressed in $Gy \cdot m^2$ with appropriate SI prefixes. The overall uncertainty in the displayed values of the cumulative DOSE AREA PRODUCT above 5 $\mu Gy \cdot m^2$ shall not exceed 35 %.

This DOSE AREA PRODUCT indication need not be provided at the working position of the OPERATOR.

X-RAY EQUIPMENT specified for INDIRECT RADIOGRAPHY shall be provided with an indication of the DOSE AREA PRODUCT for each exposure. The DOSE AREA PRODUCT may be measured or calculated.

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

X-RAY EQUIPMENT specified for DIRECT RADIOGRAPHY should satisfy the same requirement as specified above for INDIRECT RADIOGRAPHY. Alternatively, the following minimal requirements may be met:

– The value of the REFERENCE AIR KERMA resulting from the last radiographic IRRADIATION shall be displayed in mGy together with this unit, until initiation of the next radiographic IRRADIATION.
– Means shall be provided allowing the determination of the area of the X-RAY FIELD in the plane normal to the X-RAY BEAM AXIS containing the PATIENT ENTRANCE REFERENCE POINT, based on the available information concerning the extent of the X-RAY BEAM. The maximum deviation between the value determined using these means and the actual value shall be less than 40 % of the actual value for areas larger than 200 cm^2.

NOTE Examples of such means are tables, nomograms, programmable calculators or computers together with the relevant program.

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.

Additional subclauses:

203.6.4.5.101 Radiation dose structured reports

X-RAY EQUIPMENT specified for RADIOGRAPHY or RADIOSCOPY or RADIOGRAPHY and RADIOSCOPY should create RADIATION DOSE STRUCTURED REPORTS (RDSR) and have the ability to perform an RDSR END OF PROCEDURE TRANSMISSION. If RDSR is provided, it shall conform to at least the basic dose documentation specified in IEC 61910-1. The relevant elements for the specified type of X-RAY EQUIPMENT and for which data are available shall be populated with relevant data.

Compliance is checked by functional tests.

~~*Additional subclause:*~~

203.6.4.101 Indication of READY STATE

Visible indication shall be provided indicating the state when one further actuation of a control will initiate the LOADING of the X-RAY TUBE in RADIOGRAPHY.

If this state is indicated in RADIOGRAPHY by means of a single function visual indicator, the colour green shall be used.

In RADIOGRAPHY, means should be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for MOBILE X-RAY EQUIPMENT.

Compliance is checked by inspection.

203.6.5 AUTOMATIC CONTROL SYSTEM

Addition:

X-RAY EQUIPMENT specified for INDIRECT RADIOGRAPHY shall be provided with AUTOMATIC EXPOSURE CONTROL unless the MANUFACTURER provides justifications for exemptions in the RISK MANAGEMENT FILE.

NOTE Justifications for exemptions ~~may~~ can be motivated by technical reasons (e.g., MOBILE systems).

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY shall be provided with AUTOMATIC INTENSITY CONTROL. It shall be possible to limit the maximum REFERENCE AIR KERMA RATE to values given by local rules. For X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY in which AUTOMATIC CONTROL SYSTEMS vary one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

For X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL, a method by which the OPERATOR can verify the functioning of these controls shall be provided and the instructions for use shall contain the description of that method.

For X-RAY EQUIPMENT provided with AUTOMATIC INTENSITY CONTROL, a QUALITY CONTROL mode shall be provided that enables selection of values, either by a manual control mode or by selecting preset combination values, of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT or X-RAY CURRENT TIME PRODUCT, LOADING TIME, ADDITIONAL FILTRATION if any and FOCAL SPOT size if selectable.

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

Additional subclause:

203.6.5.101 Determination of the NOMINAL SHORTEST IRRADIATION TIME

For X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL the NOMINAL SHORTEST IRRADIATION TIME as defined in 203.4.101.4 shall be stated in the instructions for use. The MEASURED VALUE shall not be greater than the stated value.

Compliance is checked by inspection of the instructions for use and the following test PROCEDURE:

Make an IRRADIATION using the AUTOMATIC EXPOSURE CONTROL with > 70 % of the available generator power at approximately 80 kV. To determine the average AIR KERMA, adjust the ATTENUATION in the X-RAY BEAM (preferably by using a water PHANTOM) to achieve a LOADING TIME close to 0,1 s.

Make several IRRADIATIONS with reduced PHANTOM thicknesses using the same X-RAY TUBE VOLTAGE and generator power as mentioned above. The PHANTOM thickness shall be varied in such a way that the LOADING TIME does not vary more than a factor of two between two IRRADIATIONS.

203.6.6 SCATTERED RADIATION reduction

Replacement:

Means shall be provided to reduce the influence of RADIATION scattered in the PATIENT to the X-RAY IMAGE RECEPTOR in case of significant influence on the image quality. If such means are ANTI-SCATTER GRIDS which are removable by the OPERATOR, or that can be moved in or out under manual or automatic control by a motorized mechanism, the presence or absence of the ANTI-SCATTER GRID shall be clearly visible or indicated. If the ANTI-SCATTER GRID is removable, it shall be possible to remove and replace it without the use of TOOLS.

Means shall be provided for using X-RAY EQUIPMENT specified for paediatric applications without an ANTI-SCATTER GRID.

If different ANTI-SCATTER GRIDS can be used, it shall be possible for the OPERATOR to identify the grid in place.

The proper use of such means shall be described in the instructions for use.

Compliance is checked by inspection.

203.6.7 Imaging performance

Additional subclause:

203.6.7.101 Display of last image hold radiogram or radioscopy replay image sequence

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY shall display either a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE following termination of the radioscopic IRRADIATION, and shall comply with the following.

1) The LIH RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE shall be displayed following termination of the radioscopic IRRADIATION and shall remain visible until an action is taken by the OPERATOR.
2) Means shall be provided to clearly indicate to the OPERATOR whether a displayed image is:
   – an LIH RADIOGRAM or 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 initiation of the radioscopic IRRADIATION.

Compliance is checked by inspection and functional tests.

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Addition:

X-RAY EQUIPMENT specified for paediatric applications shall be provided with means for placing an ADDED FILTER of not less than 0,1 mm Cu or 3,5 mm Al.

NOTE An appropriate permanently mounted FILTER, not removable by the OPERATOR, satisfies the above requirement.

Compliance is checked by inspection, by examination of the ACCOMPANYING DOCUMENTS and by the use, as appropriate, of the test described in 7.5 of IEC 60601-1-3:2008.

Additional subclause:

203.7.1.101 Filtration in X-ray source assemblies

~~*Addition:*~~

X-RAY SOURCE ASSEMBLIES shall comply with the following requirements:

– unless solely intended for use in MOBILE X-RAY EQUIPMENT specified for RADIOSCOPY or for RADIOGRAPHY and RADIOSCOPY during surgery, X-RAY SOURCE ASSEMBLIES shall be provided with means to mount, to dismount, or to select one or more ADDED FILTERS, without the use of TOOLS. Any such selectable ADDED FILTERS shall comply with the following requirements:

  a) they shall be identifiable when in position for the INTENDED USE;

  b) if a selectable ADDED FILTER is necessary to attain the requirements for TOTAL FILTRATION in X-RAY EQUIPMENT, given in 7.1 of IEC 60601-1-3:2008, means shall be provided to enable the presence of the appropriate selectable ADDED FILTER to be detected by the control system of an associated HIGH-VOLTAGE GENERATOR and LOADING prevented if the necessary ADDED FILTER is not detected;

– the ACCOMPANYING DOCUMENTS shall include, in the ASSEMBLING INSTRUCTIONS given for particular applications, instructions for attaining the TOTAL FILTRATION required to comply with 7.1 of IEC 60601-1-3:2008 in respect of the items of X-RAY EQUIPMENT concerned.

Compliance is checked by inspection, by examination of the ACCOMPANYING DOCUMENTS and by the use, as appropriate, of the test described in 7.6 of IEC 60601-1-3:2008.

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

Addition:

X-RAY SOURCE ASSEMBLIES shall be so constructed that the zone of intersection of all straight lines that pass through all RADIATION APERTURES of the X-RAY SOURCE ASSEMBLY, with a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT shall not extend more than 15 cm outside the boundary of the largest selectable X-RAY FIELD.

Compliance is checked by examination of the design documentation. In Figure 203.101, w_1 represents the width of the largest selectable X-RAY FIELD in a plane P*, which is perpendicular to the REFERENCE AXIS at 1 m from the FOCAL SPOT. The zone of intersection with plane* P *of all straight lines passing through all RADIATION APERTURES extends beyond w_1 by the distance w_2. The shaded portion of this zone is a region where EXTRA-FOCAL RADIATION can extend beyond the largest X-RAY FIELD. Compliance is achieved if w_2 does not exceed 15 cm.*

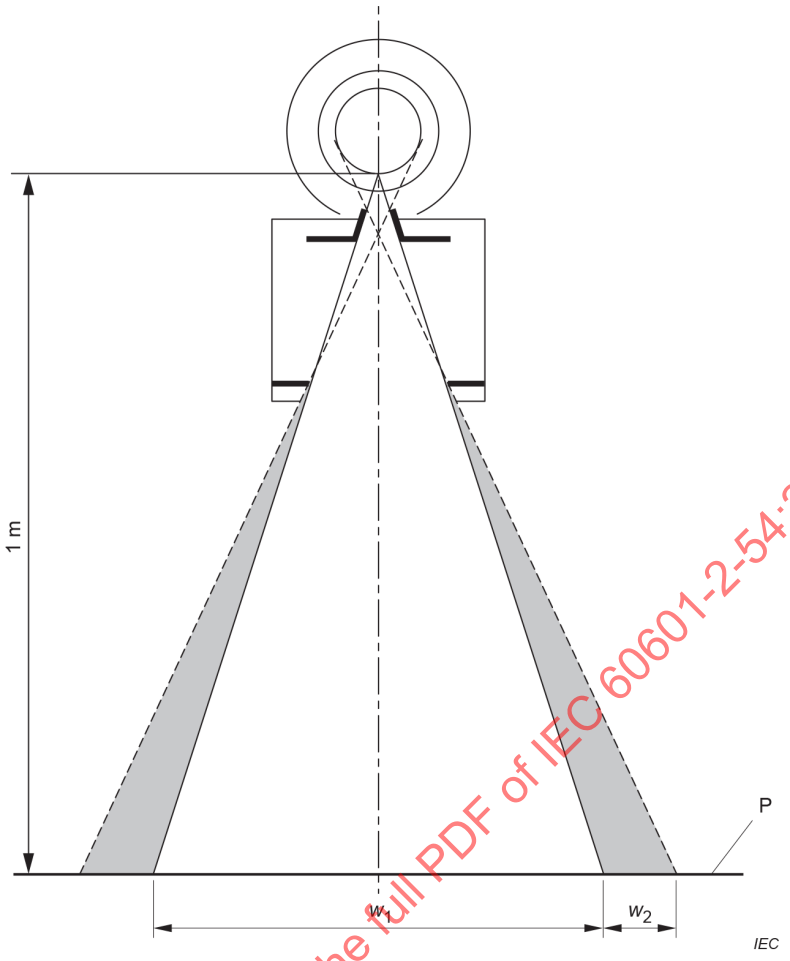


Figure 203.101 – Zone of EXTRA-FOCAL RADIATION

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

Addition:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the REGION OF INTEREST and, where applicable, the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL or AUTOMATIC INTENSITY CONTROL.

If the X-RAY FIELD is adjusted in the INTENDED USE for full coverage of the IMAGE RECEPTION AREA, it shall correspond to the IMAGE RECEPTION AREA within the following limits, as applicable:

– If the IMAGE RECEPTION AREA is circular, the X-RAY FIELD shall coincide with the IMAGE RECEPTION AREA as required in a) and b).

  a) the X-RAY FIELD measured along a diameter 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; and

  b) at least 80 % of the area of the X-RAY FIELD shall overlap the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION areas smaller than 10 cm in diameter are exempted.

  X-RAY EQUIPMENT specified for gastro-intestinal examinations with SPOTFILM DEVICES using also rectangular X-RAY IMAGE RECEPTORS need not comply with this requirement, but neither the length nor the width of the X-RAY FIELD shall exceed the diameter of the IMAGE RECEPTION AREA.

– In X-RAY EQUIPMENT specified for RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, in which

  a) there is provision for RADIOGRAPHY using a RADIOGRAPHIC CASSETTE holder, with beam limitation to a circular X-RAY FIELD for use on a rectangular IMAGE RECEPTION AREA; and

  b) the orientation of the IMAGE RECEPTION AREA is selectable; and

  c) the maximum diameter of the X-RAY FIELD does not exceed 40 cm,

  the diameter of the X-RAY FIELD may exceed the diagonal dimension of the IMAGE RECEPTION AREA by an amount not exceeding 2 cm. If the RADIOGRAPHIC CASSETTE holder can extend beyond the edges of the PRIMARY PROTECTIVE SHIELDING, a warning of this fact shall be stated in the instructions for use.

– In cases where the X-RAY FIELD does not correspond to the IMAGE RECEPTION AREA in accordance with one of the categories above, the following requirements apply:

  a) along each of the two major axes of the IMAGE RECEPTION AREA, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall not exceed 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE ~~RECEPTOR~~ RECEPTION PLANE is normal to the X-RAY BEAM AXIS;

  b) the sum of the discrepancies on both axes shall not exceed 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

NOTE If a secondary BEAM LIMITING DEVICE is used between PATIENT and X-RAY IMAGE RECEPTOR, this requirement refers to the percentage of the RADIATION reaching the IMAGE RECEPTION AREA relative to the RADIATION in front of the secondary BEAM LIMITING DEVICE.

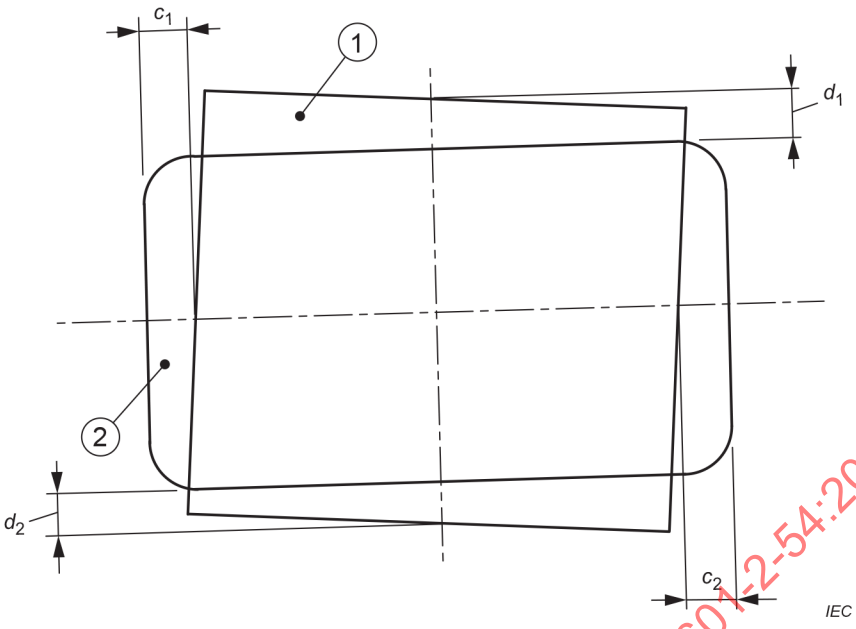
Compliance is checked with the relevant requirements above, by inspection of the ME EQUIPMENT, by examination of the instructions for use and by measurement of the X-RAY FIELDS, where appropriate. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, for the automatic mechanism to complete any adjustment occurring during the tests.

When determining compliance with the requirements at a) and b) of the last scenario above, make the measurements with the REFERENCE AXIS normal to the IMAGE ~~RECEPTOR~~ RECEPTION PLANE within three degrees. As shown in Figure 203.102, the measured discrepancies in the IMAGE ~~RECEPTOR~~ RECEPTION PLANE are represented by c_1 and c_2 on one axis and by d_1 and d_2 on the other. If the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE is S, then for compliance, the following relationships are true:

$$|c_1| + |c_2| \leq 0{,}03 \times S$$

$$|d_1| + |d_2| \leq 0{,}03 \times S$$

$$|c_1| + |c_2| + |d_1| + |d_2| \leq 0{,}04 \times S$$



1 X-ray-field

2 IMAGE RECEPTION AREA

Figure 203.102 – Discrepancies in covering the IMAGE RECEPTION AREA

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Addition:

X-RAY EQUIPMENT shall be designed in a way that the OPERATOR is able to select an X-RAY BEAM of the extent required for the applications concerned and for limiting the maximum available extent of the X-RAY BEAM to values that are consistent with the specified applications to avoid unnecessary RADIATION doses to the PATIENT and the staff.

Additional subclauses:

203.8.101 Boundary and dimensions of the X-RAY FIELD

The boundary of an X-RAY FIELD is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

The dimensions of a rectangular X-RAY FIELD are described in terms of the lengths of its intercepts on each of two orthogonal major axes in the plane of interest. Given that the X-RAY BEAM AXIS coincides with the REFERENCE AXIS, it is assumed that the plane of interest is orthogonal to the REFERENCE AXIS; also that the major axes intersect on the REFERENCE AXIS and are oriented so that one axis is collinear with the projection of the longitudinal axis of the X-RAY TUBE ASSEMBLY lying in the plane and passing through this point of intersection. If the X-RAY BEAM AXIS does not coincide with the REFERENCE AXIS, according to 203.8.104 this ~~has to~~ shall be stated in the instructions for use.

For circular X-RAY FIELDS the dimensions are described accordingly by replacing the lengths of the intercepts with the diameter.

~~NOTE These requirements are adapted from 2.202.1 of IEC 60601-1-3:1994, Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (withdrawn).~~

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

203.8.102.1 General

In X-RAY EQUIPMENT there shall be means to limit the extent of the X-RAY BEAM before impinging on the PATIENT SURFACE, as applicable:

– in X-RAY EQUIPMENT specified solely for RADIOGRAPHY with a single IMAGE RECEPTION AREA at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, by means of a FIXED BEAM LIMITING DEVICE having a RADIATION APERTURE of a single FIXED size. In X-RAY EQUIPMENT using a scanning beam, by a BEAM LIMITING DEVICE positioned between the RADIATION SOURCE and the PATIENT SURFACE;

– in X-RAY EQUIPMENT specified for RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and having an IMAGE RECEPTION AREA not exceeding 300 cm^2, by means of enabling the X-RAY FIELD at the IMAGE ~~RECEPTOR~~ RECEPTION PLANE to be reduced to 125 cm^2 or less;

– by means of a range of interchangeable or selectable components enabling RADIATION APERTURES of various FIXED sizes to be chosen;

– by means of a BEAM LIMITING DEVICE enabling the extent of the X-RAY BEAM to be adjusted within the range of NORMAL USE, by manual or automatic means, and having the following characteristics:

  a) a minimum selectable size of the X-RAY FIELD not exceeding 5 cm in length and width, in a plane orthogonal to the X-RAY BEAM AXIS at a distance of 1 m from the FOCAL SPOT;

  b) if the adjustment is not stepless, selectable steps not exceeding 1 cm in the length and width of the X-RAY FIELD, in a plane orthogonal to the REFERENCE AXIS at a distance of 1 m from the FOCAL SPOT;

  c) if the adjustment is automatic, means enabling the OPERATOR to select sizes of the X-RAY FIELD according to a) and b) above, while not permitting the OPERATOR to increase the size beyond the currently selected IMAGE RECEPTION AREA. The operation of these means shall be described in the instructions for use.

Where automatic adjustment is provided, the instructions for use shall contain details of a method by which its operation can be checked and shall describe the method by which the size of the X-RAY FIELD can be reduced, as required in item c) above.

Compliance is checked by inspection and functional test and by examination of the instructions for use.

203.8.102.2 Indication on the X-RAY EQUIPMENT

Except as stated in item a) to item c) below, information concerning the extent of the X-RAY BEAM shall be indicated by DISPLAY on the X-RAY EQUIPMENT.

Indications on the X-RAY EQUIPMENT shall give the following information numerically or by means of graphical markings or symbols:

– if numerical markings are used, they shall show the lengths and widths of the available X-RAY FIELDS at one or more typical values of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE. Information shall also be included (and ~~may~~ can, e.g., be in tabular form) concerning the variation of the dimensions of X-RAY FIELDS with respect to other relevant FOCAL SPOT TO IMAGE RECEPTOR DISTANCES;

– if the indication is given by graphical markings or symbols, these shall show on an appropriate surface (which ~~may~~ can, e.g., be the ENTRANCE SURFACE of a device containing the X-RAY IMAGE RECEPTOR), how the resultant X-RAY FIELDS are related to the FOCAL SPOT TO IMAGE RECEPTOR DISTANCES and the selectable combinations or settings of BEAM LIMITING DEVICES. If the markings do not show explicitly the extent or dimensions of the X-RAY FIELDS to be obtained, this information shall be given with an explanation of the markings in the instructions for use.

Indication by DISPLAY on the X-RAY EQUIPMENT need not be given in the following cases:

a) X-RAY EQUIPMENT so constructed that the X-RAY FIELDS at the distances of interest are obtained, prior to LOADING, without selection by the OPERATOR;

b) X-RAY EQUIPMENT constructed with an INTERLOCK that prevents LOADING unless an X-RAY FIELD of appropriate extent has been selected;

c) for modes of operation of X-RAY EQUIPMENT in which the boundaries of the X-RAY FIELD can be displayed in RADIOSCOPY.

X-RAY EQUIPMENT specified for RADIOSCOPY should 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.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.8.102.3 Indication in the instructions for use

The instructions for use shall contain the information necessary to enable the OPERATOR to determine, prior to LOADING, the extent of all X-RAY FIELDS for the INTENDED USE, in terms of their dimensions at appropriate FOCAL SPOT TO IMAGE RECEPTOR DISTANCES for the available selections, combinations and settings of the BEAM LIMITING DEVICES.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the instructions for use.

203.8.102.4 Accuracy of marked and written indications

Unless exempted below, the size of the X-RAY FIELD given by markings on the X-RAY EQUIPMENT or by statements in the instructions for use in accordance with 203.8.102.2 and 203.8.102.3 shall not differ from the size of the X-RAY FIELD, measured along each of its two major axes in the plane to which the indication relates, by more than 2 % of the distance of that plane from the FOCAL SPOT.

This requirement is not applicable for X-RAY EQUIPMENT in which the whole area of the RADIOGRAM is not irradiated simultaneously.

Compliance is checked by inspection of design data and by examination of the ACCOMPANYING DOCUMENTS. Where appropriate, measure the dimensions of the X-RAY FIELD along its two major axes, at selected indicated settings of the BEAM LIMITING SYSTEM and of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, as available for the INTENDED USE. For the purpose of calculation, assume the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to be equal to the value indicated on the X-RAY EQUIPMENT or stated in the ACCOMPANYING DOCUMENTS, for the setting used.

203.8.102.5 Indication by LIGHT FIELD-INDICATOR

In X-RAY EQUIPMENT specified for RADIOGRAPHY, a LIGHT FIELD-INDICATOR shall be provided where appropriate, to assist in delineating the position of the X-RAY FIELD on the PATIENT SURFACE.

Compliance is checked by inspection of the X-RAY EQUIPMENT.

If a LIGHT FIELD-INDICATOR is provided, it shall delineate the edges of the X-RAY FIELD and it shall provide an average illumination of not less than 100 lx in a plane normal to the X-RAY BEAM AXIS at a distance of 1 m from the FOCAL SPOT.

At this distance, the contrast at the edge of the LIGHT FIELD as defined below shall have a value of not less than 3 in MOBILE X-RAY EQUIPMENT and not less than 4 in other X-RAY EQUIPMENT.

The edge of a LIGHT FIELD is described by the locus of points at which the illumination is 25 % of the maximum illumination.

The description of a method to check the dimensions of the LIGHT FIELD at the appropriate distance from the FOCAL SPOT shall be included in the ACCOMPANYING DOCUMENTS.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the following test:

– *check that light-attenuating components as specified by the MANUFACTURER, e.g. the IONIZATION CHAMBER of a DOSE AREA PRODUCT meter, are in place.*
– *if the whole area of the indicated field is illuminated, determine the average illumination as the mean value from measurements in the approximate centre of each quarter of the LIGHT FIELD;*
– *in all other cases, determine the average illumination from at least four measurements at different points in the centres of the illuminated areas;*
– *measure the contrast, using a measuring aperture not larger than 1 mm. Take the contrast as I_1/I_2, where I_1 is the illumination 3 mm from the edge of the LIGHT FIELD towards the centre of the field and I_2 is the illumination 3 mm from the edge of the LIGHT FIELD away from the centre of the field;*
– *correct the MEASURED VALUES for ambient illumination.*

203.8.102.6 Accuracy of indication with a LIGHT FIELD-INDICATOR

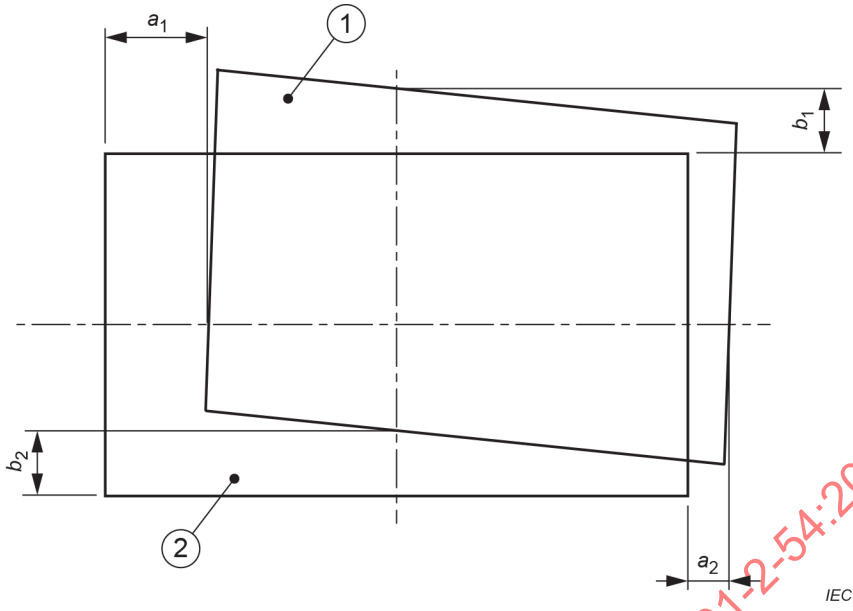
Along each of the two major axes of the X-RAY FIELD in the plane of the LIGHT FIELD, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the LIGHT FIELD shall not exceed 2 % of the distance of the measurement plane of the LIGHT FIELD from the FOCAL SPOT.

Compliance is checked by measurement, on the two major axes of the X-RAY FIELD, of the discrepancies between corresponding edges of the X-RAY FIELD and the LIGHT FIELD, in selected planes at measured distances from the FOCAL SPOT, within the range of NORMAL USE, and normal to the X-RAY BEAM AXIS within three degrees.

Referring to Figure 203.103, the measured discrepancies are represented by a_1 and a_2 on one axis and by b_1 and b_2 on the other. If the distance from the FOCAL SPOT to the measurement plane of the LIGHT FIELD is S, then, for compliance, the following relationships are true:

$$|a_1| + |a_2| \leq 0{,}02 \times S$$

$$|b_1| + |b_2| \leq 0{,}02 \times S$$



1 Visually defined field

2 X-RAY FIELD

Figure 203.103 – Discrepancies in visual indication of the X-RAY FIELD

203.8.103 Interception of the X-RAY BEAM in RADIOSCOPY

LOADING in RADIOSCOPY shall be prevented unless the X-RAY BEAM AXIS is in the position at which the correspondence of the X-RAY FIELD to the EFFECTIVE IMAGE RECEPTION AREA is specified to be in compliance with 203.8.5.3.

LOADING in RADIOSCOPY shall also be prevented if the BEAM LIMITING SYSTEM is adjusted so that, at the currently selected FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, the X-RAY FIELD can extend outside the IMAGE RECEPTION AREA by more than the amount permitted by 203.8.5.3.

For X-RAY EQUIPMENT with an adjustable BEAM LIMITING DEVICE, means shall be provided to configure the boundaries of the X-RAY FIELD so that these boundaries are visible with the X-RAY BEAM AXIS in a specified orientation. This orientation shall be described in the instructions for use.

The means ~~may~~ can be made available to the RESPONSIBLE ORGANISATION.

NOTE This configuration enables boundaries of the BEAM LIMITING DEVICE to be seen on the image DISPLAY with the X-RAY FIELD at its maximum size for each magnification mode.

Compliance is checked by inspection, functional test and by examination of the ACCOMPANYING DOCUMENTS.

203.8.104 Positioning of the X-RAY BEAM AXIS

The positioning of the X-RAY BEAM AXIS shall be indicated as follows:

a) If an X-RAY IMAGE RECEPTOR is part of the X-RAY EQUIPMENT it shall be possible, with the PATIENT in place for the examination and without the use of X-RADIATION, to position the X-RAY BEAM AXIS in relation to the IMAGE RECEPTION AREA in such a way that the X-RAY BEAM AXIS is intercepting the X-RAY IMAGE RECEPTOR in its centre.

b) The ACCOMPANYING DOCUMENTS shall describe the positions of the X-RAY BEAM available in NORMAL USE, in terms of its locations with respect to relevant IMAGE RECEPTION AREAS and its angles with respect to relevant IMAGE ~~RECEPTOR~~ RECEPTION PLANES. If the X-RAY BEAM AXIS is not coinciding with the REFERENCE AXIS, the position and the angle of the X-RAY FIELD

and the plane of interest relative to the REFERENCE AXIS shall be described in the instructions for use.

c) If the X-RAY EQUIPMENT is provided with a mechanism to adjust the position of the X-RAY BEAM AXIS in relation to the selected IMAGE RECEPTION AREA, an indication shall be given on the X-RAY EQUIPMENT to identify the position of the X-RAY BEAM AXIS at which the X-RAY FIELD is specified to correspond to the IMAGE RECEPTION AREA, to the accuracy required in 203.8.5.3.

d) If the X-RAY EQUIPMENT is provided with a mechanism to adjust the angle between the X-RAY BEAM AXIS and the selected IMAGE ~~RECEPTOR~~ RECEPTION PLANE, an indication shall be given on the X-RAY EQUIPMENT to identify either

– the state of adjustment at which the X-ray beam axis is normal to the selected image ~~RECEPTOR~~ reception plane; or

– a state of adjustment described in the accompanying documents, at which the X-ray beam axis is at a particular angle with respect to a particular image ~~RECEPTOR~~ reception plane.

Compliance is checked by inspection, functional test and by examination of the ACCOMPANYING DOCUMENTS.

203.9 FOCAL SPOT TO SKIN DISTANCE

203.9.1 General

Addition:

Means shall be provided to prevent IRRADIATION with FOCAL SPOT TO SKIN DISTANCES less than those specified in 203.9.101 and 203.9.102 for the INTENDED USE.

NOTE Means can include hardware, software, construction, or some other method.

Additional subclauses:

203.9.101 X-RAY EQUIPMENT specified for RADIOSCOPY

FIXED X-RAY EQUIPMENT specified for RADIOSCOPY should be provided with means to prevent the use, during radioscopic IRRADIATION, of FOCAL SPOT TO SKIN DISTANCES less than 38 cm.

The FOCAL SPOT TO SKIN DISTANCE shall not be less than 30 cm.

The MOBILE X-RAY EQUIPMENT specified for RADIOSCOPY shall be provided with means to prevent the use, during radioscopic IRRADIATION, of FOCAL SPOT TO SKIN DISTANCES less than:

– 20 cm if the X-RAY EQUIPMENT is specified for RADIOSCOPY during surgery; or
– 30 cm for other specified applications.

Compliance is checked by inspection and measurement.

203.9.102 X-RAY EQUIPMENT specified for RADIOGRAPHY

X-RAY EQUIPMENT specified for RADIOGRAPHY

– shall be provided with means to prevent radiographic IRRADIATION when the FOCAL SPOT TO SKIN DISTANCE is smaller than 20 cm; and
– shall permit by construction the use of FOCAL SPOT TO SKIN DISTANCES of 45 cm or more in NORMAL USE.

NOTE No means are required to prevent the use of smaller FOCAL SPOT TO SKIN DISTANCES.

Compliance is checked by inspection and measurement.

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

203.10.1 General

Addition:

The ATTENUATION EQUIVALENT of the items listed in Table 203.104, when forming part of X-RAY EQUIPMENT and located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, shall not exceed the applicable maximum values given in the table.

Compliance is checked by the test described in 203.10.101.

Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM

Item	Maximum ATTENUATION EQUIVALENT mm Al
Total of all layers composing the front panel of cassette holder	1,2
Total of all layers composing the front panel of FILM CHANGER	1,2
Total of all layers, excluding detector itself, composing the front panel of DIGITAL X-RAY IMAGING DEVICE	1,2
Cradle	2,3
PATIENT SUPPORT, stationary, without articulated joints	1,2
PATIENT SUPPORT, movable, without articulated joints (including stationary layers)	1,7
PATIENT SUPPORT, with radiolucent panel having one articulated joint	1,7
PATIENT SUPPORT, with radiolucent panel having two or more articulated joints	2,3
PATIENT SUPPORT, cantilevered	2,3
NOTE 1 Devices such as RADIATION DETECTORS are not included in the items listed in this table. NOTE 2 Requirements concerning the ATTENUATION properties of RADIOGRAPHIC CASSETTES and of INTENSIFYING SCREENS are given in ISO 4090 [3], for ANTI-SCATTER GRIDS in IEC 60627[1]. NOTE 3 ATTENUATION caused by table mattresses and similar accessories is not included in the maximum ATTENUATION EQUIVALENT for PATIENT SUPPORT. NOTE 4 Maximum ATTENUATION EQUIVALENT mm Al is only applied to the corresponding item. If several items given in this table are located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, each corresponding maximum ATTENUATION EQUIVALENT mm Al is separately applied to each item.	

203.10.2 Information in the ACCOMPANYING DOCUMENTS

Addition:

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ATTENUATION EQUIVALENT for each of the items listed in Table 203.104 and forming part of the X-RAY EQUIPMENT concerned for the measurement conditions specified in 203.10.101.

For diagnostic X-RAY EQUIPMENT specified to be used in combination with ACCESSORIES or other items not forming part of the same or another diagnostic X-RAY EQUIPMENT, the instructions for use shall include a statement drawing attention to the possible adverse effects arising from materials located in the X-RAY BEAM (e.g., parts of an operating table).

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS.

Additional subclause:

203.10.101 Test for ATTENUATION EQUIVALENT

Using an X-RAY BEAM with an X-RAY TUBE VOLTAGE of 100 kV, a PERCENTAGE RIPPLE not exceeding 10 %, and a first HALF-VALUE LAYER of 3,6 mm Al determine the ATTENUATION EQUIVALENT as the thickness of aluminium that gives the same degree of ATTENUATION as the material under consideration, from measurements of AIR KERMA under NARROW BEAM CONDITIONS.

203.11 Protection against RESIDUAL RADIATION

Additional subclauses:

203.11.101 Requirements

For the appropriate application category, as indicated in Table 203.105, X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements in Table 203.106.

These requirements shall be met

– for all combinations of X-RAY FIELDS and FOCAL SPOT TO IMAGE RECEPTOR DISTANCES in the INTENDED USE;

– in RADIOSCOPY, at all angles employed in the INTENDED USE between the X-RAY BEAM AXIS and the IMAGE ~~RECEPTOR~~ RECEPTION PLANE; and

– in RADIOGRAPHY, when the X-RAY BEAM AXIS is perpendicular to the IMAGE ~~RECEPTOR~~ RECEPTION PLANE.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection, by examination of the design documentation and ACCOMPANYING DOCUMENTS and by the test described in 203.11.102.

203.11.102 Test for attenuation of residual radiation

Use the following test PROCEDURE:

a) fit shielding as necessary in the region outside the PRIMARY PROTECTIVE SHIELDING to exclude from the measurement any X-RADIATION not transmitted through the PRIMARY PROTECTIVE SHIELDING; for X-RAY EQUIPMENT for RADIOSCOPY with C-arm the additional shielding can be positioned in the IMAGE ~~RECEPTOR~~ RECEPTION PLANE. For X-RAY EQUIPMENT with convex INPUT SCREEN the additional shielding may be positioned in the plane of the largest distance from the FOCAL SPOT as described in the ACCOMPANYING DOCUMENTS for the INTENDED USE;

b) use the smallest selectable TOTAL FILTRATION with which the X-RAY EQUIPMENT can be operated. Also, remove ANTI-SCATTER GRIDS and COMPRESSION DEVICES that are specified to be removable; use a PHANTOM having an ATTENUATION EQUIVALENT of 40 mm Al, positioned in the X-RAY BEAM as close as possible to the FOCAL SPOT.

c) according to the specified application of the X-RAY EQUIPMENT under test, select appropriate settings of distance and field size as follows:

1) in X-RAY EQUIPMENT for RADIOSCOPY in which control of LOADING is possible only from within a PROTECTED AREA, use the largest X-RAY FIELD available with RADIOSCOPY;

2) in cases not included in 1) above, set the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to the minimum FOCAL SPOT TO IMAGE RECEPTOR DISTANCES in the INTENDED USE and use the largest X-RAY FIELD available at that distance;

d) set the X-RAY TUBE VOLTAGE to the appropriate value for test as indicated in Table 203.106;

e) using appropriate known values of X-RAY TUBE CURRENT or CURRENT TIME PRODUCT, make measurements of AIR KERMA RATE or AIR KERMA so as to establish the profile of RESIDUAL RADIATION behind the PRIMARY PROTECTIVE SHIELDING. Make measurements 10 cm from any ACCESSIBLE SURFACE;

f) normalize the measurements to the AIR KERMA in one hour or the AIR KERMA per IRRADIATION at the reference LOADING FACTORS indicated in Table 203.106;

g) make any necessary adjustments to the values to take into account the permitted averaging over an area of 100 cm^2 with no principal linear dimension greater than 20 cm;

h) repeat measurements in other configurations of the X-RAY EQUIPMENT to which the requirement of 203.11.101 applies, to the extent necessary to ensure that all such configurations will have been taken into account for determining compliance;

i) compliance is achieved if no MEASURED VALUES obtained by the test PROCEDURE exceed the appropriate maximum permitted AIR KERMA given in Table 203.106.

Table 203.105 – Application categories

Specified application(s)	Application category
RADIOSCOPY with RADIOGRAPHY – OPERATOR near the PATIENT	A
RADIOSCOPY with RADIOGRAPHY – control of LOADING in RADIOGRAPHY from a PROTECTED AREA	B
RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	C
RADIOGRAPHY with a removable RADIOGRAPHIC CASSETTE holder fitted to X-RAY EQUIPMENT for RADIOSCOPY during surgery	D
INDIRECT RADIOGRAPHY for chest survey when OPERATORS or other PATIENTS are likely to stand in the vicinity of the equipment in NORMAL USE	F
RADIOGRAPHY not otherwise included in this table	None (no requirement)

Table 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING

Application category from Table 203.105	Minimum permitted extent beyond the largest IMAGE RECEPTION AREA	Maximum permitted AIR KERMA	X-RAY TUBE VOLTAGE for compliance and testing	Reference LOADING FACTORS for compliance	Additional requirements
A	30 mm	150 µGy in one hour	see [d]	see [e]	see [g]
B	30 mm [a]	150 µGy in one hour	NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY	see [e]	-
C	20 mm	150 µGy in one hour	NOMINAL X-RAY TUBE VOLTAGE	see [e]	-
D	see [b]	-	-	-	-
F	see [c]	1 µGy per IRRADIATION	NOMINAL X-RAY TUBE VOLTAGE	see [f]	-

[a] In this case, only the IMAGE RECEPTION AREA for RADIOSCOPY ~~need to~~ shall be considered.

[b] Additional PRIMARY PROTECTIVE SHIELDING need not be provided for the removable RADIOGRAPHIC CASSETTE holder. An appropriate warning shall be included in the INSTRUCTIONS FOR USE.

[c] The PRIMARY PROTECTIVE SHIELDING shall extend beyond the largest IMAGE RECEPTION AREA by at least 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

[d] The applicable voltage shall be the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY or, if a SPOTFILM DEVICE is provided, 66 % of the NOMINAL X-RAY TUBE VOLTAGE for RADIOGRAPHY, whichever is higher.

[e] The reference X-RAY TUBE CURRENT shall be 3 mA or the value corresponding to the maximum CONTINUOUS ANODE INPUT POWER, whichever is less.

[f] The reference LOADING FACTORS shall be those corresponding to the MAXIMUM ENERGY input in a single LOADING according to the RADIOGRAPHIC RATINGS.

[g] The periphery of the required extent of the PRIMARY PROTECTIVE SHIELDING shall correspond to the shape of the RADIATION APERTURE, unless the needed PRIMARY PROTECTIVE SHIELDING can be reached otherwise.

203.12 Protection against LEAKAGE RADIATION

203.12.4 LEAKAGE RADIATION in the LOADING state

Addition:

SERIAL RADIOGRAPHY initiated by a single actuation shall be considered as one LOADING for this requirement.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Addition:

Unless 203.13.3 is applicable and has been complied with, X-RAY EQUIPMENT specified exclusively for examinations that do not need the OPERATOR or staff to be close to the PATIENT during the INTENDED USE shall be provided with means to allow the following control functions to be implemented from a PROTECTED AREA after installation:

– additionally to the requirements in the collateral standard, in respect of radioscopic examinations, control of

  a) the dimensions of the X-RAY FIELD; and

  b) at least two orthogonal relative movements between the PATIENT and the X-RAY BEAM.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.3 Protection by distance

Addition:

In the following cases, protection against STRAY RADIATION is achieved without provision for control from a PROTECTED AREA in accordance with 203.13.2, by enabling the OPERATOR to control IRRADIATION from a distance not less than 2 m from the FOCAL SPOT and the X-RAY BEAM:

– MOBILE X-RAY EQUIPMENT specified exclusively for RADIOGRAPHY;

– X-RAY EQUIPMENT specified for RADIOSCOPY during surgery, with provision for RADIOGRAPHY.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.4 Designated SIGNIFICANT ZONES OF OCCUPANCY

Additional subclauses:

203.13.4.101 * Significant zones of occupancy with limited stray radiation

The following requirements apply to SIGNIFICANT ZONES OF OCCUPANCY designated in X-RAY EQUIPMENT specified for gastro-intestinal examinations, incorporating a tilting PATIENT SUPPORT, an undertable X-RAY SOURCE ASSEMBLY and a SPOTFILM DEVICE above the PATIENT SUPPORT:

– SIGNIFICANT ZONES OF OCCUPANCY designated for use in examinations with the PATIENT SUPPORT horizontal shall be contiguous to the edge of the horizontal PATIENT SUPPORT;

– SIGNIFICANT ZONES OF OCCUPANCY designated for use in examinations with the PATIENT SUPPORT vertical shall be located so that the shortest distance from the vertical PATIENT SUPPORT to the SIGNIFICANT ZONE OF OCCUPANCY, does not exceed 45 cm;

– the levels of STRAY RADIATION shall not exceed the values given in Table 203.107, according to the orientation of the PATIENT SUPPORT, and the applicable region of height above the floor;

– the measurement shall be performed in a position in which the PATIENT SUPPORT is centred horizontally or is in a home position vertically using also a centred PATIENT SUPPORT;

– the instructions for use shall

  a) cite the maximum permitted limits of AIR KERMA in each applicable region of height (see Table 203.107) and state that these limits are not exceeded;

  b) state the LOADING FACTORS applied to determine compliance by the test described in 203.13.6 and, if LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the PROCEDURE for obtaining these LOADING FACTORS;

  c) state the identity and intended position of any removable PROTECTIVE DEVICES that were in position during the test for compliance.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the test described in 203.13.6.

Table 203.107 – STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY

Orientation of PATIENT SUPPORT	Region of height related to the REFERENCE POINT of the RADIATION DETECTOR (above floor) in the SIGNIFICANT ZONE OF OCCUPANCY cm	Highest permitted AIR KERMA in one hour mGy
Horizontal or vertical	0 to 40	1,5
Horizontal	40 to 200	0,15
Vertical	40 to 170	0,15

203.13.4.102 Control from a designated SIGNIFICANT ZONE OF OCCUPANCY

Means shall be provided to allow the control functions as required in 203.13.2 from a SIGNIFICANT ZONE OF OCCUPANCY.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.5 Handgrips and control devices

Addition:

In X-RAY EQUIPMENT specified for gastro-intestinal examinations, incorporating a tilting PATIENT SUPPORT, an undertable X-RAY SOURCE ASSEMBLY and a SPOTFILM DEVICE above the PATIENT SUPPORT, the following limits of AIR KERMA in one hour shall not be exceeded at the positions of handgrips and control devices that are located outside a SIGNIFICANT ZONE OF OCCUPANCY and ~~need~~ that are intended to be handled by the OPERATOR or staff during LOADING:

– 1,5 mGy in one hour if they need to be handled only infrequently and momentarily; otherwise,

– 0,5 mGy in one hour.

The instructions for use shall list the locations of handgrips and control devices to which limits of AIR KERMA apply in this subclause. The instructions for use shall also state the applicable limits and declare that they are not exceeded under the required test conditions.

Compliance is checked by inspection of the X-RAY EQUIPMENT and, where applicable, by the test in 203.13.6 and by examination of the instructions for use.

203.13.6 Test for STRAY RADIATION

Replacement of the existing item b) by the following new item:

b) tests shall be done with representative orientations of the X-RAY BEAM for the INTENDED USE. As far as possible, follow the arrangements and dimensions shown in Figure 203.104 to Figure 203.107;

Addition:

Use the following test PROCEDURE to determine levels of STRAY RADIATION where specific limits apply:

aa) use a water equivalent PHANTOM of outside dimensions 25 cm × 25 cm × 15 cm, with walls not exceeding 10 mm in thickness and made from polymethyl-methacrylate (PMMA) or a material having a similar ATTENUATION property;

bb) as far as possible, follow the arrangements and dimensions shown in Figure 203.104 to Figure 203.105;

cc) use an X-RAY TUBE VOLTAGE equal to the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY or 66 % of the NOMINAL X-RAY TUBE VOLTAGE for RADIOGRAPHY with a SPOTFILM DEVICE, whichever is higher;

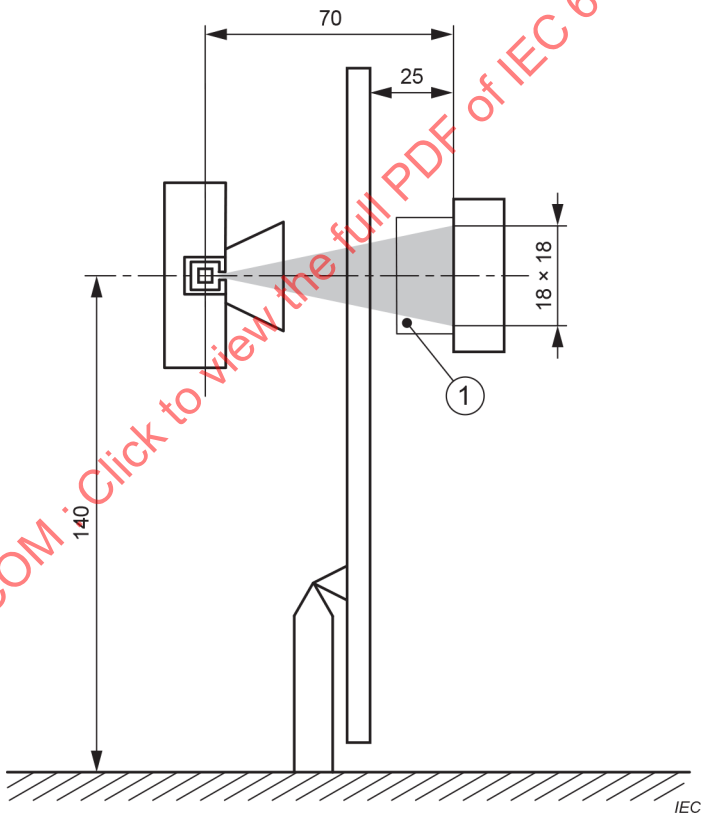
dd) use an X-RAY TUBE CURRENT of 3 mA or the value corresponding to the CONTINUOUS ANODE INPUT POWER of the X-RAY TUBE ASSEMBLY, whichever is less;

NOTE If LOADING FACTORS can only be adjusted by an AUTOMATIC CONTROL SYSTEM, follow the PROCEDURE described in the ACCOMPANYING DOCUMENTS to obtain the ~~required~~ applicable LOADING FACTORS. Otherwise, use the manual means of adjustment provided.

ee) in typical configurations of the X-RAY EQUIPMENT make a sufficient number of measurements of AIR KERMA RATE to determine the maximum value in all regions of interest. If the X-RAY TUBE CURRENT is not constant but automatically pulsed, average the measurement of AIR KERMA RATE over a suitable period of time. Where relevant to compliance, adjust the measurements to represent the levels in a volume of 500 cm^3 of which no principal linear dimension exceeds 20 cm. The point of measurement is related to the REFERENCE POINT of the RADIATION DETECTOR;

ff) compliance is achieved if no MEASURED VALUE, averaged and adjusted as described in item ee) above, exceeds the maximum permitted level of AIR KERMA in one hour in the region concerned.

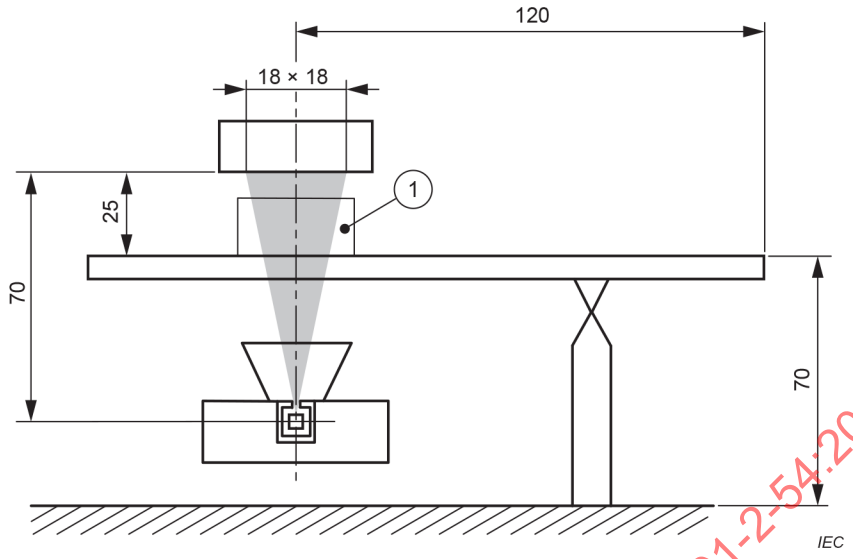
Dimensions in centimeters



1 PHANTOM

Figure 203.104 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)

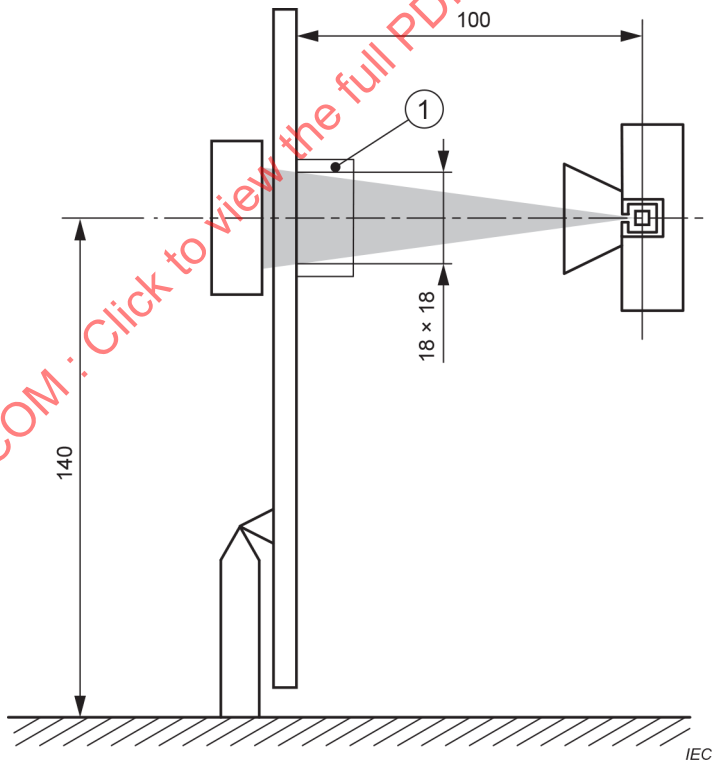
Dimensions in centimeters



1 PHANTOM

Figure 203.105 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)

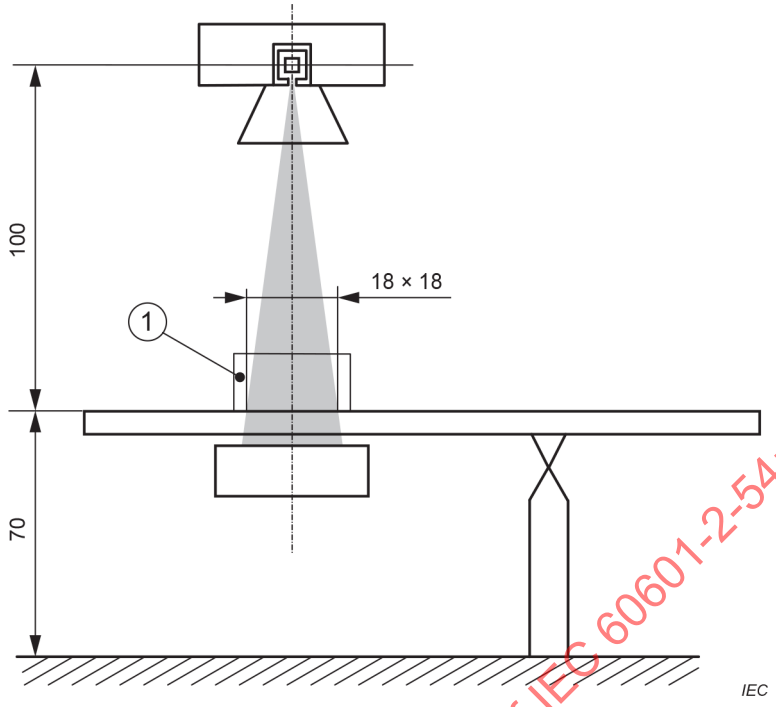
Dimensions in centimeters



1 PHANTOM

Figure 203.106 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)

Dimensions in centimeters



1 PHANTOM

Figure 203.107 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)

Annexes

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

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

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

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Beyond those given in 201.7.2, additional requirements for marking on the outside of ME EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts

Description of marking	Subclause
BEAM LIMITING DEVICE	201.7.2.101
Indication on the X-RAY EQUIPMENT	203.8.102.2

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Beyond those given in 201.7.9, 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.

Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Title	Subclause
SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	201.4.10.2
Cooling conditions	201.7.2.15
Unintended movement	201.9.2.3.1
Pressure and force limitation	201.9.2.3.101
Motion INTERLOCK for COMPRESSION DEVICES	201.9.2.3.102
Collision protection	201.9.2.2.4.4.101
MECHANICAL PROTECTIVE DEVICE	201.9.8.4.101
~~Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES~~	~~201.11.101~~

Title	Subclause
Protection against excessive temperatures of BEAM LIMITING DEVICES	201.11.~~102~~101
Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY	203.5.2.4.5.101
EXAMINATION PROTOCOLS	203.5.2.4.101
Connections of external INTERLOCKS	203.6.2.1.102
Shortened indication of LOADING FACTORS	203.6.4.3.102
Linearity and constancy in RADIOGRAPHY	203.6.3.2.102
Measuring arrangements	203.6.3.2.103.1
Indication of automatic modes	203.6.4.4
Dosimetric indications	203.6.4.5
AUTOMATIC CONTROL SYSTEM	203.6.5
SCATTERED RADIATION reduction	203.6.6
HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT	203.7.1
FILTRATION IN X-RAY SOURCE ASSEMBLIES	203.7.1.101
Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	203.8.5.3
Boundary and dimensions of the X-RAY FIELD	203.8.101
Methods of beam limitation in X-RAY EQUIPMENT	203.8.102
Indication on the X-RAY EQUIPMENT	203.8.102.2
Indication in the instructions for use	203.8.102.3
Accuracy of marked and written indications	203.8.102.4
Indication by LIGHT FIELD-INDICATOR	203.8.102.5
Interception of the X-RAY BEAM in RADIOSCOPY	203.8.103
Positioning of the X-RAY BEAM AXIS	203.8.104
Information in the ACCOMPANYING DOCUMENTS	203.10.2
Protection against RESIDUAL RADIATION	203.11
Control of X-RAY EQUIPMENT from a PROTECTED AREA	203.13.2
Protection by distance	203.13.3
SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION	203.13.4.101
Handgrips and control devices	203.13.5

Annex AA
(informative)

Particular guidance and rationale

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

Subclause 201.4.3.101 – Additional potential ESSENTIAL PERFORMANCE requirements

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD: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 of this document provides a list of requirements that can be correlated with the performance of a clinical function and that can 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 ~~by the fact that~~ because the RISK associated with ~~the use of IONIZING RADIATION to generate images for medical purposes should be compensated by the benefit expected from the PROCEDURE~~ ionizing X-RADIATION is overweighed by the benefits expected from the examination.

~~The requirements of this particular standard have been established such that the imaging performance of X-RAY EQUIPMENT complies with the technically and economically viable state of the art necessary for the production of images of sufficient quality in NORMAL CONDITIONS.~~

~~Imaging performance may be made SINGLE FAULT SAFE (e.g. against undetected degradation) by adequate maintenance PROCEDURES (including acceptance and constancy testing) for the installed equipment.~~

~~Consequently requirements that have not been identified as BASIC SAFETY are listed in Table 201.101.~~

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 clauses of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and this document or are determined by the RISK EVALUATION. There can be cases in which simply detection of single faults 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 201.8.7.3 – Allowable values

These relaxations versus the values of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 have been in place since 1998, originally in the withdrawn IEC 60601-2-7. There have been no reports that would justify a modification of these values.

Subclause 202.101 – Immunity testing of ESSENTIAL PERFORMANCE

Immunity tests on X-RAY EQUIPMENT specified for RADIOGRAPHY and RADIOSCOPY ~~may~~ can be performed only in RADIOSCOPY mode if there is sufficient evidence that RADIOSCOPY covers the same electrical sources and signalling paths leading to IRRADIATION.

Subclause 203.5.2.4.5.101 c) – RADIATION data

See rationale to 203.6.4.5.

Subclause 203.5.2.4.5.101 d) – PATIENT ENTRANCE REFERENCE POINT

This document allows the use of an indirect indication to estimate the ABSORBED DOSE to the skin. The estimate could be drawn from the indications of X-RAY EQUIPMENT parameters followed by a calculation of the primary AIR KERMA or AIR KERMA RATE at a point specified with reference to the FOCAL SPOT. The specified point, which has been defined here as the PATIENT ENTRANCE REFERENCE POINT, is intended to be representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT.

For systems with an ISOCENTRE, a point on the REFERENCE AXIS 15 cm from the ISOCENTRE towards the FOCAL SPOT has been specified as the PATIENT ENTRANCE REFERENCE POINT. This distance is assumed to represent a good approximation of the value of the actual FOCAL SPOT TO SKIN DISTANCE during RADIOLOGICAL PROCEDURES. If one considers currently available methods to estimate ABSORBED DOSES to selected tissues for RADIOSCOPIC and cine-angiographic examinations of the coronary arteries of adults [4], [5], these methods rely on the use of distinct operating conditions commonly used in RADIOLOGICAL examinations of the heart. These operating conditions are associated with a view, an arterial projection, and technique factors on the X-RAY EQUIPMENT such as the X-RAY TUBE VOLTAGE (kV), the HALF-VALUE LAYER (HVL), the FOCAL SPOT TO SKIN DISTANCE, the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and the ENTRANCE FIELD SIZE. A review of the operating conditions derived from analyses of practice [6], [9] indicates that the defined PATIENT ENTRANCE REFERENCE POINT is, in fact, a fair approximation of the FOCAL SPOT TO SKIN DISTANCE for each field.

The error in estimating the ABSORBED DOSE to the skin introduced from the defined PATIENT ENTRANCE REFERENCE POINT should average out as long as the interventional PROCEDURE is composed of multiple views. When the RADIOLOGICAL PROCEDURE is limited to one or a few views, the possibility of error in estimating the ABSORBED DOSE to the skin ~~may~~ can be higher. However, even under worst case conditions, errors should be less than a factor of two. Of course, most of this error can be eliminated by assessing the position of the PATIENT and calculating the appropriate correction factor.

The document has the flexibility of allowing an alternative to the use of the defined PATIENT ENTRANCE REFERENCE POINT for systems without an ISOCENTRE. In this case, the PATIENT ENTRANCE REFERENCE POINT is located at a position, defined by the MANUFACTURER to be representative of the point of intersection of the REFERENCE AXIS with the PATIENT SURFACE, and stated in the ACCOMPANYING DOCUMENTS. Examples of situations where the MANUFACTURER would use this alternative method of defining the PATIENT ENTRANCE REFERENCE POINT, would be X-RAY EQUIPMENT that senses the actual FOCAL-SPOT-TO-SKIN DISTANCE, deviates from traditional geometry or has a FIXED FOCAL SPOT TO SKIN DISTANCE.

NOTE Other reference documents [7], [8].

Subclause 203.5.2.4.5.102 – Test for dosimetric information

X-RAY EQUIPMENT ~~may~~ can be equipped with means for manually or automatically configuring the operating parameters for different INTENDED USES. In addition, different operating parameter sets ~~may~~ can be required to comply with differing national regulations and preferences. In accordance with 203.5.2.4.5.101 b), details of MODES OF OPERATION and certain other available settings are required to be stated. In accordance with 203.5.2.4.5.101 c), the associated values of REFERENCE AIR KERMA (RATE) are required to be given, together with the configurations and test geometries by which they can be verified by the method described in this subclause. The

first stage of compliance testing is to check this information (other than the dosimetric values) for compliance with the requirements and compatibility with the measuring method. If the information complies, it is used in the measuring PROCEDURE to verify the compliance of the stated values of REFERENCE AIR KERMA (RATE). Otherwise, the ME EQUIPMENT is considered non-compliant without further testing. Thus, the ME EQUIPMENT is delivered with a set of verified values and also with sufficient information to enable the values to be re-checked at any time. It is emphasised that, in any circumstances, the test method to be applied is intended to be only in respect of conditions that are within the range of the INTENDED USE.

Subclause 203.6.2.1 e) – Normal initiation and termination of the IRRADIATION

The purpose of RADIOSCOPY is to observe objects or structures in real time [16], [17]. A LAST IMAGE HOLD RADIOGRAM is, in essence, a RADIOGRAPH intended for review for study, consultation, or education instead of continuing RADIOSCOPY [16], [17].

The intent is to limit the number of RADIOGRAPHY images to those necessary for diagnosis or to document findings and device placement. Typical RADIOGRAPHY dose rates are at least 10 times greater than those for RADIOSCOPY [16]. If a LAST IMAGE HOLD RADIOGRAM demonstrates the finding adequately, it can be studied instead of performing RADIOGRAPHY. When no additional RADIOGRAPHY images are obtained, PATIENT RADIATION dose is reduced [16].

At present, RADIOSCOPY equipment is designed so that the RADIOSCOPY IRRADIATION terminates after the release of continuous pressure by the OPERATOR, regardless of the quality of the resultant LAST IMAGE HOLD RADIOGRAM. For radioscopic IRRADIATIONS longer than 1 s or so, this is of no consequence, as the image quality of the resultant LAST IMAGE HOLD RADIOGRAM will be adequate. However, if the RADIOSCOPY IRRADIATION is too short, the LAST IMAGE HOLD RADIOGRAM will not be usable, because image quality will not be adequate. Sufficient time is necessary to stabilize the AUTOMATIC INTENSITY CONTROL before terminating the radioscopic IRRADIATION. The new requirement permits automatic creation of a LAST IMAGE HOLD RADIOGRAM of adequate quality with a short tap on the RADIOSCOPY pedal and automatic termination of the radioscopic IRRADIATION, rather than manual termination. This avoids an IRRADIATION which is too short and results in an inadequate LAST IMAGE HOLD RADIOGRAM, or an IRRADIATION that is longer than necessary to obtain a LAST IMAGE HOLD RADIOGRAM of adequate quality. It permits a LAST IMAGE HOLD RADIOGRAM to be obtained with the shortest possible RADIOSCOPY IRRADIATION that will result in a usable image, and therefore with the lowest possible PATIENT RADIATION dose. It is understood that under certain circumstances (e.g. very low pulse rates) the time limits specified in 203.6.2.1 could result in a suboptimal LAST IMAGE HOLD RADIOGRAM.

Subclause 203.6.3.102 – High-level control (HLC)

High-level control (HLC) or high dose rate mode(s) ~~may~~ can be ~~necessary~~ applicable in cases of extreme body sizes of the PATIENT or when there is a need for extraordinarily high image quality for a certain PROCEDURE with a certain PATIENT. In such cases the higher PATIENT exposure ~~may~~ can be justified if the benefit of the PROCEDURE cannot be attained with lower dose rates. Local regulations ~~may require~~ can set different limits on the maximum AIR KERMA RATE for the normal and/or the HLC MODES OF OPERATION.

Subclause 203.6.4.3.106 – Electronic documentation of EXAMINATION PROTOCOLS

At the system level, the X-RAY EQUIPMENT includes one or more IMAGE DISPLAY DEVICES. The imaging performance characteristics of IMAGE DISPLAY SYSTEMS are provided by other standards (e.g. IEC 62563-1 [18] and DICOM, Part 14 [19]). The IMAGE DISPLAY SYSTEM settings selected under 203.6.4.3.106 are meaningful provided that the IMAGE DISPLAY DEVICE conforms to the X-RAY EQUIPMENT's specifications and the IMAGE DISPLAY DEVICE performs in accordance to its own standards.

A new addition is to provide a means (e.g. a comparison tool) to flag differences between two (or more) PRE-PROGRAMMED EXAMINATION PROTOCOLS. The comparison tool can be used to compare EXAMINATION PROTOCOLS for different examinations or different versions of the same protocol.

X-RAY EQUIPMENT ~~may~~ can contain one or more PRE-PROGRAMMED EXAMINATION PROTOCOLS (PPEP). Each PPEP usually contains settings controlling RADIATION production, X-RAY IMAGE RECEPTOR performance, and image processing for presentation. Incorrect or inappropriate settings ~~may~~ can result in inappropriate IRRADIATION of the PATIENT and/or in inappropriate clinical utility of the resulting images.

Validating the contents of each PPEP is essential for both safety and performance. For this reason, documentation of PPEPs over the life of the EQUIPMENT is useful for the RESPONSIBLE ORGANIZATION. Routine audits by the RESPONSIBLE ORGANIZATION are often performed after EQUIPMENT installation, commissioning, updates, and clinical configuration changes. Additional audits are indicated if there are unexpected changes in RADIATION use or the clinical acceptability of the resultant images.

Copies of the downloaded PPEP sets might be retained by the RESPONSIBLE ORGANIZATION to document their status over the life of the EQUIPMENT.

Audits are facilitated by comparing currently installed PPEPs against a reference set of PPEPs and flagging the differences. Sources of reference PPEPs include MANUFACTURER'S factory defaults or regional settings, as well as local settings for substantially similar EQUIPMENT as defined by the RESPONSIBLE ORGANIZATION.

This document does not require any specific content or format of a PPEP. It implies that all controls and settings within a PPEP that affect either RADIATION production or the characteristics of the resulting images be appropriately documented in a form that facilitates comparisons between versions.

Subclause 203.6.4.5 – Dosimetric indications

There is a growing demand worldwide for assessing quantitatively the RADIATION exposure of PATIENTS during diagnostic and interventional radiology PROCEDURES. Such demands can also be found in regional and national regulations. Some particular standards linked to the second edition of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 include such requirements. The first edition of IEC 60601-2-43 (2000) asks for presentation of RADIATION data, introduces terms such as skin dose levels and interventional reference point, and requires dosimetry calibration (6.8.2 of IEC 60601-2-43:2000) and dosimetric indications (51.102.4 of IEC 60601-2-43:2000). IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002 require dose statements (29.1.102.1 of IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002) and dose information (29.1.103 of IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002). The reason that these two standards were first in the introduction of such requirements is that both interventional PROCEDURES and CT examinations are high dose PROCEDURES.

The transition from the second to the third edition of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 presents a good opportunity to introduce requirements on RADIATION data and dosimetric indication into the particular standards for all medical X-ray modalities.

The introduction of the first edition of IEC 60601-1-3 (1994) states the following: “In respect of economic factors, it is recognized that certain relatively inexpensive types of X-RAY EQUIPMENT are sometimes justifiably preferred on grounds of cost. For these, this collateral standard avoids imposing requirements that would unduly restrict their medical effectiveness or would add disproportionately to the cost.” Based on this principle, this document exempts DIRECT RADIOGRAPHY EQUIPMENT from the requirements to provide dosimetric indications in 203.6.4.5. However, for X-RAY EQUIPMENT specified for DIRECT RADIOGRAPHY (including film-screen RADIOGRAPHY), a simplified dosimetric indication could be used by displaying a value, i.e. “the REFERENCE AIR KERMA resulting from the last radiographic IRRADIATION shall be displayed in mGy together with this unit”. This value might be pre-programmed as a function of the LOADING FACTORS. It also implies that when shifting from screen-film RADIOGRAPHY to CR, it is the responsibility of the RESPONSIBLE ORGANIZATION to ensure compliance with the general requirement for INDIRECT RADIOGRAPHY, or else compliance of the actual X-ray system with this

document can no longer be stated. INDIRECT RADIOGRAPHY includes CR and DR systems as well as any kind of RADIOGRAPHY performed with image intensifiers.

The accuracy requirement for dosimetric indications of ± 35 % was harmonized with EU and US requirements and is consistent with the real technically achievable level of accuracy. For RADIATION data stated in the ACCOMPANYING DOCUMENTS, the accuracy requirement of ± 50 % has been set to reflect the method used for compliance assessment and the fact that the RADIATION output of a given type of X-RAY TUBE ~~may~~ can vary within broad limits.

It ~~must~~ shall be stressed that all requirements on RADIATION data and dosimetric indication in the IEC standards are meant to give information to the OPERATOR about PATIENT doses and not to PATIENTS themselves.

Subclause 203.13.4.101 – SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION

In RADIOLOGICAL examinations which require the OPERATOR or staff to be close to the PATIENT during LOADING, a significant contribution to the total STRAY RADIATION exposure to these persons is often made by SCATTERED RADIATION from the PATIENT and other objects in the X-RAY BEAM. For X-RAY EQUIPMENT conventionally and most frequently used for performing gastro-intestinal examinations, limits of STRAY RADIATION in the SIGNIFICANT ZONES OF OCCUPANCY are required. The instructions for use shall state the applicable limits and declare that they are not exceeded. Where they apply, these requirements can provide a normalized basis for the local rules and guidelines that ~~have to~~ shall be established for the protection of persons, taking into account the local circumstances and the prevailing WORKLOAD.

Bibliography

[1] IEC 60627, *Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids*

[2] IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

[3] ISO 4090:2001, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

[4] STERN, S.H., ROSENSTEIN, M., RENAUD, L., ZANKL M. Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries. U.S. Department of Health and Human Services Publication FDA 95-8289, May 1995

[5] NAHASS, G.T. Fluoroscopy and the Skin: Implications for Radiofrequency Catheter Ablation. Am. J. of Card. 1995, 76, 174-176

[6] LESPERANCE, J. Coronary Angiography Projections. Institut de Cardiologie de Montréal, April 1982

[7] HADDI, R., RENAUD, L. Projections et Conditions Techniques en Usage en Angiocardiologie, Etude Statistique. Rapport technique, Service de Génie Biomédical, Institut de Cardiologie de Montréal, March 1993

[8] HYKES, D.L. Determination of Patient Radiation Doses Associated with Cardiac Catherization Procedures using Direct measurements and Monte Carlo Methods. Ph.D. dissertation. Medical College of Ohio, Toledo OH

[9] HUYSKENS, C.J., HUMMEL, W.A. Data Analysis on Patient Exposures in Cardiac Angiography. Radiation Protection Dosimetry 1995, 57(1), 475-480

[10] IEC 60601-2-28:2017, *Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*

[11] 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*

[12] 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*

[13] IEC 60601-1-11:2015, *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*
IEC 60601-1-11:2015/AMD1:2020

[14] IEC 60601-1-12:2014, *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 60601-1-12:2014/AMD1:2020

[15] IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
IEC 60601-2-43:2010/AMD1:2017
IEC 60601-2-43:2010/AMD2:2019

[16] ICRP 117:2010, Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department. ICRP Publication 117, Ann. ICRP 40(6)

[17] ICRP 121:2013, Radiological Protection in Paediatric Diagnostic and Interventional Radiology. ICRP Publication 121, Ann. ICRP 42(2)

[18] IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*
IEC 62563-1:2009/AMD1:2016
IEC 62563-1:2009/AMD2:2021

[19] DICOM, Part 14 (PS 3.14-2016e), *Digital Imaging and Communications in Medicine – Part 14: Grayscale Standard Display Function*

[20] 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*

[21] ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

[22] 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*

[23] IEC 60601-2-43:2000[2], *Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures*

[24] IEC 60601-2-44:2001[3], *Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography*
IEC 60601-2-44:2001/AMD1:2002

[25] IEC 60601-1-3:1994[4], *Medical electrical equipment – Part 1: General requirements for safety – Section 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

~~IEC 60601-2-7:1998 *Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*~~

~~IEC 60601-2-32:1994 *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*~~

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2 This reference was withdrawn and replaced with IEC 60601-2-43:2010, IEC 60601-2-43:2010/AMD1:2017 and IEC 60601-2-43:2010/AMD2:2019.

3 This reference was withdrawn and replaced with IEC 60601-2-44:2001, IEC 60601-2-43:2001/AMD1:2012 and IEC 60601-2-44:2001/AMD2:2016.

4 This reference was withdrawn and replaced with IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021.

~~IEC 62220-1-3:2008, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-3: Determination of the detective quantum efficiency – Detectors used in dynamic imaging*~~

Index of defined terms used in this document

NOTE In the present document only terms defined in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, its collateral standards, in IEC TR 60788:2004 or in 201.3 of this document were used. The definitions used in this document ~~may~~ can be looked up at http://std.iec.ch/glossary.

SUPPLY MAINS ..... IEC 60601-1:2005, 3.120
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THERMAL CUT-OUT ..... IEC 60601-1:2005, 3.124
TIMING DEVICE ..... ~~IEC/TR 60788:2004, rm-83-03~~ 201.3.226
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TRANSFER ..... IEC TR 60788:2004, rm-84-02
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IEC 60601-2-54

Edition 2.0 2022-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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 60601-2-54:2022-09(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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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IEC 60601-2-54 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 second edition cancels and replaces the first edition published in 2009, Amendment 1:2015 and Amendment 2:2018. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the IEC 60601-1:2005/AMD2:2020. 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;
b) terms and definitions taken exclusively from IEC TR 60788:2004 and which are specifically applicable in this document have been moved to 201.3;
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 subclause 201.11.101 “Protection against excessive temperatures of X-ray tube assemblies” has been removed from this document as its requirements are sufficiently and clearly covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017;

e) to adopt changes which are introduced with respect to indicator lights in 7.8.1 of the IEC 60601-1:2005/AMD2:2020 clarification of requirements is provided to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT;

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

The text of this document is based on the following documents:

Draft	Report on voting
62B/1285/FDIS	62B/1293/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.

INTRODUCTION

This document has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. The purpose of this second edition is to introduce changes to reference the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. Moreover, in Annex AA a clarification of the term for ESSENTIAL PERFORMANCE is provided. This document addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this document.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental or radiotherapy applications are excluded from the scope of this document. The scope of this document also excludes radiotherapy simulators.

If a clause or subclause is specifically intended to be applicable to ME 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 ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

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 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply, as modified in Clauses 202 and 203 respectively. If the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in a HOME HEALTHCARE ENVIRONMENT, then IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply and if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in an EMERGENCY MEDICAL SERVICES ENVIRONMENT, then IEC 60601-1-12:2014 and IEC 60601-1-12:2015/AMD1:2020 apply. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 1 OPERATORS of X-RAY EQUIPMENT are used to audible signals as specified in this document rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, 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 document, 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, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

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

IEC 60806, *Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis*

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

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

Amendment:

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

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, IEC 60601-1:2005/AMD2:2020, IEC TR 60788:2004 and the following apply.

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

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

NOTE An Index of defined terms is found in the last part of this document.

Addition:

201.3.201
APPARENT RESISTANCE OF SUPPLY MAINS
for diagnostic X-RAY GENERATOR, resistance of the SUPPLY MAINS determined under specific load conditions

201.3.202
AUTOMATIC INTENSITY CONTROL
in an X-RAY GENERATOR, mode of operation in which one or more LOADING FACTORS are controlled automatically in order to obtain at a pre-selected location a desired rate of a RADIATION QUANTITY

201.3.203
DIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected at an IMAGE RECEPTION AREA

Example: Film-screen or film RADIOGRAPHY.

201.3.204
DIRECT RADIOSCOPY
RADIOSCOPY in which the visible images are presented at the IMAGE RECEPTION AREA, or close to it, in the RADIATION BEAM

201.3.205
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$)

Note 1 to entry: This definition is equivalent to AIR KERMA area product.

201.3.206
DOSIMETER
EQUIPMENT which uses ionization chambers or semiconductor detectors for the measurement of AIR KERMA or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for diagnostic medical RADIOLOGICAL examinations

201.3.207
ENTRANCE FIELD SIZE
dimensions of the field in the entrance plane of an X-RAY IMAGE RECEPTOR that can be used for the transmission of an X-RAY PATTERN under specific conditions

201.3.208
EXAMINATION PROTOCOL
full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and DISPLAY

201.3.209
EXAMINATION PROTOCOL SELECTION CONTROL
control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.210
HIGH-VOLTAGE GENERATOR
in an X-RAY GENERATOR, combination of all components for control and production of the electrical energy to be supplied to an X-RAY TUBE, usually consisting of a high-voltage transformer assembly and a control assembly

201.3.211
IMAGE RECEPTION PLANE
plane containing the greatest dimensions of the IMAGE RECEPTION AREA

201.3.212
INDIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected after TRANSFER of the information obtained at an IMAGE RECEPTION AREA

Examples: CR systems, digital detector systems, image intensifier systems.

201.3.213
INDIRECT RADIOSCOPY
RADIOSCOPY in which the images are presented at a location outside the RADIATION BEAM after TRANSFER of the information

201.3.214
INTERLOCK
means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

201.3.215
ISOCENTRE
in RADIOLOGICAL equipment with several modes of movement of the REFERENCE AXIS around a common centre, centre of the smallest sphere through which the X-RAY BEAM AXIS passes

201.3.216
LAST IMAGE HOLD RADIOGRAM
LIH RADIOGRAM
single image obtained by sampling or temporal processing of one or more images from the end of a radioscopic IRRADIATION

Note 1 to entry: This note applies to the French language only.

201.3.217
NOMINAL ELECTRIC POWER
for a HIGH-VOLTAGE GENERATOR, highest constant electric power which can be delivered for a single X-RAY TUBE load in a specific LOADING TIME

201.3.218
NOMINAL SHORTEST IRRADIATION TIME
shortest LOADING TIME for which a required constancy of the controlled radiation quantity is maintained

Note 1 to entry: The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

201.3.219
PRE-PROGRAMMED EXAMINATION PROTOCOL
single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.220
QUALITY CONTROL
operational techniques and activities that are used to fulfil requirements for quality

201.3.221
RADIATION OUTPUT
AIR KERMA per CURRENT TIME PRODUCT (mGy/mAs) at a given distance from the FOCAL SPOT in the primary X-RAY BEAM

201.3.222
RADIOSCOPY REPLAY IMAGE SEQUENCE
series of the most recent images of the most recent RADIOSCOPY IRRADIATION-EVENT

201.3.223
REGION OF INTEREST
localized part of an image, which is of particular interest at a given time

201.3.224
SERIAL RADIOGRAPHY
RADIOGRAPHY in which the information is obtained and recorded in a regular or irregular series of LOADINGS with equal or unequal LOADING FACTORS

201.3.225
SIX-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a three-phase supply that delivers a rectified output voltage with six peaks during each cycle of the supply

201.3.226
TIMING DEVICE
device integrating and/or presenting time elapsed during an equipment function and optionally changing the state of operation at the end of a predetermined time interval

201.3.227
TWELVE-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a three-phase supply that delivers a rectified output voltage with twelve peaks during each cycle of the supply

201.3.228
X-RAY BEAM AXIS
for a symmetrical RADIATION BEAM, line through the centre of the RADIATION SOURCE and half way between the effective edges of the BEAM LIMITING DEVICE

Note 1 to entry: Usually, the X-RAY BEAM AXIS coincides within required tolerances with the REFERENCE AXIS of the RADIATION SOURCE.

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

Additional subclause:

201.4.3.101 * Additional potential ESSENTIAL PERFORMANCE requirements

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

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.104
Reproducibility of the RADIATION output	203.6.3.2
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS shall be considered sufficiently low for the operation of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this document are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems can be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

X-RAY EQUIPMENT is considered to comply with the requirements of this document only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the accompanying documents.

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.

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

Addition:

For ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

b) the number of phases; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

c) the frequency, in hertz; see 7.2.1 and 7.2.6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020,

d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;

e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENT, including as appropriate:

– the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;

– the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;

– the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

Additional subclause:

201.7.2.101 Beam limiting device

BEAM LIMITING DEVICES shall be provided with the following markings:

– those required in 7.2.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;

– serial designation or individual identification;

– QUALITY EQUIVALENT FILTRATION of all materials together that are permanently fixed and intercept the X-RAY BEAM.

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-RAY related states shall be excluded from 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead. Yellow and green colors of lights which are listed in Table 2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 should only be used if they are clearly distinguishable from the indication of the X-ray related states as required in these subclauses.

If applicable, conflicts which can arise from using same or similar colors for indication of X-RAY related states and other functions of the ME EQUIPMENT shall be evaluated by using the USABILITY ENGINEERING process.

Colors of indicator lights and alarm indicator lights for ME EQUIPMENT which are designated as HIGH PRIORITY, MEDIUM PRIORITY, and LOW PRIORITY ALARM CONDITION listed in Table 2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020 do not apply to X-RAY EQUIPMENT.

NOTE Even though 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 mentions the collateral standard IEC 60601-1-8 which application is excluded in 201.1.3 of this document, the selected specified references therein are considered informative and help to understand the requirements of 7.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall contain instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria for each test and frequency for each test.

NOTE The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

Additionally for X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

– an identification of adjustable or selectable image processing applied to ORIGINAL DATA including the version number or how to determine it;
– a description of the file transfer format of the images acquired with this unit and of any data associated with these images.

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Additional subclauses:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

a) The corresponding NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE CURRENT obtainable from the ME EQUIPMENT when operated at that X-RAY TUBE VOLTAGE.
b) The corresponding highest X-RAY TUBE CURRENT for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE VOLTAGE obtainable from the ME EQUIPMENT when operating at that X-RAY TUBE CURRENT.
c) The corresponding combination of X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY, and X-RAY TUBE CURRENT which results in the highest electric power in the high-voltage circuit (see 203.4.101).
d) The NOMINAL ELECTRIC POWER given as the highest constant electric power in kilowatts which the ME EQUIPMENT can produce/generate, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with nearest parameters (see 203.4.101).

   The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

e) For ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, it is possible that the lowest CURRENT TIME PRODUCT be given as a table or curve showing the dependence.

f) The NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT.

If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

The maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATIONS, controlled with the AUTOMATIC EXPOSURE CONTROL SYSTEMS, shall be stated in the instructions for use.

201.7.9.2.1.102 X-ray source assembly

The instructions for use shall state the maximum symmetrical RADIATION FIELD of the integrated X-RAY SOURCE ASSEMBLY determined according to IEC 60806.

201.7.9.2.1.103 Integrated X-RAY IMAGE RECEPTOR

For X-RAY EQUIPMENT provided with an integrated X-RAY IMAGE RECEPTOR, the instructions for use shall contain a description of the particular handling and maintenance of the X-RAY IMAGE RECEPTOR.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Replacement:

For X-RAY EQUIPMENT the instructions for use shall provide information as required in 203.5.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 X-ray source assembly

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following, in addition to the data required to be marked according to 7.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020:

a) REFERENCE AXIS;

b) TARGET ANGLE(S);

c) position and tolerances of the FOCAL SPOT(S);

d) FOCAL SPOT size(s):
If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then state the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.

NOTE These requirements are adapted from 201.7.9.3.101 of IEC 60601-2-28:2017.

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.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.4 Limitation of voltage, current or energy

201.8.4.3 ME EQUIPMENT intended to be connected to a power source by a plug

Additional subclauses:

201.8.4.3.101 High-voltage cable connections

Detachable high-voltage cable connections shall either be designed so that the use of TOOLS is required to disconnect them or they shall be provided with INTERLOCKS so that at all times when protective covers or high-voltage connections are removed:

– the ME EQUIPMENT is disconnected from its power supply, and

– capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and

– the discharged state is maintained.

Compliance is checked by inspection and by measurement.

201.8.4.101 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

201.8.5 Separation of parts

201.8.5.1 Means of protection (mop)

Additional subclause:

201.8.5.1.101 Additional limitation of voltage, current or energy

Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This can be achieved for example

– by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;

– by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

201.8.5.4 WORKING VOLTAGE

Additional subclause:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE shall be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

201.8.6.4 Impedance and current-carrying capability

Addition:

The flexible conductive screen shall not be recognized as satisfying a requirement for a PROTECTIVE EARTH CONNECTION between the devices connected by the cable.

Additional subclause:

201.8.6.101 X-RAY TUBE ASSEMBLY

a) Accessible high-voltage cables connecting X-RAY TUBE ASSEMBLIES to their associated HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding 1 Ω m^{-1}, and covered with a non-conductive material capable of protecting the screen against mechanical damage. The screen shall be connected to the conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR.

Compliance is checked by visual inspection and by measurement.

b) In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the ACCESSIBLE METAL PARTS of its receptacle on the X-RAY TUBE ASSEMBLY.

Compliance is checked by visual inspection and by measurement.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 * Allowable values

Item c) is amended as follows:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the TOUCH CURRENT under SINGLE FAULT CONDITION shall not exceed 2 mA.

Item d) is replaced with:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the allowable values of the EARTH LEAKAGE CURRENT are 2,5 mA in NORMAL CONDITION and 5 mA in SINGLE FAULT CONDITIONS. For PERMANENTLY INSTALLED ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 10 mA in NORMAL CONDITION and in SINGLE FAULT CONDITIONS.

Item e) is amended as follows:

For PERMANENTLY INSTALLED ME EQUIPMENT including HIGH-VOLTAGE GENERATORS, the allowable value of EARTH LEAKAGE CURRENT is 20 mA in NORMAL CONDITION and SINGLE FAULT CONDITION.

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of the ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min in RADIOGRAPHY and 15 min in RADIOSCOPY.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE ASSEMBLY connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE ASSEMBLY connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X- RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

For ME EQUIPMENT in which the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY does not exceed 80 % of that for RADIOGRAPHY, the test voltage for the high-voltage circuit shall be referred to the value for RADIOGRAPHY, and the test shall be carried out in that mode only.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit shall be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Additions:

aa) HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY shall be tested with an appropriately loaded X-RAY TUBE;

bb) If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test shall be reduced to such an extent that the allowable X-RAY TUBE LOAD at the increased X-RAY TUBE VOLTAGE will not be exceeded.

cc) If the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures should be taken to ensure that the values are kept as close as possible to 100 %, and are not outside the range of 100 % and 105 % of the value required.

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:

201.9.2.2.4.4 Other RISK CONTROL measures

Additional subclause:

201.9.2.2.4.4.101 Collision protection

If anti-collision features are provided with the X-RAY EQUIPMENT, the instructions for use shall describe the anti-collision features. In addition, the measures provided to prevent unnecessary interruption and to allow continuation of an examination shall be described.

Means shall be provided or warnings given in the ACCOMPANYING DOCUMENTS, to prevent injuries that could result from collision of power-driven ME EQUIPMENT parts with other moving or stationary items likely to be in proximity.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.5 Continuous activation

Amendment:

The movement of ME EQUIPMENT or ME EQUIPMENT parts which could cause physical injury to the PATIENT or OPERATOR in NORMAL USE shall require the continuous control of the OPERATOR.

The motorized movement of ME EQUIPMENT or ME EQUIPMENT parts which could crush or otherwise cause physical injury to the PATIENT or OPERATOR, and for which the response of the OPERATOR to actuate an emergency stop cannot be relied on to prevent an injury, shall be operated only by continuous actuation of two switches by the OPERATOR. Each switch shall be capable of interrupting independently the movement.

The two switches may be designed into a single control, and one switch may be in a circuit which is common to all motions.

These switches shall be in a location such that possible injury to the PATIENT can be observed by the OPERATOR. At least one set of switches shall be so located as to require the presence of the OPERATOR close to the PATIENT, to observe the moving parts of the ME EQUIPMENT.

The motorized movement of ME EQUIPMENT parts which could indirectly cause physical injury, such as a table angulation which could cause a PATIENT to fall, is not required to be controlled by two switches.

For ME EQUIPMENT designed to be set up or pre-positioned automatically, a control requiring continuous actuation which stops the mechanical motions on release shall be located at the position where movements can be visually observed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, continuous actuation is not required.

The MANUFACTURER shall identify by RISK MANAGEMENT the motorized movements which could cause the HAZARD.

Compliance is checked by inspection of the risk management file and by functional test.

201.9.2.2.6 Speed of movement(s)

Addition:

The overtravel of such movement, occurring after actuation of a control to stop the motion, shall not exceed 10 mm in NORMAL USE. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, overtravel may exceed 10 mm.

Except for MOBILE ME EQUIPMENT, when movement of power-driven ME EQUIPMENT towards the PATIENT is within 300 mm of the PATIENT table top, or 100 mm of the table side, the speed should be limited to half the maximum speed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, the speed limitation is not required.

Compliance is checked by inspection of the risk management file and by functional test and measurement.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

Means shall be provided to minimize the possibility of unintended motion, which could result in physical injury to the PATIENT or OPERATOR, in NORMAL USE and SINGLE FAULT CONDITION. The following shall apply:

a) Where failure, such as welded relay contacts, would result in uncontrolled motion, redundant control or other such protection shall be provided. A failure of one of the redundant controls shall be indicated to the OPERATOR, either directly or by a test according to the instructions for use.

b) Switching elements shall not be connected on the earthed side of a motion controlling circuit.

Compliance is checked by inspection of the circuit diagram, visual inspection and functional test.

For PERMANENTLY INSTALLED ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT parts, the following shall apply:

When placement or movement of an object or PATIENT against any motion control can actuate both switches, there shall be a motion disabling switch that permits disabling of the motion controls.

NOTE This switch can be located in the examination room and not necessarily at the table side. It can be helpful to the OPERATOR to have the motion disabling switch located near the IRRADIATION disabling switch.

The operation of the motion disabling switch shall not, in itself, be capable of initiating motions.

There shall be an indication of the motion disabling switch state at the working position of the OPERATOR.

The location, function and operation of the motion disabling switch shall be described in the instructions for use.

The motion disabling switch shall be separate from the IRRADIATION disabling switch.

The switch should be readily accessible to the OPERATOR and configured to minimize the likelihood of accidental operation.

The configurations shall be considered in the USABILITY ENGINEERING PROCESS.

Compliance is checked by functional tests and by inspection of the instructions for use and the USABILITY ENGINEERING FILE.

Additional subclauses:

201.9.2.3.1.101 Unintended movement during PATIENT loading/unloading

Means shall be provided to prevent unintended movement of ME EQUIPMENT or ME EQUIPMENT parts during PATIENT loading and unloading that could cause injury to the PATIENT or OPERATOR.

Compliance is checked by functional test taking into account the maximum NOMINAL PATIENT weight.

201.9.2.3.101 Pressure and force limitation

The pressure or force allowed to be applied to the PATIENT for diagnostic purposes shall be analysed with respect to the body part which can come in contact with the ME EQUIPMENT, to application requirements and the potential for injury. As a general guideline, the pressure on the PATIENT should be limited to 70 kPa maximum and the force to 200 N.

NOTE Higher limits of COMPRESSION DEVICE can be allowed by different local regulations.

For motorized compression movements, means shall be provided which limit the force applied to the PATIENT, according to the values given in the instructions for use.

Compliance is checked by visual inspection, functional test, measurement and inspection of the instructions for use.

201.9.2.3.102 Motion INTERLOCK for compression devices

When a compression force is applied to the PATIENT and the movements are not directly controlled by an OPERATOR in the vicinity of the PATIENT, movements which could be hazardous to the PATIENT and are not needed for the examination shall be interlocked. In case override of this INTERLOCK is necessary for the ongoing examination, provision may be given to override this INTERLOCK through a dedicated control. Visual indication shall be given to the OPERATOR as long as the INTERLOCK override is active.

Information shall be given in the instructions for use warning the OPERATOR against possible RISK resulting from the use of this INTERLOCK override.

Compliance is checked by functional test and by inspection of the ACCOMPANYING DOCUMENTS.

201.9.2.4 Emergency stopping devices

Additional subclause:

201.9.2.4.101 Controls

All power-driven motions which could cause physical injury shall be provided with an emergency stop control. In the event of an emergency stop, means shall be provided for PATIENT access and removal while the ME EQUIPMENT is disabled. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, an emergency stop control is not required.

If in NORMAL USE a power-driven ME EQUIPMENT part is intended or likely to contact the PATIENT, and when appropriate for the designed application, means shall be provided to detect PATIENT contact and stop the motion if the contact could cause physical injury to the PATIENT.

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

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

NOTE The mass is accelerated for 150 mm, and then decelerates during compression of the 60 mm of foam, resulting in a force equivalent from 2 to 3 times the SAFE WORKING LOAD.

Where mechanical analysis proves that the following alternate static load test is more severe than the dynamic load test specified in IEC 60601-1, it is possible to waive the dynamic load test based on RISK MANAGEMENT. If the dynamic load test is passed, the static test is not necessary.

Prior to performing this test, a PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

For the area of support/suspension where a PATIENT or OPERATOR can sit, adequate multiples of mass (as defined in Figure 33 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) equivalent to SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in instructions for use is applied to the area for at least 1 min. Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Additional subclauses:

201.9.8.4.101 Mechanical protective device

Ropes, chains or bands running parallel to other rope, chains or bands may be regarded as a MECHANICAL PROTECTIVE DEVICE if they are not loaded during NORMAL USE.

Ropes, chains or bands used as a MECHANICAL PROTECTIVE DEVICE shall be accessible for inspection and the ACCOMPANYING DOCUMENTS shall give appropriate instructions for inspection.

Compliance is checked by functional test and inspection of ACCOMPANYING DOCUMENTS.

201.9.8.101 Shock absorbing means

Appropriate damping means shall be provided in cases where in NORMAL USE high dynamic loads occur, for example as a result of rapid acceleration or deceleration.

Compliance is checked by functional test.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except Subclause 10.3 (Microwave radiation), which does not apply.

NOTE The collateral standard IEC 60601-1-3 is referenced in IEC 60601-1 and is covered under Clause 203 of this document.

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:

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

NOTE Restrictions on allowable maximum temperature in Table 22 of IEC 60601-1:2005 for parts in contact with oil do not apply to parts wholly immersed in oil.

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

Replacement of the first paragraph modified by IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012:

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.

Additional subclause:

201.11.101 Protection against excessive temperatures of BEAM LIMITING DEVICES

BEAM LIMITING DEVICES incorporating a LIGHT FIELD-INDICATOR shall be provided with one of the following means to reduce the possible temperature rise occurring if the lamp remains energized while the BEAM LIMITING DEVICE is covered with drapes or other material, reducing the normal heat dissipation:

a) a THERMAL CUT-OUT preventing the lamp being energized if the allowable maximum temperature, according to subclause 11.1.1 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, of any ACCESSIBLE SURFACE of the BEAM LIMITING DEVICE has been exceeded;

b) a time-limiting device preventing the lamp from remaining energized for a period exceeding 2 min after the most recent action by the OPERATOR to energize it;

c) a statement in the ACCOMPANYING DOCUMENTS giving details of the time-limiting switch to be externally connected to perform the function described in the item b) above.

Compliance is checked by functional test and inspection of ACCOMPANYING DOCUMENTS.

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:

Addition:

NOTE According to subclause 12.4.5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the dose related aspects of this question are addressed under 203.6.4.3 of this document.

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.

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, excepts as follows.

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

Replacement of the first paragraph modified by IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012:

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.

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.

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

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER shall take into account the sensitivity to the EMC environment, probability of EMC condition and SEVERITY, and probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Only non-invasive measurements shall be performed.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

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 ME EQUIPMENT, or a sub-assembly, compliance with this document is to be stated, the statement shall be made in the following form:

X-RAY EQUIPMENT for RADIOGRAPHY and/or RADIOSCOPY ... ++) IEC 60601-2-54:2022

++) MODEL OR TYPE REFERENCE

Additional subclauses:

203.4.101 Qualifying conditions for defined terms

203.4.101.1 Electric power

The electric power in the high-voltage circuit, mentioned in this document in subclause 201.7.9.2.1.101, items c) and d), is calculated according to the formula:

$$P = f\,U\,I$$

where

– P is the electric power;

– f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

  a) 0,95 for ME EQUIPMENT including a SIX-PEAK HIGH-VOLTAGE GENERATOR, or

  b) 1,00 for ME EQUIPMENT including a TWELVE-PEAK HIGH-VOLTAGE GENERATOR or a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR; or

  c) for other ME EQUIPMENT the most appropriate value, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

– U is the X-RAY TUBE VOLTAGE;

– I is the X-RAY TUBE CURRENT.

203.4.101.2 PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS

The PERCENTAGE RIPPLE of the output voltage for ME EQUIPMENT with a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR shall not exceed 4 %.

NOTE See also 7.2 of IEC 60601-1-3:2008.

203.4.101.3 LOADING TIME

The LOADING TIME is measured as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

For ME EQUIPMENT in which LOADING is controlled by electronic switching of the HIGH VOLTAGE, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME may be determined as the time interval between the instant when the TIMING DEVICE generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For ME EQUIPMENT in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

NOTE See also definition 3.37 of IEC 60601-1-3:2008.

203.4.101.4 NOMINAL SHORTEST IRRADIATION TIME

The NOMINAL SHORTEST IRRADIATION TIME is determined according to 203.6.5.101 as the shortest LOADING TIME:

– for a LOADING during which the average AIR KERMA attained does not differ by more than 20 % from the average AIR KERMA attained for a LOADING TIME at least 50 times greater, when measured in accordance with 203.6.3.2.103, and

– which is no shorter than the shortest LOADING TIME for which the requirements for consistency are met in accordance with 203.6.3.2.102 c) 2) and reproducibility in accordance with 203.6.3.2.102 d).

203.5 ME EQUIPMENT identification, marking and documents

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

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 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 MODES OF OPERATION in RADIOSCOPY designated e.g. as normal, low or high resolution, or normal, low or high dose mode;

2) the settings in a typical MODE OF OPERATION, as described in item 1), giving the default values, and the available ranges of factors 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) the settings of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, corresponding to minimal and typical values of REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE.

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 of item 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 of b) 1) and b) 2) of this subclause, and if they are adjustable by the OPERATOR in the MODE OF OPERATION concerned, for two 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 ME 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.

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

NOTE 1 The measured values are compared with stated values in the instruction for use, therefore a deviation of 50 % is appropriate.

Compliance is checked by functional tests and inspection of the instructions for use. The stated values of 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 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 RADIOSCOPY EQUIPMENT:

The PATIENT ENTRANCE REFERENCE POINT is located:

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

– 30 cm above the PATIENT SUPPORT for 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 X-RAY EQUIPMENT or

  - for C-arm 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 X-RAY EQUIPMENT with FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm,

NOTE 2 For lateral positioning of C-arm the same definition of PATIENT ENTRANCE REFERENCE POINT is used in relationship to the ISOCENTRE as described for C-arms above.

– for 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

Use the following test PROCEDURE to determine dosimetric information:

– *As the PHANTOM, use a 20 cm thick polymethyl-methacrylate (PMMA) rectangular block with sides equal to or exceeding 25 cm. (The PHANTOM may be fabricated from layers of material.)*

– *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.*

– *Adjust the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to its minimum value. Place the PHANTOM as close as possible to the X-RAY IMAGE RECEPTOR, leaving as much of the available distance as possible between X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM. (This will minimize the effect of SCATTERED RADIATION on the measurements.)*

– *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 includes scaling to the appropriate geometrical distance.*

NOTE 1 This positioning will minimize the contribution of STRAY RADIATION to the reading.

– *Measure the AIR KERMA RATE for the radioscopic 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 radiographic settings as required to be stated in 203.5.2.4.5.101 c).*

NOTE 2 If measurements are involving AUTOMATIC EXPOSURE CONTROLS, verify the LOADING FACTORS that would prevail without the measuring detector and then perform the dose measurements by setting these LOADING FACTORS in the manual mode.

– *For each setting, the AIR KERMA (RATE) shall be measured, using the described PHANTOM, for two settings of the following factors:*

- *selectable ADDED FILTERS*,
- *representative OPERATOR selectable ENTRANCE FIELD SIZES*,
- *X-RADIATION pulse repetition frequency*.

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the instructions for use shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the instructions for use.

203.6 RADIATION management

203.6.1 General

Additional subclauses:

203.6.1.101 Management of RADIOSCOPY image storage

X-RAY EQUIPMENT specified for RADIOSCOPY should 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 seconds of RADIOSCOPY;
- for pulse rates greater than 10 pulses per second, the last 300 images;
- for continuous RADIOSCOPY, the last 10 seconds of RADIOSCOPY.

Compliance is checked by functional test.

203.6.1.102 Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and if the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For equipment without an AUTOMATIC CONTROL SYSTEM:

– at least three PATIENT size choices should be selectable by the OPERATOR for adult PATIENTS;

– if the INTENDED USE includes paediatric applications, at least three PATIENT size choices should be selectable by the OPERATOR for paediatric PATIENTS.

Compliance is checked by inspection or by the appropriate functional tests.

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Addition:

a) It shall not be possible to initiate any subsequent IRRADIATION or, in SERIAL RADIOGRAPHY, any subsequent series without releasing the control by which the previous IRRADIATION was initiated.

b) Means shall be provided for the OPERATOR to terminate each LOADING at any time before its intended completion, except during SERIAL RADIOGRAPHY or for single LOADINGS with a LOADING TIME of 0,5 s or less.

During SERIAL RADIOGRAPHY, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to permit completion of any single LOADING of the series in progress.

c) For operation in RADIOSCOPY, when the duration of IRRADIATION is determined by the OPERATOR while it is in progress, a TIMING DEVICE shall be provided to give an audible warning signal to the OPERATOR of the completion of accumulated periods of LOADING. The TIMING DEVICE shall have the following characteristics:

1) it shall be possible to set the timing period of the device so as to permit LOADINGS with a maximum cumulative duration of 5 min without any warning being given. Provision may also be made for periods shorter than 5 min to be set. Any LOADING made without the device having been set and any LOADING made subsequently to the expiry of its most recently set period shall cause an audible warning signal to be given continuously while such LOADING is taking place;

2) it shall be possible to reset the device, without prevention or interruption of LOADING, in order to stop the warning and to permit further periods of LOADING, each not exceeding 5 min, to be accumulated, during which no warning is given;

3) any control for setting or resetting the time period shall be separate from any IRRADIATION SWITCH.

d) In addition to the TIMING DEVICE required in item c) above, means shall be provided to ensure automatic termination in the event of LOADING in RADIOSCOPY having continued without interruption for a period exceeding 10 min. In the event of termination being effected by these means in NORMAL CONDITION, it shall be possible to resume LOADING by releasing and re-actuating the IRRADIATION SWITCH.

e) * For a RADIOSCOPY IRRADIATION-EVENT of more than 0,5 s, the X-RAY EQUIPMENT shall terminate the LOADING within 0,1 s from the time the OPERATOR releases the control (e.g., by releasing pressure on a foot pedal). The shortest possible time is desirable.

For a RADIOSCOPY IRRADIATION-EVENT of 0,5 s or less, the X-RAY EQUIPMENT shall terminate the LOADING within 0,5 s from the time the OPERATOR releases the control (e.g., by releasing pressure on a foot pedal).

The instructions for use shall indicate the RADIOSCOPY IRRADIATION-EVENT times for which RADIOSCOPY can continue after the control is released, as described in 203.6.2.1 e), and the maximum amount of time that RADIOSCOPY can continue in each of the described cases.

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

Additional subclauses:

203.6.2.1.101 Charging mode INTERLOCK

Every MOBILE X-RAY EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorized persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present but battery charging is also possible in the absence of the key.

Compliance is checked by inspection.

203.6.2.1.102 Connections of external INTERLOCKS

X-RAY EQUIPMENT, except MOBILE X-RAY EQUIPMENT, shall be provided with connections for external electrical devices separate from the ME EQUIPMENT that either

– can prevent the X-RAY GENERATOR from starting to emit X-RADIATION,
– can cause the X-RAY GENERATOR to stop emitting X-RADIATION,
– or both.

If the state of the signals from these external electrical devices is not displayed on the CONTROL PANEL, the ACCOMPANYING DOCUMENTS shall contain information for the RESPONSIBLE ORGANISATION that this state should be indicated by visual means in the installation.

NOTE An example of the use of this facility would be to ensure the presence of PROTECTIVE SHIELDING during RADIOSCOPY.

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

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Addition:

If the normal termination depends upon a RADIATION measurement

– the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination, and

– either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and LOADING TIME shall be limited to not more than 60 kWs per IRRADIATION, or the CURRENT TIME PRODUCT shall be limited to not more than 600 mAs per IRRADIATION.

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

203.6.3 RADIATION dose and RADIATION quality

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Addition:

a) Systems for automatic control of LOADING FACTORS shall provide an adequate range of combinations of preselectable LOADING FACTORS, so that the automatic control is applied in ranges enabling the requirement of the collateral standard to be met.

b) In systems for automatic control of LOADING FACTORS and/or automatically controlled ADDITIONAL FILTRATION in RADIOSCOPY, the requirement of the collateral standard shall be considered to be met if

   – at least two appropriately differentiated levels of the controlled quantity can be selected, or

   – at least two appropriately differentiated levels of one characteristic LOADING FACTOR and/or automatically controlled ADDITIONAL FILTRATION, or appropriately differentiated functions of interdependent LOADING FACTORS and/or automatically controlled ADDITIONAL FILTRATION can be selected, or

   – additionally, manual control without the use of the AUTOMATIC CONTROL SYSTEM is possible.

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

203.6.3.2 Reproducibility of the RADIATION output

Additional subclauses:

203.6.3.2.101 Reproducibility of the RADIATION output in RADIOGRAPHY

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS.

Compliance is checked by the following test PROCEDURE:

Make 10 measurements of air kerma in 1 h under the test conditions according to subclause 203.6.3.2.103, at each of the test settings A, B, C and D according to Table 203.101.

Calculate the coefficient of variation for each of the measurement series and the average AIR KERMA for test settings C and D, to verify compliance.

203.6.3.2.102 Linearity and constancy in RADIOGRAPHY

a) Linearity of AIR KERMA over limited intervals of LOADING FACTORS

For operation in RADIOGRAPHY the quotients of the average of the MEASURED VALUES of AIR KERMA divided by the preselected values or the indicated values of CURRENT TIME PRODUCT, or the product of the values of X-RAY TUBE CURRENT and LOADING TIME, obtained

– at either two consecutive settings of LOADING TIME or X-RAY TUBE CURRENT or CURRENT TIME PRODUCT,

– or at any two settings of the above LOADING FACTORS when preselection is continuous and the preselected values differ by a factor as close as possible to but not exceeding 2,

shall not differ by more than 0,2 times the mean value of these quotients:

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{I_1 t_1} + \frac{\overline{K}_2}{I_2 t_2}}{2}$$

where

$\overline{K}_1$, $\overline{K}_2$ are the averages of the MEASURED VALUES of AIR KERMA;

Q_1 and Q_2 are the indicated CURRENT TIME PRODUCTS;

I_1 and I_2 are the indicated X-RAY TUBE CURRENTS;

t_1 and t_2 are the indicated LOADING TIMES.

Compliance is checked by the following test PROCEDURE:

Make 10 measurements of AIR KERMA in 1 h under the test conditions according to 203.6.3.2.103, at each of the test settings E and F according to Table 203.101.

Calculate the average value of AIR KERMA for the two measurements series. Use these average values and those for test settings C and D to verify compliance according to the formula.

Table 203.101 – Tests for verifying reproducibility and linearity

Test setting	A	B	C	D	E	F
X-RAY TUBE VOLTAGE	Lowest	Highest	50 % of highest	80 % of highest	50 % of highest	80 % of highest
X-RAY TUBE CURRENT *or* CURRENT TIME PRODUCT [a]	Highest	Lowest	Giving 1 µGy to 5 µGy [b]		Adjacent to setting for C and D	
LOADING TIME	Between 0,01 s and 0,32 s for all settings					

[a] As available with the settings defined in previous rows.

[b] DOSE values correspond to the air kerma in the IMAGE RECEPTION PLANE.

b) Reproducibility of automatic exposure controls for direct radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for DIRECT RADIOGRAPHY, the reproducibility shall comply with the following requirements, either:

– the coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05; or

– the variation of optical density in the resultant RADIOGRAMS shall not exceed a value of 0,10 for unchanged X-RAY TUBE VOLTAGE and constant thickness of the irradiated object.

Compliance is checked by the following test PROCEDURES:

i) *Compliance of coefficient of variation of MEASURED VALUES OF AIR KERMA:*

– *Test conditions*

Use the test conditions according to 203.6.3.2.103 with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Make 10 measurements of AIR KERMA in 1 h. Calculate the coefficient of variation of AIR KERMA.

ii) *Compliance of variation of optical density, see test PROCEDURE in item c).*

c) Consistency of automatic exposure controls for direct radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for DIRECT RADIOGRAPHY, the variation of optical density in the resultant RADIOGRAMS shall not exceed a value of

1) 0,15 arising from changes of the X-RAY TUBE VOLTAGE, the thickness of the irradiated object being constant,

2) 0,20 arising from changes in the thickness of the irradiated object, the X-RAY TUBE VOLTAGE being constant,

3) 0,20 arising from changes in both the X-RAY TUBE VOLTAGE and the thickness of the irradiated object.

Compliance is checked by the following test PROCEDURE:

i) *Method*

Measure the optical density of RADIOGRAMS of PHANTOMS made of water or other tissue equivalent material, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations of density for different PHANTOM thicknesses and for different X-RAY TUBE VOLTAGES.

ii) *Test arrangement*

Use a test arrangement with the following characteristics:

1) a FOCAL SPOT TO IMAGE RECEPTOR DISTANCE of 1 m or corresponding to the INTENDED USE, remaining unchanged for all tests in a series;

2) an 18 cm x 24 cm RADIOGRAPHIC CASSETTE as X-RAY IMAGE RECEPTOR, the same cassette being used for all tests in a series;

3) an X-RAY SOURCE ASSEMBLY of a type specified for use with the HIGH-VOLTAGE GENERATOR under test. The X-RAY FIELD is aligned and adjusted to 18 cm x 24 cm at the ENTRANCE SURFACE of the cassette and remains unchanged for all tests in a series;

4) provision for mounting the measuring chamber of the AUTOMATIC EXPOSURE CONTROL in a manner and position corresponding to the INTENDED USE;

5) provision of PHANTOMS of three different thicknesses, 10 cm, 15 cm and 20 cm, each of a size to cover the cassette fully, the PHANTOM in use for a particular test being mounted as close as possible to the ENTRANCE SURFACE of the cassette;

6) provision of a focused grid having the appropriate application limits;

7) provision for accurate and reproducible film processing and for measuring the optical density of the processed films.

iii) *Radiographic film and intensifying screen*

Use a combination of RADIOGRAPHIC FILM and INTENSIFYING SCREEN of a type specified to be suitable for the INTENDED USE of the AUTOMATIC EXPOSURE CONTROL.

For any one series of tests, select pieces of film from the same batch, for which consistency of characteristics has been verified.

iv) *Setting the automatic exposure control*

1) *Select the central field of the measuring chamber of the AUTOMATIC EXPOSURE CONTROL.*

2) *Make any adjustments required in accordance with the instructions for use to apply the density correction for the type of film-screen combination in use and to produce a measured optical density in the processed film of 1,1 to 1,3, when operating at an X-RAY TUBE VOLTAGE of 80 kV, using the 15 cm PHANTOM.*

v) *Selecting the X-RAY TUBE CURRENT*

Except when testing an AUTOMATIC EXPOSURE CONTROL that operates with a fixed LOADING TIME, select a value of X-RAY TUBE CURRENT that will result in LOADING TIMES during the tests exceeding three times the shortest specified LOADING TIME but not exceeding 1 s. Record any selected value.

If no suitable value of X-RAY TUBE CURRENT can be selected, use a different FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to enable the stated range of LOADING TIMES to be achieved with the available setting of X-RAY TUBE CURRENT closest to the determined suitable value.

vi) *Test LOADINGS*

Make eight test LOADINGS, using the combinations of X-RAY TUBE VOLTAGE and PHANTOM thickness indicated in Table 203.102 and four additional LOADINGS at 80 kV with 15 cm PHANTOM thickness. Process the films; measure and record the optical density of each image.

Table 203.102 – LOADINGS for testing automatic exposure controls

X-RAY TUBE VOLTAGE [a] kV	PHANTOM thicknesses cm
60 [b]	10 and 15
80	15 and 20
100	15 and 20
120 [b]	10 and 15

[a] If any of these values are not selectable, use the nearest selectable value.

[b] If this value is outside the specified range, use the nearest value within the specified range and select other values as evenly spaced as possible in the reduced range.

vii) *Compliance criteria*

Compliance is achieved if

1) for the four LOADINGS made with the 15 cm PHANTOM with different X-RAY TUBE VOLTAGES, no MEASURED VALUE of optical density differs by more than 0,15 from the mean of the four values and no value differs by more than 0,15 from the value for an adjacent step of X-RAY TUBE VOLTAGE,

2) for each of the four pairs of LOADINGS made at the same X-RAY TUBE VOLTAGE (with PHANTOMS of different thickness), no MEASURED VALUE of optical density differs by more than 0,2 from the other value in the pair,

3) for the whole series of eight LOADINGS, no MEASURED VALUE of optical density differs by more than 0,2 from the mean of the eight values,

4) for five LOADINGS at constant test parameters, 80 kV with 15 cm PHANTOM thickness, no MEASURED VALUE of optical density differs by more than 0,1 from the mean value of the five values.

d) Reproducibility of automatic exposure controls for indirect radiography

In the operation of an AUTOMATIC EXPOSURE CONTROL in RADIOGRAPHY to control IRRADIATION for INDIRECT RADIOGRAPHY with DIGITAL X-RAY IMAGING DEVICES, the reproducibility shall comply with one of the following requirements:

– either the ratio between the highest and the lowest MEASURED VALUES of AIR KERMA shall be less than 1,2; or

– with integrated DIGITAL X-RAY IMAGING DEVICES the ratio between the highest and the lowest mean LINEARIZED DATA on a constant REGION OF INTEREST shall be less than 1,2 for constant X-RAY TUBE VOLTAGE and constant thickness of the irradiated object; or

– with integrated DIGITAL X-RAY IMAGING DEVICES and if the EXPOSURE INDEX according to IEC 62494-1:2008 is displayed the ratio between the highest and the lowest EXPOSURE INDEX in the RELEVANT IMAGE REGION shall be less than 1,2 for constant X-RAY TUBE VOLTAGE and constant thickness of the irradiated object.

Compliance is checked by the following test PROCEDURES:

i) *Compliance of ratio of MEASURED VALUES of AIR KERMA:*

– *Test conditions*

Use the test conditions according to 203.6.3.2.103 with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Make 10 measurements of AIR KERMA in 1 h. Calculate the ratio between the highest and the lowest MEASURED VALUES of AIR KERMA.

ii) *Compliance of ratio in the mean LINEARIZED DATA or EXPOSURE INDEX:*

– *Test conditions*

Use the X-RAY EQUIPMENT in conditions representative of the specified INTENDED USE, in terms of geometric settings and selection of MODE OF OPERATION, the PATIENT being replaced by a PHANTOM made of PMMA, the section and thickness of which match this INTENDED USE.

As a minimum, a PHANTOM with a thickness of 20 cm and a square area of 25 cm × 25 cm shall be used, with an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE, or 80 kV if manually adjustable.

Acquire 10 images per set of conditions. Calculate the ratio between the highest and the lowest mean LINEARIZED DATA or EXPOSURE INDEX.

203.6.3.2.103 Conditions for measuring AIR KERMA

203.6.3.2.103.1 Measuring arrangements

Arrange the HIGH-VOLTAGE GENERATOR or subassembly under test in a suitable combination with an X-RAY SOURCE ASSEMBLY (and, if applicable, with other subassemblies needed to constitute an X-RAY GENERATOR) specified in the ACCOMPANYING DOCUMENTS of the unit under test as suitable for this purpose.

Align the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR under NARROW BEAM CONDITION.

Arrange the attenuating material needed near the X-RAY SOURCE ASSEMBLY or select the attenuating material specified in 203.6.3.2.103.2 b). Verify the RADIATION QUALITY according to 203.6.3.2.103.2 a).

203.6.3.2.103.2 ATTENUATION and RADIATION QUALITY for measurement of AIR KERMA

a) *Radiation quality*

Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with the HALF-VALUE LAYER requirements in IEC 60601-1-3:2008, Table 3, as applicable.

b) *Attenuation*

To simulate the presence of a PATIENT during the measurement of AIR KERMA, add a layer of aluminium with a thickness related to the selected X-RAY TUBE VOLTAGE in accordance with Table 203.103 and of sufficient size to intercept the whole of the X-RAY BEAM.

Table 203.103 – ATTENUATION for the measurement of AIR KERMA

X-RAY TUBE VOLTAGE up to and including kV	Thickness of aluminium mm
40	4
50	10
60	16
70	21
80	26
90	30
100	34
120	40
150	45
NOTE RADIATION QUALITIES RQA 2 to RQA 10, IEC 61267:2005. [2] [1)]	

203.6.3.101 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

ME EQUIPMENT designed for RADIOSCOPY shall be provided with means for the available combinations of LOADING FACTORS in RADIOSCOPY to be restricted to correspond, in particular installations, to any limit on the maximum AIR KERMA RATE that is necessary to comply with local regulations.

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

203.6.3.102 * High-level control (HLC)

If X-RAY EQUIPMENT specified for RADIOSCOPY include MODES OF OPERATION designed to produce REFERENCE AIR KERMA RATES greater than 88 mGy/min or than those REFERENCE AIR KERMA RATES specified in 203.6.3.101, these MODES OF OPERATION, described as high-level controls, shall be operable only when the OPERATOR provides continuous manual activation. When a high-level control is provided, a continuous signal audible to the OPERATOR shall indicate that the high-level control is being activated. When high-level controls are activated, the X-RAY EQUIPMENT shall not be operable at any combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT that will result in a REFERENCE AIR KERMA RATE in excess of 176 mGy/min.

1) Figures in square brackets refer to the bibliography.

For the application of this requirement to C-arm X-RAY EQUIPMENT, the REFERENCE AIR KERMA RATE shall be replaced by the AIR KERMA RATE measured at 30 cm from the ACCESSIBLE SURFACE of the X-RAY IMAGE RECEPTOR.

NOTE Lower limits can be applicable according to different local regulations.

Compliance is checked by inspection and tests. Tests shall be performed by measurement of the maximum entrance REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT for non-C-arm X-RAY EQUIPMENT, and, for C-arm X-RAY EQUIPMENT, at the point specified above.

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.

Compliance is checked by inspection.

203.6.4.3 Indication of loading factors and modes of operation

Additional subclauses:

203.6.4.3.101 General requirements for the indication of LOADING FACTORS

The units of indication shall be as follows:

– for X-RAY TUBE VOLTAGE, kilovolts;
– for X-RAY TUBE CURRENT, milliamperes;
– for LOADING TIME, seconds and/or milliseconds;
– for CURRENT TIME PRODUCT, milliampereseconds;
– in RADIOSCOPY, the LOADING TIME may be indicated in minutes and seconds or decimally in minutes.

If pulse rate or pulse width in pulsed RADIOSCOPY is selectable, then the units of indication shall be as follows:

– for duration of X-RADIATION pulse, milliseconds;
– for X-RADIATION pulse repetition frequency, number of pulses per second.

Compliance is checked by inspection.

203.6.4.3.102 Shortened indication of LOADING FACTORS

a) For HIGH-VOLTAGE GENERATORS operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

   In this case, the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the instructions for use.

   In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

b) For HIGH-VOLTAGE GENERATORS operating with fixed combinations of semi-permanently preselectable (such as anatomic programmable) LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination.

In this case, provisions shall be made to enable

– the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the instructions for use, and in addition to enable

– the values to be listed in a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.

Compliance is checked by inspection.

203.6.4.3.103 Indication of varying LOADING FACTORS

For HIGH-VOLTAGE GENERATORS operating with AUTOMATIC INTENSITY CONTROL in RADIOSCOPY, continuous indication of the LOADING FACTORS that vary shall be given at the CONTROL PANEL.

Compliance is checked by inspection.

203.6.4.3.104 Accuracy of LOADING FACTORS

203.6.4.3.104.1 General aspects for the accuracy of LOADING FACTORS

In HIGH-VOLTAGE GENERATORS the requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is checked by inspection and tests.

203.6.4.3.104.2 Accuracy of LOADING FACTORS in automatic control mode

In X-RAY EQUIPMENT with AUTOMATIC CONTROL SYSTEMS when the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT, or both, is intended to vary during the IRRADIATION, the accuracy of the intentionally varied LOADING FACTOR required in 203.6.4.3.104.3 and 203.6.4.3.104.4, shall be disregarded.

203.6.4.3.104.3 Accuracy of X-RAY TUBE VOLTAGE

For operation of a HIGH-VOLTAGE GENERATOR in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE VOLTAGE, in any combination of LOADING FACTORS, shall be not greater than 8 %.

The increment or decrement of the X-RAY TUBE VOLTAGE between any two indicated settings shall be within 50 % and 150 % of the indicated change.

Compliance is checked by the following test PROCEDURE, using a test instrument with appropriate uncertainty:

a) *RADIOGRAPHY*

One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and the shortest indicated value of LOADING TIME.

One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

One measurement shall be made at the highest indicated value of X-RAY TUBE VOLTAGE and the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

b) *RADIOSCOPY*

One measurement shall be made at 90 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

One measurement shall be made at 60 % of the maximum available X-RAY TUBE VOLTAGE and any X-RAY TUBE CURRENT.

203.6.4.3.104.4 Accuracy of X-RAY TUBE CURRENT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE CURRENT, in any combination of LOADING FACTORS, shall be not greater than 20 %.

Compliance is checked by the following test PROCEDURE:

a) RADIOGRAPHY

One measurement shall be made at the lowest indicated value of X-RAY TUBE CURRENT, the highest indicated value of X-RAY TUBE VOLTAGE and the shortest indicated value of LOADING TIME.

One measurement shall be made at the lowest indicated value of X-RAY TUBE CURRENT, the highest indicated value of X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 0,1 s.

One measurement shall be made at the highest indicated value of X-RAY TUBE CURRENT, the highest available X-RAY TUBE VOLTAGE for the tested X-RAY TUBE CURRENT and a LOADING TIME of approximately 0,1 s.

b) RADIOSCOPY

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the lowest available X-RAY TUBE VOLTAGE.

One measurement shall be made at 20 % of the maximum available X-RAY TUBE CURRENT and the highest available X-RAY TUBE VOLTAGE.

203.6.4.3.104.5 Accuracy of LOADING TIME

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE LOADING TIME, in any combination of LOADING FACTORS, shall be not greater than ± (10 % + 1 ms).

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest indicated value of LOADING TIME, the highest indicated value of X-RAY TUBE VOLTAGE and any indicated value of X-RAY TUBE CURRENT.

One measurement shall be made at the lowest indicated value of LOADING TIME and the highest available electric power, P.

203.6.4.3.104.6 Accuracy of CURRENT TIME PRODUCT

For operation of HIGH-VOLTAGE GENERATORS in any specified combination with subassemblies and components of an X-RAY GENERATOR, the error in the indicated value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.105 Indication of ADDED FILTERS

If the X-RAY EQUIPMENT has provisions to select ADDED FILTERS by remote control or through an automatic system, the selected ADDED FILTER shall be indicated to the OPERATOR at a location appropriate for the INTENDED USE. If the FILTER change is automatic, it may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and functional tests.

203.6.4.3.106 * Electronic documentation of EXAMINATION PROTOCOLS

X-RAY EQUIPMENT that includes EXAMINATION PROTOCOL SELECTION CONTROL should provide access to the electronic documentation of those parameters invoked by each available PRE-PROGRAMMED EXAMINATION PROTOCOL in a defined format file (e.g., xml format, comma-separated format, space-separated format) and export to an output device. This electronic documentation should include the selected settings for each adjustable or selectable parameter in each PRE-PROGRAMMED EXAMINATION PROTOCOL.

Data elements incorporated in the electronic documentation should also include the date of configuration of the set of PRE-PROGRAMMED EXAMINATION PROTOCOLS.

If access to modify the PRE-PROGRAMMED EXAMINATION PROTOCOLS is provided, means shall be provided to track the date of the last change, and means shall be provided to enter an identifier for the agent responsible for the change.

X-RAY EQUIPMENT that provides electronic documentation of EXAMINATION PROTOCOLS shall provide either:

– access to a media output device; or
– access to a networked output device to transmit the electronic documentation through.

NOTE Additional equipment can be applicable (e.g., PC, CD/DVD drive, approved USB device, laptop wired by Ethernet connection, etc.) to enable export.

If a PRE-PROGRAMMED EXAMINATION PROTOCOL contains adjustable or selectable parameters, the MANUFACTURERS default value of each such parameter shall be provided.

Means should be recommended or provided to allow flagging differences between two or more PRE-PROGRAMMED EXAMINATION PROTOCOLS to assist in the local review and clinical audit process.

The means may be external to the X-RAY EQUIPMENT and, if so, it does not need to be considered a medical device.

Compliance is checked by inspection and appropriate functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For X-RAY EQUIPMENT operating in RADIOGRAPHY in which AUTOMATIC EXPOSURE CONTROL is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

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

203.6.4.5 * Dosimetric indications

Addition:

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

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

- The value of the REFERENCE AIR KERMA RATE shall be displayed during RADIOSCOPY 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.

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY and/or SERIAL RADIOGRAPHY shall be provided with an indication of the cumulative DOSE AREA PRODUCT resulting from RADIOGRAPHY and, when applicable, from RADIOSCOPY since the last reset operation. The DOSE AREA PRODUCT may be measured or calculated. The value shall be expressed in $Gy \cdot m^2$ with appropriate SI prefixes. The overall uncertainty in the displayed values of the cumulative DOSE AREA PRODUCT above 5 $\mu Gy \cdot m^2$ shall not exceed 35 %.

This DOSE AREA PRODUCT indication need not be provided at the working position of the OPERATOR.

X-RAY EQUIPMENT specified for INDIRECT RADIOGRAPHY shall be provided with an indication of the DOSE AREA PRODUCT for each exposure. The DOSE AREA PRODUCT may be measured or calculated.

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

X-RAY EQUIPMENT specified for DIRECT RADIOGRAPHY should satisfy the same requirement as specified above for INDIRECT RADIOGRAPHY. Alternatively, the following minimal requirements may be met:

– The value of the REFERENCE AIR KERMA resulting from the last radiographic IRRADIATION shall be displayed in mGy together with this unit, until initiation of the next radiographic IRRADIATION.

– Means shall be provided allowing the determination of the area of the X-RAY FIELD in the plane normal to the X-RAY BEAM AXIS containing the PATIENT ENTRANCE REFERENCE POINT, based on the available information concerning the extent of the X-RAY BEAM. The maximum deviation between the value determined using these means and the actual value shall be less than 40 % of the actual value for areas larger than 200 cm^2.

NOTE Examples of such means are tables, nomograms, programmable calculators or computers together with the relevant program.

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.

Additional subclauses:

203.6.4.5.101 Radiation dose structured reports

X-RAY EQUIPMENT specified for RADIOGRAPHY or RADIOSCOPY or RADIOGRAPHY and RADIOSCOPY should create RADIATION DOSE STRUCTURED REPORTS (RDSR) and have the ability to perform an RDSR END OF PROCEDURE TRANSMISSION. If RDSR is provided, it shall conform to at least the basic dose documentation specified in IEC 61910-1. The relevant elements for the specified type of X-RAY EQUIPMENT and for which data are available shall be populated with relevant data.

Compliance is checked by functional tests.

203.6.4.101 Indication of READY STATE

Visible indication shall be provided indicating the state when one further actuation of a control will initiate the LOADING of the X-RAY TUBE in RADIOGRAPHY.

If this state is indicated in RADIOGRAPHY by means of a single function visual indicator, the colour green shall be used.

In RADIOGRAPHY, means should be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for MOBILE X-RAY EQUIPMENT.

Compliance is checked by inspection.

203.6.5 AUTOMATIC CONTROL SYSTEM

Addition:

X-RAY EQUIPMENT specified for INDIRECT RADIOGRAPHY shall be provided with AUTOMATIC EXPOSURE CONTROL unless the MANUFACTURER provides justifications for exemptions in the RISK MANAGEMENT FILE.

NOTE Justifications for exemptions can be motivated by technical reasons (e.g., MOBILE systems).

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY shall be provided with AUTOMATIC INTENSITY CONTROL. It shall be possible to limit the maximum REFERENCE AIR KERMA RATE to values given by local rules. For X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY in which AUTOMATIC CONTROL SYSTEMS vary one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

For X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL, a method by which the OPERATOR can verify the functioning of these controls shall be provided and the instructions for use shall contain the description of that method.

For X-RAY EQUIPMENT provided with AUTOMATIC INTENSITY CONTROL, a QUALITY CONTROL mode shall be provided that enables selection of values, either by a manual control mode or by selecting preset combination values, of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT or X-RAY CURRENT TIME PRODUCT, LOADING TIME, ADDITIONAL FILTRATION if any and FOCAL SPOT size if selectable.

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

Additional subclause:

203.6.5.101 Determination of the NOMINAL SHORTEST IRRADIATION TIME

For X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL the NOMINAL SHORTEST IRRADIATION TIME as defined in 203.4.101.4 shall be stated in the instructions for use. The MEASURED VALUE shall not be greater than the stated value.

Compliance is checked by inspection of the instructions for use and the following test PROCEDURE:

Make an IRRADIATION using the AUTOMATIC EXPOSURE CONTROL with > 70 % of the available generator power at approximately 80 kV. To determine the average AIR KERMA, adjust the ATTENUATION in the X-RAY BEAM (preferably by using a water PHANTOM) to achieve a LOADING TIME close to 0,1 s.

Make several IRRADIATIONS with reduced PHANTOM thicknesses using the same X-RAY TUBE VOLTAGE and generator power as mentioned above. The PHANTOM thickness shall be varied in such a way that the LOADING TIME does not vary more than a factor of two between two IRRADIATIONS.

203.6.6 SCATTERED RADIATION reduction

Replacement:

Means shall be provided to reduce the influence of RADIATION scattered in the PATIENT to the X-RAY IMAGE RECEPTOR in case of significant influence on the image quality. If such means are ANTI-SCATTER GRIDS which are removable by the OPERATOR, or that can be moved in or out under manual or automatic control by a motorized mechanism, the presence or absence of the ANTI-SCATTER GRID shall be clearly visible or indicated. If the ANTI-SCATTER GRID is removable, it shall be possible to remove and replace it without the use of TOOLS.

Means shall be provided for using X-RAY EQUIPMENT specified for paediatric applications without an ANTI-SCATTER GRID.

If different ANTI-SCATTER GRIDS can be used, it shall be possible for the OPERATOR to identify the grid in place.

The proper use of such means shall be described in the instructions for use.

Compliance is checked by inspection.

203.6.7 Imaging performance

Additional subclause:

203.6.7.101 Display of last image hold radiogram or radioscopy replay image sequence

X-RAY EQUIPMENT specified for INDIRECT RADIOSCOPY shall display either a LIH RADIOGRAM or a RADIOSCOPY REPLAY IMAGE SEQUENCE following termination of the radioscopic IRRADIATION, and shall comply with the following.

1) The LIH RADIOGRAM or RADIOSCOPY REPLAY IMAGE SEQUENCE shall be displayed following termination of the radioscopic IRRADIATION and shall remain visible until an action is taken by the OPERATOR.
2) Means shall be provided to clearly indicate to the OPERATOR whether a displayed image is:
   – an LIH RADIOGRAM or 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 initiation of the radioscopic IRRADIATION.

Compliance is checked by inspection and functional tests.

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Addition:

X-RAY EQUIPMENT specified for paediatric applications shall be provided with means for placing an ADDED FILTER of not less than 0,1 mm Cu or 3,5 mm Al.

NOTE An appropriate permanently mounted FILTER, not removable by the OPERATOR, satisfies the above requirement.

Compliance is checked by inspection, by examination of the ACCOMPANYING DOCUMENTS and by the use, as appropriate, of the test described in 7.5 of IEC 60601-1-3:2008.

Additional subclause:

203.7.1.101 Filtration in X-ray source assemblies

X-RAY SOURCE ASSEMBLIES shall comply with the following requirements:

– unless solely intended for use in MOBILE X-RAY EQUIPMENT specified for RADIOSCOPY or for RADIOGRAPHY and RADIOSCOPY during surgery, X-RAY SOURCE ASSEMBLIES shall be provided with means to mount, to dismount, or to select one or more ADDED FILTERS, without the use of TOOLS. Any such selectable ADDED FILTERS shall comply with the following requirements:
  a) they shall be identifiable when in position for the INTENDED USE;
  b) if a selectable ADDED FILTER is necessary to attain the requirements for TOTAL FILTRATION in X-RAY EQUIPMENT, given in 7.1 of IEC 60601-1-3:2008, means shall be provided to enable the presence of the appropriate selectable ADDED FILTER to be detected by the control system of an associated HIGH-VOLTAGE GENERATOR and LOADING prevented if the necessary ADDED FILTER is not detected;

– the ACCOMPANYING DOCUMENTS shall include, in the ASSEMBLING INSTRUCTIONS given for particular applications, instructions for attaining the TOTAL FILTRATION required to comply with 7.1 of IEC 60601-1-3:2008 in respect of the items of X-RAY EQUIPMENT concerned.

Compliance is checked by inspection, by examination of the ACCOMPANYING DOCUMENTS and by the use, as appropriate, of the test described in 7.6 of IEC 60601-1-3:2008.

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

Addition:

X-RAY SOURCE ASSEMBLIES shall be so constructed that the zone of intersection of all straight lines that pass through all RADIATION APERTURES of the X-RAY SOURCE ASSEMBLY, with a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT shall not extend more than 15 cm outside the boundary of the largest selectable X-RAY FIELD.

Compliance is checked by examination of the design documentation. In Figure 203.101, w_1 represents the width of the largest selectable X-RAY FIELD in a plane P*, which is perpendicular to the REFERENCE AXIS at 1 m from the FOCAL SPOT. The zone of intersection with plane* P *of all straight lines passing through all RADIATION APERTURES extends beyond w_1 by the distance w_2. The shaded portion of this zone is a region where EXTRA-FOCAL RADIATION can extend beyond the largest X-RAY FIELD. Compliance is achieved if w_2 does not exceed 15 cm.*

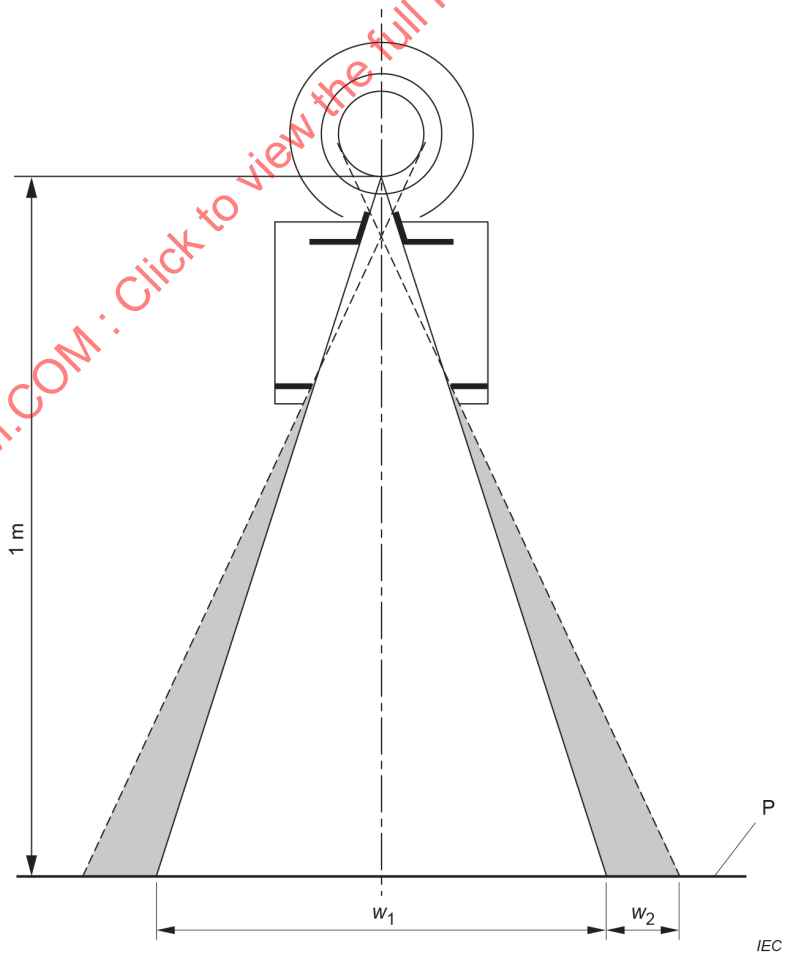


Figure 203.101 – Zone of EXTRA-FOCAL RADIATION

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

Addition:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the REGION OF INTEREST and, where applicable, the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL or AUTOMATIC INTENSITY CONTROL.

If the X-RAY FIELD is adjusted in the INTENDED USE for full coverage of the IMAGE RECEPTION AREA, it shall correspond to the IMAGE RECEPTION AREA within the following limits, as applicable:

– If the IMAGE RECEPTION AREA is circular, the X-RAY FIELD shall coincide with the IMAGE RECEPTION AREA as required in a) and b).

  a) the X-RAY FIELD measured along a diameter 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; and

  b) at least 80 % of the area of the X-RAY FIELD shall overlap the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION areas smaller than 10 cm in diameter are exempted.

  X-RAY EQUIPMENT specified for gastro-intestinal examinations with SPOTFILM DEVICES using also rectangular X-RAY IMAGE RECEPTORS need not comply with this requirement, but neither the length nor the width of the X-RAY FIELD shall exceed the diameter of the IMAGE RECEPTION AREA.

– In X-RAY EQUIPMENT specified for RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, in which

  a) there is provision for RADIOGRAPHY using a RADIOGRAPHIC CASSETTE holder, with beam limitation to a circular X-RAY FIELD for use on a rectangular IMAGE RECEPTION AREA; and

  b) the orientation of the IMAGE RECEPTION AREA is selectable; and

  c) the maximum diameter of the X-RAY FIELD does not exceed 40 cm,

  the diameter of the X-RAY FIELD may exceed the diagonal dimension of the IMAGE RECEPTION AREA by an amount not exceeding 2 cm. If the RADIOGRAPHIC CASSETTE holder can extend beyond the edges of the PRIMARY PROTECTIVE SHIELDING, a warning of this fact shall be stated in the instructions for use.

– In cases where the X-RAY FIELD does not correspond to the IMAGE RECEPTION AREA in accordance with one of the categories above, the following requirements apply:

  a) along each of the two major axes of the IMAGE RECEPTION AREA, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall not exceed 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTION PLANE is normal to the X-RAY BEAM AXIS;

  b) the sum of the discrepancies on both axes shall not exceed 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

NOTE If a secondary BEAM LIMITING DEVICE is used between PATIENT and X-RAY IMAGE RECEPTOR, this requirement refers to the percentage of the RADIATION reaching the IMAGE RECEPTION AREA relative to the RADIATION in front of the secondary BEAM LIMITING DEVICE.

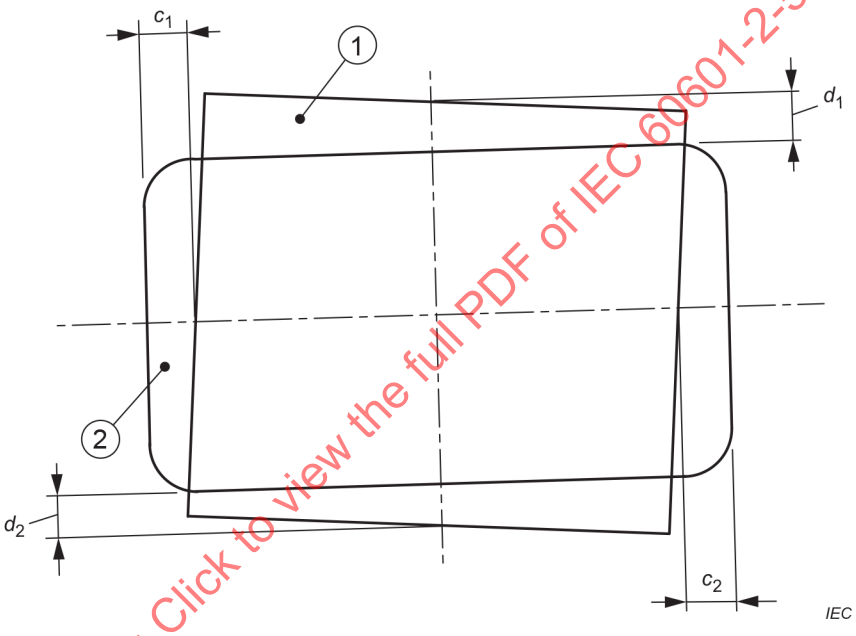
Compliance is checked with the relevant requirements above, by inspection of the ME EQUIPMENT, by examination of the instructions for use and by measurement of the X-RAY FIELDS, where appropriate. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, for the automatic mechanism to complete any adjustment occurring during the tests.

When determining compliance with the requirements at a) and b) of the last scenario above, make the measurements with the REFERENCE AXIS *normal to the* IMAGE RECEPTION PLANE *within three degrees. As shown in Figure 203.102, the measured discrepancies in the* IMAGE RECEPTION PLANE *are represented by c_1 and c_2 on one axis and by d_1 and d_2 on the other. If the* FOCAL SPOT TO IMAGE RECEPTOR DISTANCE *is S, then for compliance, the following relationships are true:*

$$|c_1| + |c_2| \leq 0{,}03 \times S$$

$$|d_1| + |d_2| \leq 0{,}03 \times S$$

$$|c_1| + |c_2| + |d_1| + |d_2| \leq 0{,}04 \times S$$



1 X-ray-field

2 IMAGE RECEPTION AREA

Figure 203.102 – Discrepancies in covering the IMAGE RECEPTION AREA

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Addition:

X-RAY EQUIPMENT shall be designed in a way that the OPERATOR is able to select an X-RAY BEAM of the extent required for the applications concerned and for limiting the maximum available extent of the X-RAY BEAM to values that are consistent with the specified applications to avoid unnecessary RADIATION doses to the PATIENT and the staff.

Additional subclauses:

203.8.101 Boundary and dimensions of the X-RAY FIELD

The boundary of an X-RAY FIELD is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

The dimensions of a rectangular X-RAY FIELD are described in terms of the lengths of its intercepts on each of two orthogonal major axes in the plane of interest. Given that the X-RAY BEAM AXIS coincides with the REFERENCE AXIS, it is assumed that the plane of interest is orthogonal to the REFERENCE AXIS; also that the major axes intersect on the REFERENCE AXIS and are oriented so that one axis is collinear with the projection of the longitudinal axis of the X-RAY TUBE ASSEMBLY lying in the plane and passing through this point of intersection. If the X-RAY BEAM AXIS does not coincide with the REFERENCE AXIS, according to 203.8.104 this shall be stated in the instructions for use.

For circular X-RAY FIELDS the dimensions are described accordingly by replacing the lengths of the intercepts with the diameter.

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

203.8.102.1 General

In X-RAY EQUIPMENT there shall be means to limit the extent of the X-RAY BEAM before impinging on the PATIENT SURFACE, as applicable:

– in X-RAY EQUIPMENT specified solely for RADIOGRAPHY with a single IMAGE RECEPTION AREA at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, by means of a FIXED BEAM LIMITING DEVICE having a RADIATION APERTURE of a single FIXED size. In X-RAY EQUIPMENT using a scanning beam, by a BEAM LIMITING DEVICE positioned between the RADIATION SOURCE and the PATIENT SURFACE;

– in X-RAY EQUIPMENT specified for RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and having an IMAGE RECEPTION AREA not exceeding 300 cm^2, by means of enabling the X-RAY FIELD at the IMAGE RECEPTION PLANE to be reduced to 125 cm^2 or less;

– by means of a range of interchangeable or selectable components enabling RADIATION APERTURES of various FIXED sizes to be chosen;

– by means of a BEAM LIMITING DEVICE enabling the extent of the X-RAY BEAM to be adjusted within the range of NORMAL USE, by manual or automatic means, and having the following characteristics:

  a) a minimum selectable size of the X-RAY FIELD not exceeding 5 cm in length and width, in a plane orthogonal to the X-RAY BEAM AXIS at a distance of 1 m from the FOCAL SPOT;

  b) if the adjustment is not stepless, selectable steps not exceeding 1 cm in the length and width of the X-RAY FIELD, in a plane orthogonal to the REFERENCE AXIS at a distance of 1 m from the FOCAL SPOT;

  c) if the adjustment is automatic, means enabling the OPERATOR to select sizes of the X-RAY FIELD according to a) and b) above, while not permitting the OPERATOR to increase the size beyond the currently selected IMAGE RECEPTION AREA. The operation of these means shall be described in the instructions for use.

Where automatic adjustment is provided, the instructions for use shall contain details of a method by which its operation can be checked and shall describe the method by which the size of the X-RAY FIELD can be reduced, as required in item c) above.

Compliance is checked by inspection and functional test and by examination of the instructions for use.

203.8.102.2 Indication on the X-RAY EQUIPMENT

Except as stated in item a) to item c) below, information concerning the extent of the X-RAY BEAM shall be indicated by DISPLAY on the X-RAY EQUIPMENT.

Indications on the X-RAY EQUIPMENT shall give the following information numerically or by means of graphical markings or symbols:

– if numerical markings are used, they shall show the lengths and widths of the available X-RAY FIELDS at one or more typical values of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE. Information shall also be included (and can, e.g., be in tabular form) concerning the variation of the dimensions of X-RAY FIELDS with respect to other relevant FOCAL SPOT TO IMAGE RECEPTOR DISTANCES;

– if the indication is given by graphical markings or symbols, these shall show on an appropriate surface (which can, e.g., be the ENTRANCE SURFACE of a device containing the X-RAY IMAGE RECEPTOR), how the resultant X-RAY FIELDS are related to the FOCAL SPOT TO IMAGE RECEPTOR DISTANCES and the selectable combinations or settings of BEAM LIMITING DEVICES. If the markings do not show explicitly the extent or dimensions of the X-RAY FIELDS to be obtained, this information shall be given with an explanation of the markings in the instructions for use.

Indication by DISPLAY on the X-RAY EQUIPMENT need not be given in the following cases:

a) X-RAY EQUIPMENT so constructed that the X-RAY FIELDS at the distances of interest are obtained, prior to LOADING, without selection by the OPERATOR;

b) X-RAY EQUIPMENT constructed with an INTERLOCK that prevents LOADING unless an X-RAY FIELD of appropriate extent has been selected;

c) for modes of operation of X-RAY EQUIPMENT in which the boundaries of the X-RAY FIELD can be displayed in RADIOSCOPY.

X-RAY EQUIPMENT specified for RADIOSCOPY should 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.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.8.102.3 Indication in the instructions for use

The instructions for use shall contain the information necessary to enable the OPERATOR to determine, prior to LOADING, the extent of all X-RAY FIELDS for the INTENDED USE, in terms of their dimensions at appropriate FOCAL SPOT TO IMAGE RECEPTOR DISTANCES for the available selections, combinations and settings of the BEAM LIMITING DEVICES.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the instructions for use.

203.8.102.4 Accuracy of marked and written indications

Unless exempted below, the size of the X-RAY FIELD given by markings on the X-RAY EQUIPMENT or by statements in the instructions for use in accordance with 203.8.102.2 and 203.8.102.3 shall not differ from the size of the X-RAY FIELD, measured along each of its two major axes in the plane to which the indication relates, by more than 2 % of the distance of that plane from the FOCAL SPOT.

This requirement is not applicable for X-RAY EQUIPMENT in which the whole area of the RADIOGRAM is not irradiated simultaneously.

Compliance is checked by inspection of design data and by examination of the ACCOMPANYING DOCUMENTS. Where appropriate, measure the dimensions of the X-RAY FIELD along its two major axes, at selected indicated settings of the BEAM LIMITING SYSTEM and of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, as available for the INTENDED USE. For the purpose of calculation, assume the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to be equal to the value indicated on the X-RAY EQUIPMENT or stated in the ACCOMPANYING DOCUMENTS, for the setting used.

203.8.102.5 Indication by LIGHT FIELD-INDICATOR

In X-RAY EQUIPMENT specified for RADIOGRAPHY, a LIGHT FIELD-INDICATOR shall be provided where appropriate, to assist in delineating the position of the X-RAY FIELD on the PATIENT SURFACE.

Compliance is checked by inspection of the X-RAY EQUIPMENT.

If a LIGHT FIELD-INDICATOR is provided, it shall delineate the edges of the X-RAY FIELD and it shall provide an average illumination of not less than 100 lx in a plane normal to the X-RAY BEAM AXIS at a distance of 1 m from the FOCAL SPOT.

At this distance, the contrast at the edge of the LIGHT FIELD as defined below shall have a value of not less than 3 in MOBILE X-RAY EQUIPMENT and not less than 4 in other X-RAY EQUIPMENT.

The edge of a LIGHT FIELD is described by the locus of points at which the illumination is 25 % of the maximum illumination.

The description of a method to check the dimensions of the LIGHT FIELD at the appropriate distance from the FOCAL SPOT shall be included in the ACCOMPANYING DOCUMENTS.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the following test:

- *check that light-attenuating components as specified by the MANUFACTURER, e.g. the IONIZATION CHAMBER of a DOSE AREA PRODUCT meter, are in place.*
- *if the whole area of the indicated field is illuminated, determine the average illumination as the mean value from measurements in the approximate centre of each quarter of the LIGHT FIELD;*
- *in all other cases, determine the average illumination from at least four measurements at different points in the centres of the illuminated areas;*
- *measure the contrast, using a measuring aperture not larger than 1 mm. Take the contrast as I_1/I_2, where I_1 is the illumination 3 mm from the edge of the LIGHT FIELD towards the centre of the field and I_2 is the illumination 3 mm from the edge of the LIGHT FIELD away from the centre of the field;*
- *correct the MEASURED VALUES for ambient illumination.*

203.8.102.6 Accuracy of indication with a LIGHT FIELD-INDICATOR

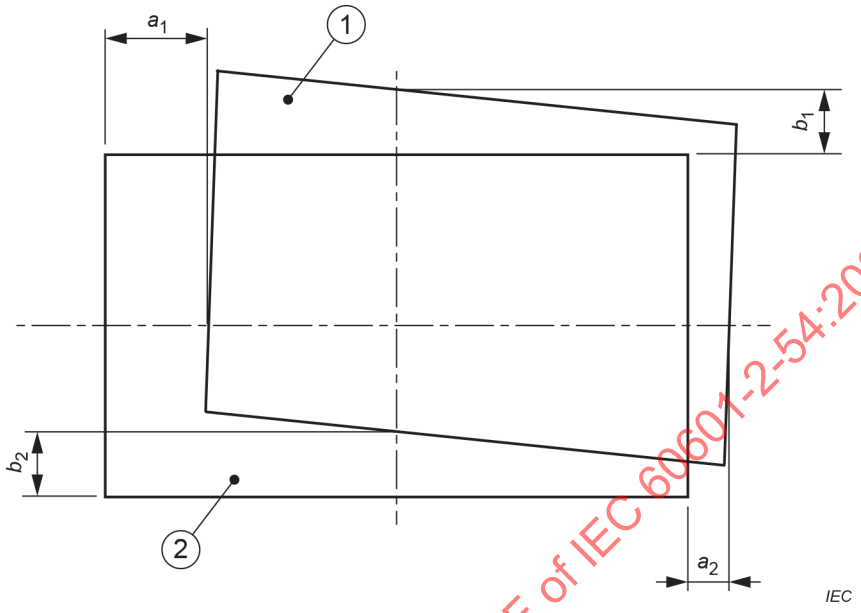
Along each of the two major axes of the X-RAY FIELD in the plane of the LIGHT FIELD, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the LIGHT FIELD shall not exceed 2 % of the distance of the measurement plane of the LIGHT FIELD from the FOCAL SPOT.

Compliance is checked by measurement, on the two major axes of the X-RAY FIELD, of the discrepancies between corresponding edges of the X-RAY FIELD and the LIGHT FIELD, in selected planes at measured distances from the FOCAL SPOT, within the range of NORMAL USE, and normal to the X-RAY BEAM AXIS within three degrees.

Referring to Figure 203.103, the measured discrepancies are represented by a_1 and a_2 on one axis and by b_1 and b_2 on the other. If the distance from the FOCAL SPOT to the measurement plane of the LIGHT FIELD is S, then, for compliance, the following relationships are true:

$$|a_1| + |a_2| \leq 0{,}02 \times S$$

$$|b_1| + |b_2| \leq 0{,}02 \times S$$



1 Visually defined field

2 X-RAY FIELD

Figure 203.103 – Discrepancies in visual indication of the X-RAY FIELD

203.8.103 Interception of the X-RAY BEAM in RADIOSCOPY

LOADING in RADIOSCOPY shall be prevented unless the X-RAY BEAM AXIS is in the position at which the correspondence of the X-RAY FIELD to the EFFECTIVE IMAGE RECEPTION AREA is specified to be in compliance with 203.8.5.3.

LOADING in RADIOSCOPY shall also be prevented if the BEAM LIMITING SYSTEM is adjusted so that, at the currently selected FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, the X-RAY FIELD can extend outside the IMAGE RECEPTION AREA by more than the amount permitted by 203.8.5.3.

For X-RAY EQUIPMENT with an adjustable BEAM LIMITING DEVICE, means shall be provided to configure the boundaries of the X-RAY FIELD so that these boundaries are visible with the X-RAY BEAM AXIS in a specified orientation. This orientation shall be described in the instructions for use.

The means can be made available to the RESPONSIBLE ORGANISATION.

NOTE This configuration enables boundaries of the BEAM LIMITING DEVICE to be seen on the image DISPLAY with the X-RAY FIELD at its maximum size for each magnification mode.

Compliance is checked by inspection, functional test and by examination of the ACCOMPANYING DOCUMENTS.

203.8.104 Positioning of the X-RAY BEAM AXIS

The positioning of the X-RAY BEAM AXIS shall be indicated as follows:

a) If an X-RAY IMAGE RECEPTOR is part of the X-RAY EQUIPMENT it shall be possible, with the PATIENT in place for the examination and without the use of X-RADIATION, to position the X-RAY BEAM AXIS in relation to the IMAGE RECEPTION AREA in such a way that the X-RAY BEAM AXIS is intercepting the X-RAY IMAGE RECEPTOR in its centre.

b) The ACCOMPANYING DOCUMENTS shall describe the positions of the X-RAY BEAM available in NORMAL USE, in terms of its locations with respect to relevant IMAGE RECEPTION AREAS and its angles with respect to relevant IMAGE RECEPTION PLANES. If the X-RAY BEAM AXIS is not coinciding with the REFERENCE AXIS, the position and the angle of the X-RAY FIELD and the plane of interest relative to the REFERENCE AXIS shall be described in the instructions for use.

c) If the X-RAY EQUIPMENT is provided with a mechanism to adjust the position of the X-RAY BEAM AXIS in relation to the selected IMAGE RECEPTION AREA, an indication shall be given on the X-RAY EQUIPMENT to identify the position of the X-RAY BEAM AXIS at which the X-RAY FIELD is specified to correspond to the IMAGE RECEPTION AREA, to the accuracy required in 203.8.5.3.

d) If the X-RAY EQUIPMENT is provided with a mechanism to adjust the angle between the X-RAY BEAM AXIS and the selected IMAGE RECEPTION PLANE, an indication shall be given on the X-RAY EQUIPMENT to identify either

   – the state of adjustment at which the X-ray beam axis is normal to the selected image reception plane; or

   – a state of adjustment described in the accompanying documents, at which the X-ray beam axis is at a particular angle with respect to a particular image reception plane.

Compliance is checked by inspection, functional test and by examination of the ACCOMPANYING DOCUMENTS.

203.9 FOCAL SPOT TO SKIN DISTANCE

203.9.1 General

Addition:

Means shall be provided to prevent IRRADIATION with FOCAL SPOT TO SKIN DISTANCES less than those specified in 203.9.101 and 203.9.102 for the INTENDED USE.

NOTE Means can include hardware, software, construction, or some other method.

Additional subclauses:

203.9.101 X-RAY EQUIPMENT specified for RADIOSCOPY

FIXED X-RAY EQUIPMENT specified for RADIOSCOPY should be provided with means to prevent the use, during radioscopic IRRADIATION, of FOCAL SPOT TO SKIN DISTANCES less than 38 cm.

The FOCAL SPOT TO SKIN DISTANCE shall not be less than 30 cm.

The MOBILE X-RAY EQUIPMENT specified for RADIOSCOPY shall be provided with means to prevent the use, during radioscopic IRRADIATION, of FOCAL SPOT TO SKIN DISTANCES less than:

– 20 cm if the X-RAY EQUIPMENT is specified for RADIOSCOPY during surgery; or

– 30 cm for other specified applications.

Compliance is checked by inspection and measurement.

203.9.102 X-RAY EQUIPMENT specified for RADIOGRAPHY

X-RAY EQUIPMENT specified for RADIOGRAPHY

– shall be provided with means to prevent radiographic IRRADIATION when the FOCAL SPOT TO SKIN DISTANCE is smaller than 20 cm; and

– shall permit by construction the use of FOCAL SPOT TO SKIN DISTANCES of 45 cm or more in NORMAL USE.

NOTE No means are required to prevent the use of smaller FOCAL SPOT TO SKIN DISTANCES.

Compliance is checked by inspection and measurement.

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

203.10.1 General

Addition:

The ATTENUATION EQUIVALENT of the items listed in Table 203.104, when forming part of X-RAY EQUIPMENT and located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, shall not exceed the applicable maximum values given in the table.

Compliance is checked by the test described in 203.10.101.

Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM

Item	Maximum ATTENUATION EQUIVALENT mm Al
Total of all layers composing the front panel of cassette holder	1,2
Total of all layers composing the front panel of FILM CHANGER	1,2
Total of all layers, excluding detector itself, composing the front panel of DIGITAL X-RAY IMAGING DEVICE	1,2
Cradle	2,3
PATIENT SUPPORT, stationary, without articulated joints	1,2
PATIENT SUPPORT, movable, without articulated joints (including stationary layers)	1,7
PATIENT SUPPORT, with radiolucent panel having one articulated joint	1,7
PATIENT SUPPORT, with radiolucent panel having two or more articulated joints	2,3
PATIENT SUPPORT, cantilevered	2,3
NOTE 1 Devices such as RADIATION DETECTORS are not included in the items listed in this table. NOTE 2 Requirements concerning the ATTENUATION properties of RADIOGRAPHIC CASSETTES and of INTENSIFYING SCREENS are given in ISO 4090 [3], for ANTI-SCATTER GRIDS in IEC 60627[1]. NOTE 3 ATTENUATION caused by table mattresses and similar accessories is not included in the maximum ATTENUATION EQUIVALENT for PATIENT SUPPORT. NOTE 4 Maximum ATTENUATION EQUIVALENT mm Al is only applied to the corresponding item. If several items given in this table are located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, each corresponding maximum ATTENUATION EQUIVALENT mm Al is separately applied to each item.	

203.10.2 Information in the ACCOMPANYING DOCUMENTS

Addition:

The ACCOMPANYING DOCUMENTS shall state the maximum value of the ATTENUATION EQUIVALENT for each of the items listed in Table 203.104 and forming part of the X-RAY EQUIPMENT concerned for the measurement conditions specified in 203.10.101.

For diagnostic X-RAY EQUIPMENT specified to be used in combination with ACCESSORIES or other items not forming part of the same or another diagnostic X-RAY EQUIPMENT, the instructions for use shall include a statement drawing attention to the possible adverse effects arising from materials located in the X-RAY BEAM (e.g., parts of an operating table).

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS.

Additional subclause:

203.10.101 Test for ATTENUATION EQUIVALENT

Using an X-RAY BEAM with an X-RAY TUBE VOLTAGE of 100 kV, a PERCENTAGE RIPPLE not exceeding 10 %, and a first HALF-VALUE LAYER of 3,6 mm Al, determine the ATTENUATION EQUIVALENT as the thickness of aluminium that gives the same degree of ATTENUATION as the material under consideration, from measurements of AIR KERMA under NARROW BEAM CONDITIONS.

203.11 Protection against RESIDUAL RADIATION

Additional subclauses:

203.11.101 Requirements

For the appropriate application category, as indicated in Table 203.105, X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements in Table 203.106.

These requirements shall be met

– for all combinations of X-RAY FIELDS and FOCAL SPOT TO IMAGE RECEPTOR DISTANCES in the INTENDED USE;
– in RADIOSCOPY, at all angles employed in the INTENDED USE between the X-RAY BEAM AXIS and the IMAGE RECEPTION PLANE; and
– in RADIOGRAPHY, when the X-RAY BEAM AXIS is perpendicular to the IMAGE RECEPTION PLANE.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection, by examination of the design documentation and ACCOMPANYING DOCUMENTS and by the test described in 203.11.102.

203.11.102 Test for attenuation of residual radiation

Use the following test PROCEDURE:

a) fit shielding as necessary in the region outside the PRIMARY PROTECTIVE SHIELDING to exclude from the measurement any X-RADIATION not transmitted through the PRIMARY PROTECTIVE SHIELDING; for X-RAY EQUIPMENT for RADIOSCOPY with C-arm the additional shielding can be positioned in the IMAGE RECEPTION PLANE. For X-RAY EQUIPMENT with convex INPUT SCREEN the additional shielding may be positioned in the plane of the largest distance from the FOCAL SPOT as described in the ACCOMPANYING DOCUMENTS for the INTENDED USE;

b) use the smallest selectable TOTAL FILTRATION with which the X-RAY EQUIPMENT can be operated. Also, remove ANTI-SCATTER GRIDS and COMPRESSION DEVICES that are specified to be removable; use a PHANTOM having an ATTENUATION EQUIVALENT of 40 mm Al, positioned in the X-RAY BEAM as close as possible to the FOCAL SPOT.

c) according to the specified application of the X-RAY EQUIPMENT under test, select appropriate settings of distance and field size as follows:

1) in X-RAY EQUIPMENT for RADIOSCOPY in which control of LOADING is possible only from within a PROTECTED AREA, use the largest X-RAY FIELD available with RADIOSCOPY;

2) in cases not included in 1) above, set the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to the minimum FOCAL SPOT TO IMAGE RECEPTOR DISTANCES in the INTENDED USE and use the largest X-RAY FIELD available at that distance;

d) set the X-RAY TUBE VOLTAGE to the appropriate value for test as indicated in Table 203.106;

e) using appropriate known values of X-RAY TUBE CURRENT or CURRENT TIME PRODUCT, make measurements of AIR KERMA RATE or AIR KERMA so as to establish the profile of RESIDUAL RADIATION behind the PRIMARY PROTECTIVE SHIELDING. Make measurements 10 cm from any ACCESSIBLE SURFACE;

f) normalize the measurements to the AIR KERMA in one hour or the AIR KERMA per IRRADIATION at the reference LOADING FACTORS indicated in Table 203.106;

g) make any necessary adjustments to the values to take into account the permitted averaging over an area of 100 cm^2 with no principal linear dimension greater than 20 cm;

h) repeat measurements in other configurations of the X-RAY EQUIPMENT to which the requirement of 203.11.101 applies, to the extent necessary to ensure that all such configurations will have been taken into account for determining compliance;

i) compliance is achieved if no MEASURED VALUES obtained by the test PROCEDURE exceed the appropriate maximum permitted AIR KERMA given in Table 203.106.

Table 203.105 – Application categories

Specified application(s)	Application category
RADIOSCOPY with RADIOGRAPHY – OPERATOR near the PATIENT	A
RADIOSCOPY with RADIOGRAPHY – control of LOADING in RADIOGRAPHY from a PROTECTED AREA	B
RADIOSCOPY during surgery at a FIXED FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	C
RADIOGRAPHY with a removable RADIOGRAPHIC CASSETTE holder fitted to X-RAY EQUIPMENT for RADIOSCOPY during surgery	D
INDIRECT RADIOGRAPHY for chest survey when OPERATORS or other PATIENTS are likely to stand in the vicinity of the equipment in NORMAL USE	F
RADIOGRAPHY not otherwise included in this table	None (no requirement)

Table 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING

Application category from Table 203.105	Minimum permitted extent beyond the largest IMAGE RECEPTION AREA	Maximum permitted AIR KERMA	X-RAY TUBE VOLTAGE for compliance and testing	Reference LOADING FACTORS for compliance	Additional requirements
A	30 mm	150 µGy in one hour	see [d]	see [e]	see [g]
B	30 mm [a]	150 µGy in one hour	NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY	see [e]	-
C	20 mm	150 µGy in one hour	NOMINAL X-RAY TUBE VOLTAGE	see [e]	-
D	see [b]	-	-	-	-
F	see [c]	1 µGy per IRRADIATION	NOMINAL X-RAY TUBE VOLTAGE	see [f]	-

[a] In this case, only the IMAGE RECEPTION AREA for RADIOSCOPY shall be considered.

[b] Additional PRIMARY PROTECTIVE SHIELDING need not be provided for the removable RADIOGRAPHIC CASSETTE holder. An appropriate warning shall be included in the INSTRUCTIONS FOR USE.

[c] The PRIMARY PROTECTIVE SHIELDING shall extend beyond the largest IMAGE RECEPTION AREA by at least 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

[d] The applicable voltage shall be the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY or, if a SPOTFILM DEVICE is provided, 66 % of the NOMINAL X-RAY TUBE VOLTAGE for RADIOGRAPHY, whichever is higher.

[e] The reference X-RAY TUBE CURRENT shall be 3 mA or the value corresponding to the maximum CONTINUOUS ANODE INPUT POWER, whichever is less.

[f] The reference LOADING FACTORS shall be those corresponding to the MAXIMUM ENERGY input in a single LOADING according to the RADIOGRAPHIC RATINGS.

[g] The periphery of the required extent of the PRIMARY PROTECTIVE SHIELDING shall correspond to the shape of the RADIATION APERTURE, unless the needed PRIMARY PROTECTIVE SHIELDING can be reached otherwise.

203.12 Protection against LEAKAGE RADIATION

203.12.4 LEAKAGE RADIATION in the LOADING state

Addition:

SERIAL RADIOGRAPHY initiated by a single actuation shall be considered as one LOADING for this requirement.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Addition:

Unless 203.13.3 is applicable and has been complied with, X-RAY EQUIPMENT specified exclusively for examinations that do not need the OPERATOR or staff to be close to the PATIENT during the INTENDED USE shall be provided with means to allow the following control functions to be implemented from a PROTECTED AREA after installation:

– additionally to the requirements in the collateral standard, in respect of radioscopic examinations, control of

  a) the dimensions of the X-RAY FIELD; and

  b) at least two orthogonal relative movements between the PATIENT and the X-RAY BEAM.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.3 Protection by distance

Addition:

In the following cases, protection against STRAY RADIATION is achieved without provision for control from a PROTECTED AREA in accordance with 203.13.2, by enabling the OPERATOR to control IRRADIATION from a distance not less than 2 m from the FOCAL SPOT and the X-RAY BEAM:

– MOBILE X-RAY EQUIPMENT specified exclusively for RADIOGRAPHY;

– X-RAY EQUIPMENT specified for RADIOSCOPY during surgery, with provision for RADIOGRAPHY.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.4 Designated SIGNIFICANT ZONES OF OCCUPANCY

Additional subclauses:

203.13.4.101 * Significant zones of occupancy with limited stray radiation

The following requirements apply to SIGNIFICANT ZONES OF OCCUPANCY designated in X-RAY EQUIPMENT specified for gastro-intestinal examinations, incorporating a tilting PATIENT SUPPORT, an undertable X-RAY SOURCE ASSEMBLY and a SPOTFILM DEVICE above the PATIENT SUPPORT:

– SIGNIFICANT ZONES OF OCCUPANCY designated for use in examinations with the PATIENT SUPPORT horizontal shall be contiguous to the edge of the horizontal PATIENT SUPPORT;

– SIGNIFICANT ZONES OF OCCUPANCY designated for use in examinations with the PATIENT SUPPORT vertical shall be located so that the shortest distance from the vertical PATIENT SUPPORT to the SIGNIFICANT ZONE OF OCCUPANCY, does not exceed 45 cm;

– the levels of STRAY RADIATION shall not exceed the values given in Table 203.107, according to the orientation of the PATIENT SUPPORT, and the applicable region of height above the floor;

– the measurement shall be performed in a position in which the PATIENT SUPPORT is centred horizontally or is in a home position vertically using also a centred PATIENT SUPPORT;

– the instructions for use shall

  a) cite the maximum permitted limits of AIR KERMA in each applicable region of height (see Table 203.107) and state that these limits are not exceeded;

  b) state the LOADING FACTORS applied to determine compliance by the test described in 203.13.6 and, if LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the PROCEDURE for obtaining these LOADING FACTORS;

  c) state the identity and intended position of any removable PROTECTIVE DEVICES that were in position during the test for compliance.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the test described in 203.13.6.

Table 203.107 – STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY

Orientation of PATIENT SUPPORT	Region of height related to the REFERENCE POINT of the RADIATION DETECTOR (above floor) in the SIGNIFICANT ZONE OF OCCUPANCY cm	Highest permitted AIR KERMA in one hour mGy
Horizontal or vertical	0 to 40	1,5
Horizontal	40 to 200	0,15
Vertical	40 to 170	0,15

203.13.4.102 Control from a designated SIGNIFICANT ZONE OF OCCUPANCY

Means shall be provided to allow the control functions as required in 203.13.2 from a SIGNIFICANT ZONE OF OCCUPANCY.

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.5 Handgrips and control devices

Addition:

In X-RAY EQUIPMENT specified for gastro-intestinal examinations, incorporating a tilting PATIENT SUPPORT, an undertable X-RAY SOURCE ASSEMBLY and a SPOTFILM DEVICE above the PATIENT SUPPORT, the following limits of AIR KERMA in one hour shall not be exceeded at the positions of handgrips and control devices that are located outside a SIGNIFICANT ZONE OF OCCUPANCY and that are intended to be handled by the OPERATOR or staff during LOADING:

– 1,5 mGy in one hour if they need to be handled only infrequently and momentarily; otherwise,
– 0,5 mGy in one hour.

The instructions for use shall list the locations of handgrips and control devices to which limits of AIR KERMA apply in this subclause. The instructions for use shall also state the applicable limits and declare that they are not exceeded under the required test conditions.

Compliance is checked by inspection of the X-RAY EQUIPMENT and, where applicable, by the test in 203.13.6 and by examination of the instructions for use.

203.13.6 Test for STRAY RADIATION

Replacement of the existing item b) by the following new item:

b) tests shall be done with representative orientations of the X-RAY BEAM for the INTENDED USE. As far as possible, follow the arrangements and dimensions shown in Figure 203.104 to Figure 203.107;

Addition:

Use the following test PROCEDURE to determine levels of STRAY RADIATION where specific limits apply:

aa) use a water equivalent PHANTOM of outside dimensions 25 cm × 25 cm × 15 cm, with walls not exceeding 10 mm in thickness and made from polymethyl-methacrylate (PMMA) or a material having a similar ATTENUATION property;

bb) as far as possible, follow the arrangements and dimensions shown in Figure 203.104 to Figure 203.105;

cc) use an X-RAY TUBE VOLTAGE equal to the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY or 66 % of the NOMINAL X-RAY TUBE VOLTAGE for RADIOGRAPHY with a SPOTFILM DEVICE, whichever is higher;

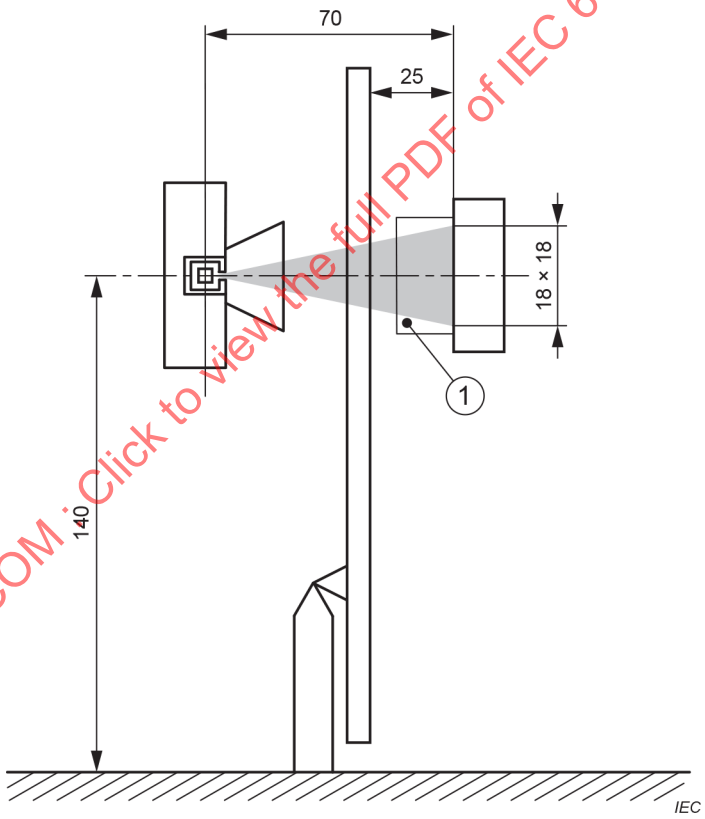
dd) use an X-RAY TUBE CURRENT of 3 mA or the value corresponding to the CONTINUOUS ANODE INPUT POWER of the X-RAY TUBE ASSEMBLY, whichever is less;

NOTE If LOADING FACTORS can only be adjusted by an AUTOMATIC CONTROL SYSTEM, follow the PROCEDURE described in the ACCOMPANYING DOCUMENTS to obtain the applicable LOADING FACTORS. Otherwise, use the manual means of adjustment provided.

ee) in typical configurations of the X-RAY EQUIPMENT make a sufficient number of measurements of AIR KERMA RATE to determine the maximum value in all regions of interest. If the X-RAY TUBE CURRENT is not constant but automatically pulsed, average the measurement of AIR KERMA RATE over a suitable period of time. Where relevant to compliance, adjust the measurements to represent the levels in a volume of 500 cm^3 of which no principal linear dimension exceeds 20 cm. The point of measurement is related to the REFERENCE POINT of the RADIATION DETECTOR;

ff) compliance is achieved if no MEASURED VALUE, averaged and adjusted as described in item ee) above, exceeds the maximum permitted level of AIR KERMA in one hour in the region concerned.

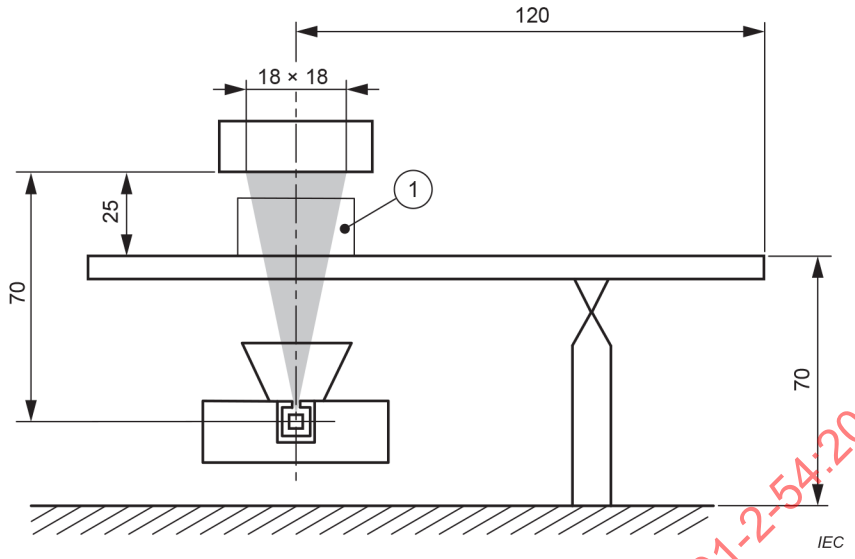
Dimensions in centimeters



1 PHANTOM

Figure 203.104 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)

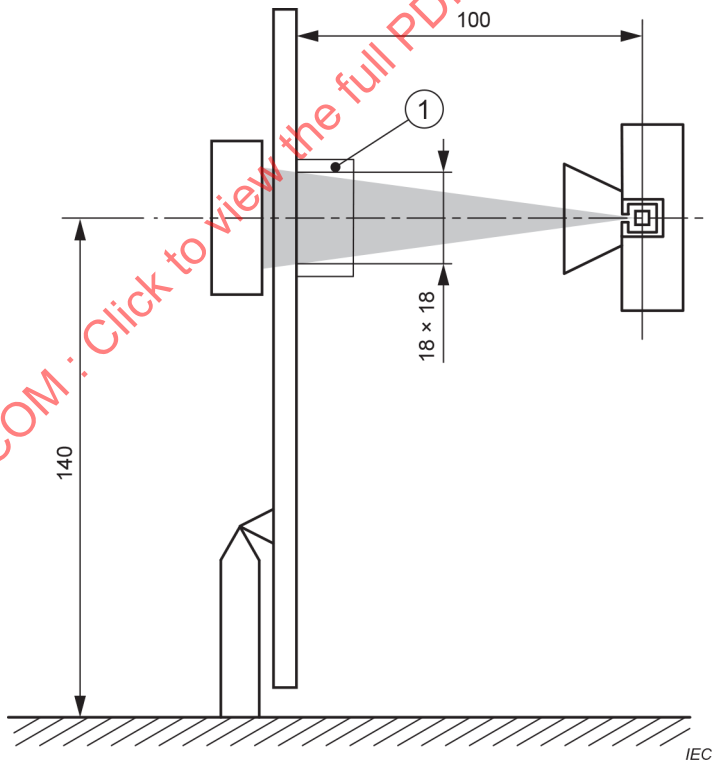
Dimensions in centimeters



1 PHANTOM

Figure 203.105 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)

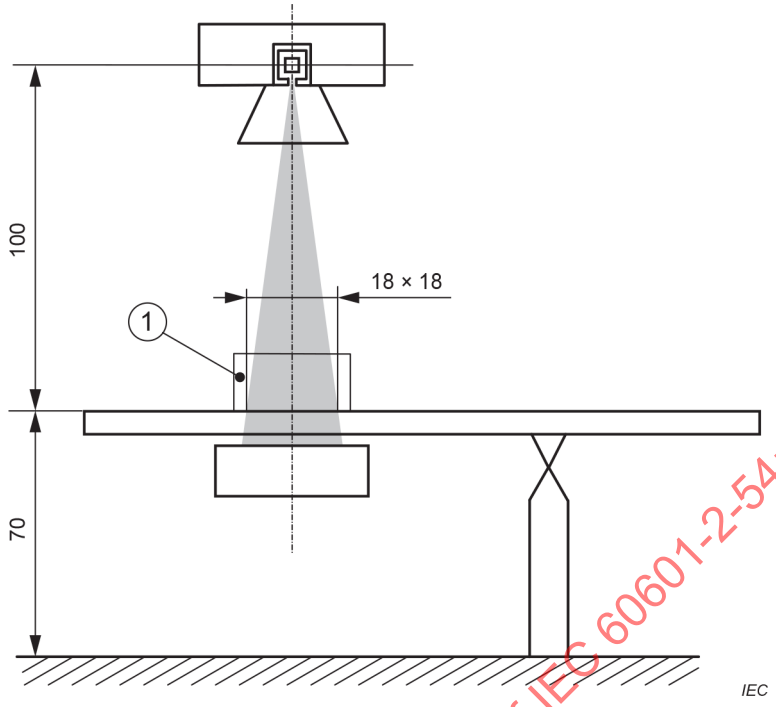
Dimensions in centimeters



1 PHANTOM

Figure 203.106 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)

Dimensions in centimeters



1 PHANTOM

Figure 203.107 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)

Annexes

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

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

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

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Beyond those given in 201.7.2, additional requirements for marking on the outside of ME EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts

Description of marking	Subclause
BEAM LIMITING DEVICE	201.7.2.101
Indication on the X-RAY EQUIPMENT	203.8.102.2

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Beyond those given in 201.7.9, 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.

Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Title	Subclause
SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	201.4.10.2
Cooling conditions	201.7.2.15
Unintended movement	201.9.2.3.1
Pressure and force limitation	201.9.2.3.101
Motion INTERLOCK for COMPRESSION DEVICES	201.9.2.3.102
Collision protection	201.9.2.2.4.4.101
MECHANICAL PROTECTIVE DEVICE	201.9.8.4.101
Protection against excessive temperatures of BEAM LIMITING DEVICES	201.11.101
Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY	203.5.2.4.5.101
EXAMINATION PROTOCOLS	203.5.2.4.101
Connections of external INTERLOCKS	203.6.2.1.102
Shortened indication of LOADING FACTORS	203.6.4.3.102
Linearity and constancy in RADIOGRAPHY	203.6.3.2.102
Measuring arrangements	203.6.3.2.103.1
Indication of automatic modes	203.6.4.4
Dosimetric indications	203.6.4.5
AUTOMATIC CONTROL SYSTEM	203.6.5
SCATTERED RADIATION reduction	203.6.6
HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT	203.7.1
FILTRATION IN X-RAY SOURCE ASSEMBLIES	203.7.1.101
Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	203.8.5.3
Boundary and dimensions of the X-RAY FIELD	203.8.101
Methods of beam limitation in X-RAY EQUIPMENT	203.8.102
Indication on the X-RAY EQUIPMENT	203.8.102.2
Indication in the instructions for use	203.8.102.3
Accuracy of marked and written indications	203.8.102.4
Indication by LIGHT FIELD-INDICATOR	203.8.102.5
Interception of the X-RAY BEAM in RADIOSCOPY	203.8.103
Positioning of the X-RAY BEAM AXIS	203.8.104
Information in the ACCOMPANYING DOCUMENTS	203.10.2
Protection against RESIDUAL RADIATION	203.11
Control of X-RAY EQUIPMENT from a PROTECTED AREA	203.13.2
Protection by distance	203.13.3
SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION	203.13.4.101
Handgrips and control devices	203.13.5

Annex AA
(informative)

Particular guidance and rationale

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

Subclause 201.4.3.101 – Additional potential ESSENTIAL PERFORMANCE requirements

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD: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 of this document provides a list of requirements that can be correlated with the performance of a clinical function and that can 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 clauses of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and this document or are determined by the RISK EVALUATION. There can be cases in which simply detection of single faults 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 201.8.7.3 – Allowable values

These relaxations versus the values of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 have been in place since 1998, originally in the withdrawn IEC 60601-2-7. There have been no reports that would justify a modification of these values.

Subclause 202.101 – Immunity testing of ESSENTIAL PERFORMANCE

Immunity tests on X-RAY EQUIPMENT specified for RADIOGRAPHY and RADIOSCOPY can be performed only in RADIOSCOPY mode if there is sufficient evidence that RADIOSCOPY covers the same electrical sources and signalling paths leading to IRRADIATION.

Subclause 203.5.2.4.5.101 c) – RADIATION data

See rationale to 203.6.4.5.

Subclause 203.5.2.4.5.101 d) – PATIENT ENTRANCE REFERENCE POINT

This document allows the use of an indirect indication to estimate the ABSORBED DOSE to the skin. The estimate could be drawn from the indications of X-RAY EQUIPMENT parameters followed by a calculation of the primary AIR KERMA or AIR KERMA RATE at a point specified with reference to the FOCAL SPOT. The specified point, which has been defined here as the PATIENT ENTRANCE REFERENCE POINT, is intended to be representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT.

For systems with an ISOCENTRE, a point on the REFERENCE AXIS 15 cm from the ISOCENTRE towards the FOCAL SPOT has been specified as the PATIENT ENTRANCE REFERENCE POINT. This distance is assumed to represent a good approximation of the value of the actual FOCAL SPOT TO SKIN DISTANCE during RADIOLOGICAL PROCEDURES. If one considers currently available methods to estimate ABSORBED DOSES to selected tissues for RADIOSCOPIC and cine-angiographic examinations of the coronary arteries of adults [4], [5], these methods rely on the use of distinct operating conditions commonly used in RADIOLOGICAL examinations of the heart. These operating conditions are associated with a view, an arterial projection, and technique factors on the X-RAY EQUIPMENT such as the X-RAY TUBE VOLTAGE (kV), the HALF-VALUE LAYER (HVL), the FOCAL SPOT TO SKIN DISTANCE**,** the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and the ENTRANCE FIELD SIZE. A review of the operating conditions derived from analyses of practice [6], [9] indicates that the defined PATIENT ENTRANCE REFERENCE POINT is, in fact, a fair approximation of the FOCAL SPOT TO SKIN DISTANCE for each field.

The error in estimating the ABSORBED DOSE to the skin introduced from the defined PATIENT ENTRANCE REFERENCE POINT should average out as long as the interventional PROCEDURE is composed of multiple views. When the RADIOLOGICAL PROCEDURE is limited to one or a few views, the possibility of error in estimating the ABSORBED DOSE to the skin can be higher. However, even under worst case conditions, errors should be less than a factor of two. Of course, most of this error can be eliminated by assessing the position of the PATIENT and calculating the appropriate correction factor.

The document has the flexibility of allowing an alternative to the use of the defined PATIENT ENTRANCE REFERENCE POINT for systems without an ISOCENTRE. In this case, the PATIENT ENTRANCE REFERENCE POINT is located at a position, defined by the MANUFACTURER to be representative of the point of intersection of the REFERENCE AXIS with the PATIENT SURFACE, and stated in the ACCOMPANYING DOCUMENTS. Examples of situations where the MANUFACTURER would use this alternative method of defining the PATIENT ENTRANCE REFERENCE POINT, would be X-RAY EQUIPMENT that senses the actual FOCAL-SPOT-TO-SKIN DISTANCE, deviates from traditional geometry or has a FIXED FOCAL SPOT TO SKIN DISTANCE.

NOTE Other reference documents [7], [8].

Subclause 203.5.2.4.5.102 – Test for dosimetric information

X-RAY EQUIPMENT can be equipped with means for manually or automatically configuring the operating parameters for different INTENDED USES. In addition, different operating parameter sets can be required to comply with differing national regulations and preferences. In accordance with 203.5.2.4.5.101 b), details of MODES OF OPERATION and certain other available settings are required to be stated. In accordance with 203.5.2.4.5.101 c), the associated values of REFERENCE AIR KERMA (RATE) are required to be given, together with the configurations and test geometries by which they can be verified by the method described in this subclause. The first stage of compliance testing is to check this information (other than the dosimetric values) for compliance with the requirements and compatibility with the measuring method. If the information complies, it is used in the measuring PROCEDURE to verify the compliance of the stated values of REFERENCE AIR KERMA (RATE). Otherwise, the ME EQUIPMENT is considered non-compliant without further testing. Thus, the ME EQUIPMENT is delivered with a set of verified values and also with sufficient information to enable the values to be re-checked at any time. It is emphasised that, in any circumstances, the test method to be applied is intended to be only in respect of conditions that are within the range of the INTENDED USE.

Subclause 203.6.2.1 e) – Normal initiation and termination of the IRRADIATION

The purpose of RADIOSCOPY is to observe objects or structures in real time [16], [17]. A LAST IMAGE HOLD RADIOGRAM is, in essence, a RADIOGRAPH intended for review for study, consultation, or education instead of continuing RADIOSCOPY [16], [17].

The intent is to limit the number of RADIOGRAPHY images to those necessary for diagnosis or to document findings and device placement. Typical RADIOGRAPHY dose rates are at least 10 times greater than those for RADIOSCOPY [16]. If a LAST IMAGE HOLD RADIOGRAM demonstrates the finding adequately, it can be studied instead of performing RADIOGRAPHY. When no additional RADIOGRAPHY images are obtained, PATIENT RADIATION dose is reduced [16].

At present, RADIOSCOPY equipment is designed so that the RADIOSCOPY IRRADIATION terminates after the release of continuous pressure by the OPERATOR, regardless of the quality of the resultant LAST IMAGE HOLD RADIOGRAM. For radioscopic IRRADIATIONS longer than 1 s or so, this is of no consequence, as the image quality of the resultant LAST IMAGE HOLD RADIOGRAM will be adequate. However, if the RADIOSCOPY IRRADIATION is too short, the LAST IMAGE HOLD RADIOGRAM will not be usable, because image quality will not be adequate. Sufficient time is necessary to stabilize the AUTOMATIC INTENSITY CONTROL before terminating the radioscopic IRRADIATION. The new requirement permits automatic creation of a LAST IMAGE HOLD RADIOGRAM of adequate quality with a short tap on the RADIOSCOPY pedal and automatic termination of the radioscopic IRRADIATION, rather than manual termination. This avoids an IRRADIATION which is too short and results in an inadequate LAST IMAGE HOLD RADIOGRAM, or an IRRADIATION that is longer than necessary to obtain a LAST IMAGE HOLD RADIOGRAM of adequate quality. It permits a LAST IMAGE HOLD RADIOGRAM to be obtained with the shortest possible RADIOSCOPY IRRADIATION that will result in a usable image, and therefore with the lowest possible PATIENT RADIATION dose. It is understood that under certain circumstances (e.g. very low pulse rates) the time limits specified in 203.6.2.1 could result in a suboptimal LAST IMAGE HOLD RADIOGRAM.

Subclause 203.6.3.102 – High-level control (HLC)

High-level control (HLC) or high dose rate mode(s) can be applicable in cases of extreme body sizes of the PATIENT or when there is a need for extraordinarily high image quality for a certain PROCEDURE with a certain PATIENT. In such cases the higher PATIENT exposure can be justified if the benefit of the PROCEDURE cannot be attained with lower dose rates. Local regulations can set different limits on the maximum AIR KERMA RATE for the normal and/or the HLC MODES OF OPERATION.

Subclause 203.6.4.3.106 – Electronic documentation of EXAMINATION PROTOCOLS

At the system level, the X-RAY EQUIPMENT includes one or more IMAGE DISPLAY DEVICES. The imaging performance characteristics of IMAGE DISPLAY SYSTEMS are provided by other standards (e.g. IEC 62563-1 [18] and DICOM, Part 14 [19]). The IMAGE DISPLAY SYSTEM settings selected under 203.6.4.3.106 are meaningful provided that the IMAGE DISPLAY DEVICE conforms to the X-RAY EQUIPMENT's specifications and the IMAGE DISPLAY DEVICE performs in accordance to its own standards.

A new addition is to provide a means (e.g. a comparison tool) to flag differences between two (or more) PRE-PROGRAMMED EXAMINATION PROTOCOLS. The comparison tool can be used to compare EXAMINATION PROTOCOLS for different examinations or different versions of the same protocol.

X-RAY EQUIPMENT can contain one or more PRE-PROGRAMMED EXAMINATION PROTOCOLS (PPEP). Each PPEP usually contains settings controlling RADIATION production, X-RAY IMAGE RECEPTOR performance, and image processing for presentation. Incorrect or inappropriate settings can result in inappropriate IRRADIATION of the PATIENT and/or in inappropriate clinical utility of the resulting images.

Validating the contents of each PPEP is essential for both safety and performance. For this reason, documentation of PPEPs over the life of the EQUIPMENT is useful for the RESPONSIBLE ORGANIZATION. Routine audits by the RESPONSIBLE ORGANIZATION are often performed after EQUIPMENT installation, commissioning, updates, and clinical configuration changes. Additional audits are indicated if there are unexpected changes in RADIATION use or the clinical acceptability of the resultant images.

Copies of the downloaded PPEP sets might be retained by the RESPONSIBLE ORGANIZATION to document their status over the life of the EQUIPMENT.

Audits are facilitated by comparing currently installed PPEPs against a reference set of PPEPs and flagging the differences. Sources of reference PPEPs include MANUFACTURER'S factory defaults or regional settings, as well as local settings for substantially similar EQUIPMENT as defined by the RESPONSIBLE ORGANIZATION.

This document does not require any specific content or format of a PPEP. It implies that all controls and settings within a PPEP that affect either RADIATION production or the characteristics of the resulting images be appropriately documented in a form that facilitates comparisons between versions.

Subclause 203.6.4.5 – Dosimetric indications

There is a growing demand worldwide for assessing quantitatively the RADIATION exposure of PATIENTS during diagnostic and interventional radiology PROCEDURES. Such demands can also be found in regional and national regulations. Some particular standards linked to the second edition of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 include such requirements. The first edition of IEC 60601-2-43 (2000) asks for presentation of RADIATION data, introduces terms such as skin dose levels and interventional reference point, and requires dosimetry calibration (6.8.2 of IEC 60601-2-43:2000) and dosimetric indications (51.102.4 of IEC 60601-2-43:2000). IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002 require dose statements (29.1.102.1 of IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002) and dose information (29.1.103 of IEC 60601-2-44:2001 and IEC 60601-2-44:2001/AMD1:2002). The reason that these two standards were first in the introduction of such requirements is that both interventional PROCEDURES and CT examinations are high dose PROCEDURES.

The transition from the second to the third edition of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 presents a good opportunity to introduce requirements on RADIATION data and dosimetric indication into the particular standards for all medical X-ray modalities.

The introduction of the first edition of IEC 60601-1-3 (1994) states the following: “In respect of economic factors, it is recognized that certain relatively inexpensive types of X-RAY EQUIPMENT are sometimes justifiably preferred on grounds of cost. For these, this collateral standard avoids imposing requirements that would unduly restrict their medical effectiveness or would add disproportionately to the cost.” Based on this principle, this document exempts DIRECT RADIOGRAPHY EQUIPMENT from the requirements to provide dosimetric indications in 203.6.4.5. However, for X-RAY EQUIPMENT specified for DIRECT RADIOGRAPHY (including film-screen RADIOGRAPHY), a simplified dosimetric indication could be used by displaying a value, i.e. “the REFERENCE AIR KERMA resulting from the last radiographic IRRADIATION shall be displayed in mGy together with this unit”. This value might be pre-programmed as a function of the LOADING FACTORS. It also implies that when shifting from screen-film RADIOGRAPHY to CR, it is the responsibility of the RESPONSIBLE ORGANIZATION to ensure compliance with the general requirement for INDIRECT RADIOGRAPHY, or else compliance of the actual X-ray system with this document can no longer be stated. INDIRECT RADIOGRAPHY includes CR and DR systems as well as any kind of RADIOGRAPHY performed with image intensifiers.

The accuracy requirement for dosimetric indications of ± 35 % was harmonized with EU and US requirements and is consistent with the real technically achievable level of accuracy. For RADIATION data stated in the ACCOMPANYING DOCUMENTS, the accuracy requirement of ± 50 % has been set to reflect the method used for compliance assessment and the fact that the RADIATION output of a given type of X-RAY TUBE can vary within broad limits.

It shall be stressed that all requirements on RADIATION data and dosimetric indication in the IEC standards are meant to give information to the OPERATOR about PATIENT doses and not to PATIENTS themselves.

Subclause 203.13.4.101 – SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION

In RADIOLOGICAL examinations which require the OPERATOR or staff to be close to the PATIENT during LOADING, a significant contribution to the total STRAY RADIATION exposure to these persons is often made by SCATTERED RADIATION from the PATIENT and other objects in the X-RAY BEAM. For X-RAY EQUIPMENT conventionally and most frequently used for performing gastro-intestinal examinations, limits of STRAY RADIATION in the SIGNIFICANT ZONES OF OCCUPANCY are required. The instructions for use shall state the applicable limits and declare that they are not exceeded. Where they apply, these requirements can provide a normalized basis for the local rules and guidelines that shall be established for the protection of persons, taking into account the local circumstances and the prevailing WORKLOAD.

Bibliography

[1] IEC 60627, *Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids*

[2] IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

[3] ISO 4090:2001, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

[4] STERN, S.H., ROSENSTEIN, M., RENAUD, L., ZANKL M. Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries. U.S. Department of Health and Human Services Publication FDA 95-8289, May 1995

[5] NAHASS, G.T. Fluoroscopy and the Skin: Implications for Radiofrequency Catheter Ablation. Am. J. of Card. 1995, 76, 174-176

[6] LESPERANCE, J. Coronary Angiography Projections. Institut de Cardiologie de Montréal, April 1982

[7] HADDI, R., RENAUD, L. Projections et Conditions Techniques en Usage en Angiocardiologie, Etude Statistique. Rapport technique, Service de Génie Biomédical, Institut de Cardiologie de Montréal, March 1993

[8] HYKES, D.L. Determination of Patient Radiation Doses Associated with Cardiac Catherization Procedures using Direct measurements and Monte Carlo Methods. Ph.D. dissertation. Medical College of Ohio, Toledo OH

[9] HUYSKENS, C.J., HUMMEL, W.A. Data Analysis on Patient Exposures in Cardiac Angiography. Radiation Protection Dosimetry 1995, 57(1), 475-480

[10] IEC 60601-2-28:2017, *Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*

[11] 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*

[12] 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*

[13] IEC 60601-1-11:2015, *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*
IEC 60601-1-11:2015/AMD1:2020

[14] IEC 60601-1-12:2014, *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 60601-1-12:2014/AMD1:2020

[15] IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
IEC 60601-2-43:2010/AMD1:2017
IEC 60601-2-43:2010/AMD2:2019

[16] ICRP 117:2010, Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department. ICRP Publication 117, Ann. ICRP 40(6)

[17] ICRP 121:2013, Radiological Protection in Paediatric Diagnostic and Interventional Radiology. ICRP Publication 121, Ann. ICRP 42(2)

[18] IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*
IEC 62563-1:2009/AMD1:2016
IEC 62563-1:2009/AMD2:2021

[19] DICOM, Part 14 (PS 3.14-2016e), *Digital Imaging and Communications in Medicine – Part 14: Grayscale Standard Display Function*

[20] 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*

[21] ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

[22] 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*

[23] IEC 60601-2-43:2000[2], *Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures*

[24] IEC 60601-2-44:2001[3], *Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography*
IEC 60601-2-44:2001/AMD1:2002

[25] IEC 60601-1-3:1994[4], *Medical electrical equipment – Part 1: General requirements for safety – Section 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

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2 This reference was withdrawn and replaced with IEC 60601-2-43:2010, IEC 60601-2-43:2010/AMD1:2017 and IEC 60601-2-43:2010/AMD2:2019.

3 This reference was withdrawn and replaced with IEC 60601-2-44:2001, IEC 60601-2-43:2001/AMD1:2012 and IEC 60601-2-44:2001/AMD2:2016.

4 This reference was withdrawn and replaced with IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021.

Index of defined terms used in this document

NOTE In the present document only terms defined in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, its collateral standards, in IEC TR 60788:2004 or in 201.3 of this document were used. The definitions used in this document can be looked up at http://std.iec.ch/glossary.

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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

AVANT-PROPOS

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L'IEC 60601-2-54 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 deuxième édition annule et remplace la première édition parue en 2009, l'Amendement 1:2015 et l'Amendement 2:2018. Cette édition constitue une révision technique.

La présente édition comprend des modifications techniques et rédactionnelles destinées à représenter l'IEC 60601-1:2005/AMD2:2020. Elle contient également des corrections et des améliorations techniques. Les modifications techniques majeures par rapport à l'édition précédente sont les suivantes:

a) déplacement en 201.3 des termes issus exclusivement de l'IEC TR 60788:2004 et qui sont spécifiquement applicables dans le présent document;

b) si le FABRICANT le déclare, 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 s'appliquent;

c) le paragraphe 201.11.101 "Protection contre les températures excessives des gaines équipées" a été supprimé du présent document, car ses exigences sont suffisamment et clairement traitées 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;

d) clarification des exigences pour l'adoption des modifications introduites concernant les voyants lumineux au paragraphe 7.8.1 de l'IEC 60601-1:2005/AMD2:2020 afin d'éviter les conflits avec les exigences relatives aux voyants lumineux stipulées pour les APPAREILS A RAYONNEMENT X;

e) explication du terme PERFORMANCE ESSENTIELLE fournie dans l'Annexe AA afin de mettre l'accent sur la fonction clinique en CONDITION NORMALE ET DE PREMIER DEFAUT.

Le texte de ce document est issu des documents suivants:

Projet	Rapport de vote
62B/1285/FDIS	62B/1293/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.

Le présent 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;

– *modalités d'essais: caractères italiques*;

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

– LES TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 ET DE L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU LORSQUE MENTIONNES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 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 des conditions quelle qu'elle soit est vraie.

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

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire 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 titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601 et de la série 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 du présent 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.

INTRODUCTION

Le présent document a été établi pour fournir, sur la base de l'IEC 60601-1:2005 (troisième édition), et de ses normes collatérales, un ensemble complet d'exigences de sécurité applicables aux APPAREILS ELECTROMEDICAUX (EM) utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE. Cette deuxième édition a pour objet d'introduire des changements qui font référence au deuxième amendement (2020) de l'IEC 60601-1 :2005 ainsi qu'aux normes collatérales associées. De plus, l'Annexe AA fournit une clarification du terme relatif aux PERFORMANCES ESSENTIELLES. Le présent document traite des APPAREILS A RAYONNEMENT X considérés au niveau système, lequel se compose d'un GROUPE RADIOGENE, d'EQUIPEMENTS ASSOCIES et d'ACCESSOIRES. Les fonctions des composants sont traitées au besoin.

Les exigences de sécurité minimales spécifiées dans le présent document sont estimées assurer un degré de sécurité réalisable dans le cadre du fonctionnement des APPAREILS EM utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE. Les exigences relatives aux dispositions supplémentaires concernant les procédures d'intervention applicables aux APPAREILS EM sont traitées dans l'IEC 60601-2-43.

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de 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 EM et des SYSTEMES EM destinés à la RADIOGRAPHIE de projection et à la RADIOSCOPIE INDIRECTE. L'IEC 60601-2-43 est applicable aux APPAREILS EM et aux SYSTEMES EM destinés à être utilisés lors de procédures d'interventions et se réfère aux exigences applicables du présent document.

Les APPAREILS EM et SYSTEMES EM destinés à l'ostéodensitométrie par absorption, à la tomodensitométrie, à la mammographie ou aux applications dentaires ou de radiothérapie, sont exclus du domaine d'application du présent document. Le domaine d'application du présent document exclut également les simulateurs de radiothérapie.

Lorsqu'un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, son titre et son contenu l'indiquent. Lorsque cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

201.1.2 Objet

Remplacement:

Le présent document vise à établir des exigences particulières relatives à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS EM et des SYSTEMES EM utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE.

201.1.3 Normes collatérales

Addition:

Le présent document se réfère aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020, tel qu'il est modifié en 201.2.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-3:2008 et l'IEC 60601-1-3:2008/AMD1:2013 ainsi que l'IEC 60601-1-3:2008/AMD2:2021 s'appliquent telles que modifiées respectivement par les Articles 202 et 203. Dans le cas où le FABRICANT déclare qu'il est prévu que l'APPAREIL EM ou le SYSTEME EM soit utilisé dans un ENVIRONNEMENT DE SOINS A DOMICILE, alors l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 s'appliquent et lorsque le FABRICANT déclare qu'il est prévu que l'APPAREIL EM ou le SYSTEME EM soit utilisé dans un ENVIRONNEMENT DE SERVICES MEDICAUX D'URGENCE, alors l'IEC 60601-1-12:2014 et l'IEC 60601-1-12:2015/AMD1:2020 s'appliquent. L'IEC 60601-1-8, l'IEC 60601-1-9, l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales parues dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

NOTE Les OPERATEURS d'APPAREILS A RAYONNEMENT X sont habitués aux signaux sonores, comme cela est spécifié dans le présent document, plutôt qu'aux concepts de l'IEC 60601-1-8. De ce fait, l'IEC 60601-1-8 ne s'applique pas.

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 considéré, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

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

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, 201.1 dans le présent document couvre le contenu de l'Article 1 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020) ou de la norme collatérale applicable avec le préfixe "20x", où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans le présent document couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans le présent document 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, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

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

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

Les paragraphes, les figures ou les tableaux qui sont ajoutés 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 le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsque l'objectif est qu'une partie quelconque de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne doive pas s'appliquer, cela est expressément mentionné dans le présent document.

201.2 Références normatives

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

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

Addition:

IEC 60336:2020, *Appareils électromédicaux – Gaines équipées pour diagnostic médical – Dimensions des foyers et caractéristiques connexes*

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

IEC 60806, *Détermination du champ de rayonnement maximal symétrique des gaines équipées et des ensembles radiogènes utilisés en diagnostic médical*

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 62494-1:2008, *Appareils électromédicaux – Indice d'exposition des systèmes d'imagerie numérique à rayonnement X – Partie 1: Définitions et exigences pour la radiographie générale*

Amendement:

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

201.3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012, de l'IEC 60601-1:2005/AMD2:2020 et de l'IEC TR 60788:2004, ainsi que les suivants s'appliquent.

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

NOTE Un Index des termes définis constitue la dernière partie du présent document.

Addition:

201.3.201
RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION
pour un GROUPE RADIOGENE de diagnostic, résistance du RESEAU D'ALIMENTATION déterminée dans des conditions de charge spécifiques

201.3.202
COMMANDE AUTOMATIQUE D'INTENSITE
dans un GROUPE RADIOGENE, mode de fonctionnement dans lequel un PARAMETRE DE CHARGE ou plus est contrôlé de manière automatique afin d'obtenir, à un emplacement présélectionné, le débit désiré d'une GRANDEUR LIEE AU RAYONNEMENT

201.3.203
RADIOGRAPHIE DIRECTE
RADIOGRAPHIE dans laquelle l'enregistrement permanent est effectué sur une SURFACE RECEPTRICE DE L'IMAGE

Exemple: RADIOGRAPHIE sur film ou sur film avec écran.

201.3.204
RADIOSCOPIE DIRECTE
RADIOSCOPIE dans laquelle les images visibles sont présentées sur la SURFACE RECEPTRICE DE l'IMAGE ou à proximité, dans le FAISCEAU DE RAYONNEMENT

201.3.205
PRODUIT DOSE-SURFACE
produit de la surface de la section transversale d'un FAISCEAU DE RAYONNEMENT X et du KERMA DANS L'AIR moyenné sur cette section transversale. L'unité applicable est le gray par mètre carré ($Gy \cdot m^2$)

Note 1 à l'article: Cette définition est équivalente au produit KERMA DANS L'AIR-surface.

201.3.206
DOSIMETRE
APPAREIL qui utilise les chambres d'ionisation et/ou les détecteurs à semi-conducteur pour le mesurage du KERMA DANS L'AIR et/ou du DEBIT DE KERMA DANS L'AIR dans le faisceau d'un APPAREIL A RAYONNEMENT X utilisé pour les examens RADIOLOGIQUES médicaux de diagnostic

201.3.207
DIMENSION DU CHAMP D'ENTREE
dimensions du champ dans le plan d'entrée d'un RECEPTEUR D'IMAGE RADIOLOGIQUE pouvant être utilisé pour la transmission d'une IMAGE RADIOLOGIQUE POTENTIELLE dans des conditions spécifiques

201.3.208
PROTOCOLE D'EXAMEN
ensemble complet de facteurs techniques programmés, de fonctions et de réglages de commande, y compris les réglages de traitement d'image, conçu pour optimiser l'acquisition et l'AFFICHAGE d'images

201.3.209
COMMANDE DE SELECTION DU PROTOCOLE D'EXAMEN
commande permettant de sélectionner un PROTOCOLE D'EXAMEN PREPROGRAMME

201.3.210
GENERATEUR RADIOLOGIQUE
dans un GROUPE RADIOGENE, combinaison de tous les composants pour la commande et la production de l'énergie électrique à fournir à un TUBE RADIOGENE, généralement composé d'un assemblage transformateur à haute tension et d'un assemblage de commande

201.3.211
PLAN DU RECEPTEUR D'IMAGE
plan qui contient les dimensions les plus grandes de la SURFACE RECEPTRICE DE L'IMAGE

201.3.212
RADIOGRAPHIE INDIRECTE
RADIOGRAPHIE dans laquelle l'enregistrement permanent est effectué après TRANSFERT de l'information obtenue sur une SURFACE RECEPTRICE DE L'IMAGE

Exemples: Systèmes CR, systèmes de détection numérique, intensificateurs d'image.

201.3.213
RADIOSCOPIE INDIRECTE
RADIOSCOPIE dans laquelle les images sont présentées en un emplacement situé à l'extérieur du FAISCEAU DE RAYONNEMENT, après TRANSFERT de l'information

201.3.214
VERROUILLAGE
moyen empêchant la mise en marche ou le fonctionnement continu de l'APPAREIL EM tant que certaines conditions prédéfinies ne sont pas réunies

201.3.215
ISOCENTRE
dans les appareils RADIOLOGIQUES qui proposent plusieurs modes de déplacement de l'AXE DE REFERENCE autour d'un centre commun, centre de la sphère la plus petite par laquelle passe l'AXE DU FAISCEAU DE RAYONNEMENT X

201.3.216
RADIOGRAMME A DERNIERE IMAGE MEMORISEE
RADIOGRAMME LIH
image unique obtenue par échantillonnage ou traitement temporaire d'une ou de plusieurs images à partir de la fin d'une IRRADIATION radioscopique

Note 1 à l'article: L'abréviation "LIH" est dérivée du terme anglais développé correspondant "last-image hold".

201.3.217
PUISSANCE ELECTRIQUE NOMINALE
pour un GENERATEUR RADIOLOGIQUE, puissance électrique constante la plus élevée qui peut être fournie pour une seule charge de TUBE RADIOGENE dans un TEMPS DE CHARGE spécifique

201.3.218
TEMPS MINIMAL D'IRRADIATION NOMINAL
TEMPS DE CHARGE minimal pendant lequel une valeur constante exigée de la grandeur liée au rayonnement contrôlée est maintenue

Note 1 à l'article: Le TEMPS D'IRRADIATION est contrôlé par un GENERATEUR RADIOLOGIQUE avec SYSTEMES DE COMMANDE AUTOMATIQUE.

201.3.219
PROTOCOLE D'EXAMEN PREPROGRAMME
réglage unique de matériel ou de logiciel, ou les deux, qui est associé à un PROTOCOLE D'EXAMEN

201.3.220
CONTROLE QUALITE
techniques et activités opérationnelles utilisées pour satisfaire aux exigences liées à la qualité

201.3.221
CARACTERISTIQUES DE SORTIE DU RAYONNEMENT
KERMA DANS L'AIR divisé par le PRODUIT COURANT TEMPS (mGy/mAs) à une distance donnée du FOYER dans le FAISCEAU DE RAYONNEMENT X

201.3.222
SEQUENCE DE REPETITION DE LECTURE D'IMAGES DE RADIOSCOPIE
série d'images les plus récentes de l'EVENEMENT D'IRRADIATION de RADIOSCOPIE le plus récent

201.3.223
REGION D'INTERET
partie localisée d'une image, qui présente un intérêt particulier à un moment donné

201.3.224
SERIOGRAPHIE
RADIOGRAPHIE dans laquelle l'information est obtenue et enregistrée dans une série régulière ou irrégulière d'applications de CHARGE avec des PARAMETRES DE CHARGE égaux ou inégaux

201.3.225
GENERATEUR RADIOLOGIQUE A SIX CRETES
GENERATEUR RADIOLOGIQUE qui s'utilise avec une source triphasée qui fournit une tension de sortie rectifiée à six crêtes à chaque cycle de la source

201.3.226
INTEGRATEUR DE TEMPS
dispositif qui intègre et/ou présente le temps écoulé pendant le fonctionnement d'un appareil et éventuellement change l'état de fonctionnement à la fin d'un intervalle de temps prédéterminé

201.3.227
GENERATEUR RADIOLOGIQUE A DOUZE CRETES
GENERATEUR RADIOLOGIQUE qui s'utilise avec une source triphasée qui fournit une tension de sortie rectifiée à douze crêtes à chaque cycle de la source

201.3.228
AXE DU FAISCEAU DE RAYONNEMENT X
dans un FAISCEAU DE RAYONNEMENT X symétrique, droite qui passe par le centre de la source de rayonnement et à équidistance des bords efficaces du LIMITEUR DE FAISCEAU

Note 1 à l'article: L'AXE DU FAISCEAU DE RAYONNEMENT X coïncide habituellement, au sein des tolérances exigées, avec l'AXE DE REFERENCE de la SOURCE DE RAYONNEMENT.

201.4 Exigences générales

L'Article 4 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.4.3 PERFORMANCES ESSENTIELLES

Paragraphe complémentaire:

201.4.3.101 * Exigences supplémentaires relatives aux PERFORMANCES ESSENTIELLES potentielles

Des exigences supplémentaires relatives aux PERFORMANCES ESSENTIELLES potentielles sont spécifiées dans les paragraphes indiqués dans le Tableau 201.101.

Tableau 201.101 – Références des exigences relatives aux PERFORMANCES ESSENTIELLES potentielles

Exigence	Paragraphe
Précision des PARAMETRES DE CHARGE	203.6.4.3.104
Reproductibilité des CARACTERISTIQUES DE SORTIE DU RAYONNEMENT	203.6.3.2
SYSTEME DE COMMANDE AUTOMATIQUE	203.6.5
Performances d'imagerie	203.6.7

201.4.10.2 Réseau d'alimentation pour APPAREILS EM et SYSTEMES EM

Addition:

L'impédance interne d'un RESEAU D'ALIMENTATION doit être considérée comme suffisamment basse pour le fonctionnement d'un APPAREIL A RAYONNEMENT X utilisé pour la RADIOGRAPHIE et la RADIOSCOPIE lorsque la valeur de la RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION ne dépasse pas la valeur spécifiée dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent spécifier la RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION ou d'autres spécifications relatives au RESEAU D'ALIMENTATION applicables à une installation.

NOTE Dans le cas où une tension NOMINALE est déclarée pour un système d'alimentation sur secteur, il n'existe par hypothèse aucune tension supérieure entre l'un quelconque des conducteurs du système ou entre l'un quelconque de ces conducteurs et la terre.

En pratique, une tension alternative est considérée comme sinusoïdale lorsque toute valeur instantanée de la forme d'onde concernée diffère simultanément de la valeur instantanée de la forme d'onde idéale d'une valeur inférieure ou égale à ±2 % de la valeur de crête de la forme d'onde idéale.

Un RESEAU D'ALIMENTATION triphasé est considéré comme présentant une symétrie pratique s'il fournit des tensions symétriques et produit, en charge symétrique, des courants symétriques.

Les exigences du présent document se fondent sur l'hypothèse selon laquelle les systèmes triphasés présentent une configuration symétrique de la TENSION RESEAU par rapport à la terre. Les systèmes monophasés peuvent être dérivés des systèmes triphasés de ce type. Lorsque le système d'alimentation n'est pas mis à la terre au niveau de la source, des mesures adéquates ont été mises en œuvre par hypothèse pour détecter, limiter et corriger toute perturbation de symétrie dans un délai raisonnablement court.

L'APPAREIL A RAYONNEMENT X est considéré comme satisfaisant aux exigences du présent document uniquement si sa PUISSANCE ELECTRIQUE NOMINALE spécifiée peut être démontrée à une RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION qui présente une valeur supérieure ou égale à la RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION spécifiée par le FABRICANT dans les DOCUMENTS D'ACCOMPAGNEMENT.

La vérification est effectuée par l'examen des documents d'accompagnement.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de 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, de l'IEC 60601-1:2005/AMD1:2012 et de 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

Addition:

En ce qui concerne les APPAREILS EM spécifiés comme étant INSTALLES DE FAÇON PERMANENTE, les informations ne peuvent figurer que dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les informations relatives à la puissance absorbée doivent être spécifiées en associant

a) la TENSION DE RESEAU ASSIGNEE de l'APPAREIL EM en volts; voir le 7.2.1 et le 7.2.6 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020;

b) le nombre de phases; voir le 7.2.1 et le 7.2.6 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020;

c) la fréquence, en hertz; voir le 7.2.1 et le 7.2.6 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020;

d) la valeur maximale admissible pour la RESISTANCE APPARENTE DU RESEAU D'ALIMENTATION, en ohms;

e) les caractéristiques des DECLENCHEURS A MAXIMUM DE COURANT exigés sur le RESEAU D'ALIMENTATION.

201.7.2.15 Conditions de refroidissement

Addition:

Dans le cas où un refroidissement est nécessaire pour un fonctionnement en toute sécurité de l'APPAREIL EM ou d'un sous-ensemble de l'appareil, les exigences relatives au refroidissement doivent être indiquées dans le DOCUMENT D'ACCOMPAGNEMENT et spécifier, selon le cas:

– la dissipation maximale de chaleur dans l'air ambiant, indiquée séparément pour chaque sous-ensemble qui dissipe plus de 100 W et qui peut être installé séparément lors de l'installation;

– la dissipation maximale de chaleur dans les systèmes de refroidissement à air pulsé, le débit correspondant et l'élévation de température du flux d'air pulsé;

– la dissipation maximale de chaleur par l'intermédiaire d'un fluide de refroidissement, avec, pour ce fluide, la plage de températures d'entrée admissible et l'exigence des valeurs minimales pour le débit et la pression.

Paragraphe complémentaire:

201.7.2.101 Limiteur de faisceau

Des LIMITEURS DE FAISCEAU doivent comporter les marquages suivants:

– ceux qui sont exigés au paragraphe 7.2.2 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020;

– le numéro de série ou d'identification individuelle;

– la FILTRATION DE QUALITE EQUIVALENTE de tous les appareils installés de façon permanente et qui interceptent le FAISCEAU DE RAYONNEMENT X.

201.7.8.1 Couleurs des voyants lumineux

Addition:

Les états liés du RAYONNEMENT X doivent être exclus du paragraphe 7.8 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020, Les paragraphes 203.6.4.2 et 203.6.4.101 doivent s'appliquer à la place. Il convient que les lumières de couleurs jaunes et vertes, énumérées dans le Tableau 2 de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD2:2020, ne soient utilisées que si elles peuvent être clairement distinguées de l'indication des états liés du RAYONNEMENT X comme cela est exigé dans ces paragraphes.

Le cas échéant, les conflits que peut entraîner l'utilisation des mêmes couleurs ou de couleurs similaires pour indiquer les états du RAYONNEMENT X ainsi que d'autres fonctions de l'APPAREIL EM doivent être évalués au moyen du processus d'INGENIERIE DE L'APTITUDE A L'UTILISATION.

Les couleurs des voyants lumineux et des voyants lumineux d'alarme pour les APPAREILS EM désignées comme CONDITIONS D'ALARME DE HAUTE PRIORITE, DE PRIORITE MOYENNE ET DE BASSE PRIORITE, énoncées dans le Tableau 2 de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD2:2020, ne s'appliquent pas aux APPAREILS A RAYONNEMENT X.

NOTE Bien que le paragraphe 7.8 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 mentionne la norme collatérale IEC 60601-1-8 dont l'application est exclue au 201.1.3 du présent document, les références spécifiées sélectionnées ici sont considérées comme informatives. Elles aident à comprendre les exigences contenues dans le paragraphe 7.8 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020.

La vérification est effectuée par l'examen du DOSSIER D'INGENIERIE DE L'APTITUDE A L'UTILISATION.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.1 Généralités

Addition:

Les DOCUMENTS D'ACCOMPAGNEMENT doivent contenir les instructions relatives aux PROCEDURES DE CONTROLE QUALITE et aux essais recommandés par le FABRICANT à réaliser par l'ORGANISME RESPONSABLE sur l'APPAREIL A RAYONNEMENT X. Ces documents doivent inclure les critères d'acceptation et la fréquence de chaque essai.

NOTE Le but est de suivre ces PROCEDURES DE CONTROLE QUALITE et d'effectuer ces essais en utilisant uniquement les informations fournies.

En outre, en ce qui concerne les APPAREILS A RAYONNEMENT X équipés d'un RECEPTEUR D'IMAGE RADIOLOGIQUE numérique intégré, les DOCUMENTS D'ACCOMPAGNEMENT doivent contenir:

– une identification du traitement réglable ou sélectionnable de l'image appliqué aux DONNEES ORIGINALES indiquant le numéro de version ou comment le déterminer;

– une description du format de transfert des fichiers contenant les images acquises avec cet appareil et de toutes données associées à ces images.

La performance des moyens exigés pour la présentation d'images à des fins de diagnostic doit être spécifiée en fonction de l'UTILISATION PREVUE.

Dans le cas où l'essai ou la PROCEDURE exige un OUTIL spécifique au dispositif uniquement disponible auprès du FABRICANT, ce dernier doit mettre cet OUTIL à disposition de l'ORGANISME RESPONSABLE.

La vérification est effectuée par l'examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Paragraphes complémentaires:

201.7.9.2.1.101 PARAMETRES DE CHARGE

Les instructions d'utilisation doivent spécifier les PARAMETRES DE CHARGE comme suit. Les combinaisons et données suivantes doivent être déclarées:

a) les valeurs de la HAUTE TENSION RADIOGENE NOMINALE correspondante pour la RADIOSCOPIE et la RADIOGRAPHIE, et de la plus forte intensité du COURANT DANS LE TUBE RADIOGENE que l'APPAREIL EM peut fournir lorsqu'il fonctionne à cette HAUTE TENSION RADIOGENE;

b) les valeurs de la plus forte intensité du COURANT DANS LE TUBE RADIOGENE correspondant pour la RADIOSCOPIE et la RADIOGRAPHIE, et de la plus la HAUTE TENSION RADIOGENE que l'APPAREIL EM peut fournir lorsqu'il fonctionne à ce COURANT DANS LE TUBE RADIOGENE;

c) la combinaison correspondante de la HAUTE TENSION RADIOGENE pour la RADIOSCOPIE et la RADIOGRAPHIE, et du COURANT DANS LE TUBE RADIOGENE qui délivre la puissance électrique la plus élevée dans le circuit haute tension (voir 203.4.101);

d) la PUISSANCE ELECTRIQUE NOMINALE spécifiée comme la puissance électrique constante la plus élevée, exprimée en kilowatts, que l'APPAREIL EM peut produire/générer, pour un TEMPS DE CHARGE de 0,1 s à une HAUTE TENSION RADIOGENE de 100 kV ou, si ce réglage n'est pas prévu, aux valeurs les plus proches (voir 203.4.101);

   La PUISSANCE ELECTRIQUE NOMINALE doit être indiquée avec la combinaison HAUTE TENSION RADIOGENE/COURANT DANS LE TUBE RADIOGENE, ainsi qu'avec le TEMPS DE CHARGE;

e) en ce qui concerne les APPAREILS EM qui indiquent un PRODUIT COURANT TEMPS précalculé ou mesuré, la valeur la plus basse du PRODUIT COURANT TEMPS ou les combinaisons de PARAMETRES DE CHARGE qui fournissent le PRODUIT COURANT TEMPS le plus faible.

   Lorsque la valeur du PRODUIT COURANT TEMPS le plus faible dépend de la HAUTE TENSION RADIOGENE ou de certaines combinaisons de valeurs de PARAMETRES DE CHARGE, le PRODUIT COURANT TEMPS le plus faible peut être indiqué sous la forme d'un tableau ou d'une courbe qui fait apparaître la relation;

f) le TEMPS MINIMAL D'IRRADIATION NOMINAL utilisé dans les SYSTEMES DE COMMANDE AUTOMATIQUE D'EXPOSITION de l'APPAREIL EM.

   Lorsque le TEMPS MINIMAL D'IRRADIATION NOMINAL dépend des PARAMETRES DE CHARGE tels que la HAUTE TENSION RADIOGENE et le COURANT DANS LE TUBE RADIOGENE, les plages de ces PARAMETRES DE CHARGE, pour lesquelles le TEMPS MINIMAL D'IRRADIATION NOMINAL est valable, doivent être déclarées.

   La plage maximale possible de la HAUTE TENSION RADIOGENE et/ou du COURANT DANS LE TUBE RADIOGENE pendant les IRRADIATIONS, contrôlées par les SYSTEMES DE COMMANDE AUTOMATIQUE D'EXPOSITION, doit être déclarée dans les instructions d'utilisation.

201.7.9.2.1.102 Ensemble radiogène

Les instructions d'utilisation doivent indiquer le CHAMP DE RAYONNEMENT maximal symétrique de l'ENSEMBLE RADIOGENE A RAYONNEMENT X intégré, déterminé selon l'IEC 60806.

201.7.9.2.1.103 RECEPTEUR D'IMAGE RADIOLOGIQUE intégré

En ce qui concerne les APPAREILS A RAYONNEMENT X équipés d'un RECEPTEUR D'IMAGE RADIOLOGIQUE intégré, les instructions d'utilisation doivent contenir une description de la manipulation et de la maintenance spécifiques du RECEPTEUR D'IMAGE RADIOLOGIQUE.

La vérification est effectuée par l'examen des instructions d'utilisation.

201.7.9.2.17 APPAREIL EM émettant des rayonnements

Remplacement:

Pour les APPAREILS A RAYONNEMENT X, les instructions d'utilisation doivent fournir les informations exigées en 203.5.

201.7.9.3 Description technique

Paragraphes complémentaires:

201.7.9.3.101 ENSEMBLE RADIOGENE

La description technique des ENSEMBLES RADIOGENES intégrés doit, en plus des données à marquer obligatoirement conformément au paragraphe 7.2 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020, spécifier ce qui suit:

a) l'AXE DE REFERENCE;

b) l'ANGLE ou les ANGLES CIBLE(S);

c) la position et la tolérance du ou des FOYER(S);

d) la ou les tailles du FOYER:
Lorsque la ou les tailles du FOYER se situent dans la plage des VALEURS NOMINALES DU FOYER de l'IEC 60336, déclarer que la ou les tailles du FOYER sont des VALEURS NOMINALES DU FOYER selon l'IEC 60336.

NOTE Ces exigences sont adaptées du 201.7.9.3.101 de l'IEC 60601-2-28:2017.

201.7.9.101 Déclarations supplémentaires dans les DOCUMENTS D'ACCOMPAGNEMENT

Les paragraphes indiqués dans le Tableau 201.C.102 spécifient des exigences supplémentaires relatives aux déclarations dans les DOCUMENTS D'ACCOMPAGNEMENT (qui incluent les instructions d'utilisation et la description technique).

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.8.4 Limitation de la tension, du courant ou de l'énergie

201.8.4.3 APPAREILS EM destinés à être connectés à une source de puissance par une fiche

Paragraphes complémentaires:

201.8.4.3.101 Raccordements par câbles haute tension

Les raccordements par câbles haute tension non fixés à demeure doivent soit être conçus de façon que l'utilisation d'OUTILS soit exigée pour les débrancher, soit être équipés de VERROUILLAGES, tels que, chaque fois que les capots de protection ou les raccordements haute tension sont retirés:

– l'APPAREIL EM soit déconnecté de son alimentation électrique, et
– les capacités du circuit haute tension soient déchargées dans le temps minimal nécessaire pour accéder au circuit haute tension, et
– l'état déchargé soit maintenu.

La vérification est effectuée par examen et mesurage.

201.8.4.101 Limitation de la HAUTE TENSION RADIOGENE

L'APPAREIL EM doit être conçu de sorte à ne délivrer, dans l'UTILISATION PREVUE, à aucune GAINE EQUIPEE raccordée, une tension supérieure à la HAUTE TENSION RADIOGENE NOMINALE du TUBE RADIOGENE en question ou supérieure à la HAUTE TENSION RADIOGENE NOMINALE pour laquelle la GAINE EQUIPEE est conçue, en prenant celle des deux tensions qui est la plus faible.

201.8.5 Séparation des parties

201.8.5.1 Moyens de protection

Paragraphe complémentaire:

201.8.5.1.101 Limitation supplémentaire de tension, de courant ou d'énergie

Des dispositions doivent être prises pour empêcher l'apparition d'une haute tension inacceptable dans la PARTIE RELIEE AU RESEAU ou dans tout autre circuit basse tension.

NOTE Ceci peut être réalisé par exemple

– au moyen d'une couche d'enroulement ou d'un écran conducteur raccordé à la BORNE DE TERRE DE PROTECTION entre des circuits haute tension et basse tension;
– en prévoyant un dispositif limiteur de tension aux bornes auxquelles les dispositifs externes sont connectés et entre lesquelles une tension excessive peut apparaître si le chemin externe devenait discontinu.

La vérification est effectuée par examen des données de conception et de la construction.

201.8.5.4 TENSION DE SERVICE

Paragraphe complémentaire:

201.8.5.4.101 Essai de tension de tenue du stator et du circuit du stator

La tension d'essai employée pour l'essai de tension de tenue du stator et de son circuit, utilisés dans le fonctionnement de l'anode tournante du TUBE RADIOGENE, doit être fondée sur la tension existante lorsque la tension d'alimentation du stator est retombée à la valeur correspondant au fonctionnement en régime stabilisé.

201.8.6 Mise à la terre de protection, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM

201.8.6.4 Impédance et courant admissible

Addition:

Le gainage conducteur flexible ne doit pas être reconnu comme satisfaisant à une exigence relative à une CONNEXION DE TERRE DE PROTECTION entre les dispositifs raccordés par le câble.

Paragraphe complémentaire:

201.8.6.101 GAINE EQUIPEE

a) Les câbles haute tension accessibles qui connectent les GAINES EQUIPEES à leur GENERATEUR RADIOLOGIQUE associé, doivent comporter un gainage conducteur flexible, dont l'isolement linéique ne dépasse pas 1 $\Omega\ m^{-1}$, et être recouverts d'un matériau non conducteur assurant la protection du gainage contre les dommages mécaniques. Le gainage doit être connecté à l'ENVELOPPE conductrice du GENERATEUR RADIOLOGIQUE.

La vérification est effectuée par examen visuel et mesurage.

b) Dans tous les cas, il doit y avoir une continuité électrique entre le gainage du câble haute tension monté et les PARTIES METALLIQUES ACCESSIBLES de ses embases réceptacles sur la GAINE EQUIPEE.

La vérification est effectuée par examen visuel et mesurage.

201.8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT

201.8.7.3 *Valeurs admissibles

Le point c) est modifié comme suit:

En ce qui concerne les APPAREILS A RAYONNEMENT X MOBILES et les APPAREILS A RAYONNEMENT X TRANSPORTABLES, le COURANT DE CONTACT en CONDITION DE PREMIER DEFAUT ne doit pas dépasser 2 mA.

Le point d) est remplacé par le texte suivant:

En ce qui concerne les APPAREILS A RAYONNEMENT X MOBILES et les APPAREILS A RAYONNEMENT X TRANSPORTABLES, les valeurs admissibles du COURANT DE FUITE A LA TERRE sont 2,5 mA en CONDITION NORMALE et 5 mA en CONDITIONS DE PREMIER DEFAUT. En ce qui concerne les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, la valeur admissible du COURANT DE FUITE A LA TERRE est égale à 10 mA en CONDITION NORMALE et en CONDITIONS DE PREMIER DEFAUT.

Le point e) est modifié comme suit:

En ce qui concerne les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, y compris les GENERATEURS RADIOLOGIQUES, la valeur admissible du COURANT DE FUITE A LA TERRE est égale à 20 mA en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT.

201.8.8.3 Tension de tenue

Modification à l'essai de conformité du circuit haute tension:

Le circuit haute tension de l'APPAREIL EM est soumis à l'essai en appliquant une tension inférieure ou égale à la moitié de la tension d'essai, puis la tension d'essai est progressivement augmentée sur une période de 10 s pour atteindre sa pleine valeur, qui est maintenue pendant 3 min pour la RADIOGRAPHIE et 15 min pour la RADIOSCOPIE.

Ajout par rapport aux conditions d'essai du circuit haute tension:

L'essai du circuit haute tension doit être effectué sans GAINE EQUIPEE raccordée et avec une tension d'essai égale à 1,2 fois la HAUTE TENSION RADIOGENE NOMINALE de l'APPAREIL EM.

Lorsque l'APPAREIL EM peut être soumis à l'essai uniquement avec la GAINE EQUIPEE raccordée et lorsque le TUBE RADIOGENE ne permet pas que l'APPAREIL EM soit soumis à l'essai avec une tension d'essai égale à 1,2 fois la HAUTE TENSION RADIOGENE NOMINALE, la tension d'essai peut être inférieure, mais pas inférieure à 1,1 fois cette tension.

En ce qui concerne les APPAREILS EM dans lesquels la HAUTE TENSION RADIOGENE NOMINALE définie pour la RADIOSCOPIE ne dépasse pas une valeur égale à 80 % de celle définie pour la RADIOGRAPHIE, la tension d'essai appliquée au circuit haute tension doit être déterminée en référence à la valeur définie pour la RADIOGRAPHIE, et l'essai doit être effectué dans ce mode uniquement.

Dans le cas où au cours de l'essai de tension de tenue, il existe un RISQUE de surchauffe d'un transformateur soumis à l'essai, il est admis d'effectuer l'essai à une fréquence d'alimentation supérieure.

Au cours de l'essai de tension de tenue, il convient de maintenir la tension d'essai dans le circuit haute tension à une valeur aussi proche que possible de 100 %. En outre, la tension d'essai ne doit pas se situer en dehors de la plage comprise entre 100 % et 105 % de la valeur exigée.

Au cours de l'essai de tension de tenue, les légères décharges en couronne qui se produisent dans le circuit haute tension ne doivent pas être prises en compte si elles cessent lorsque la tension d'essai est abaissée à une valeur égale à 110 % de la tension de référence de la condition d'essai.

Additions:

aa) Les GENERATEURS RADIOLOGIQUES ou des sous-ensembles de ceux-ci, intégrés avec une GAINE EQUIPEE doivent être soumis aux essais, en chargeant le TUBE RADIOGENE de façon appropriée.

bb) Lorsque dans les GENERATEURS RADIOLOGIQUES, il n'est pas possible de régler séparément le COURANT DANS LE TUBE RADIOGENE, la durée de l'essai de tension de tenue doit être réduite de sorte que la CHARGE DU TUBE RADIOGENE admissible à la HAUTE TENSION RADIOGENE augmentée ne soit pas dépassée.

cc) Lorsque le circuit haute tension n'est pas accessible pour le mesurage de la tension d'essai appliquée, il convient de prendre les dispositions appropriées pour que les valeurs soient maintenues aussi proches que possible de 100 %, et qu'elles ne se situent pas en dehors de la plage comprise entre 100 % et 105 % de la valeur exigée.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et des SYSTEMES EM

L'Article 9 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.9.2.2.4.4 Autres mesures de MAITRISE DU RISQUE

Paragraphe complémentaire:

201.9.2.2.4.4.101 Protection contre les collisions

Dans le cas où l'APPAREIL A RAYONNEMENT X est équipé de dispositifs anticollision, les instructions d'utilisation doivent décrire ces dispositifs. De plus, les mesures prévues pour empêcher toute interruption inutile et assurer le déroulement continu d'un examen doivent être décrites.

Un moyen doit être prévu ou des mises en garde doivent figurer dans les DOCUMENTS D'ACCOMPAGNEMENT afin d'éviter le risque de dommages corporels susceptibles d'être occasionnés par une collision entre les parties motorisées de l'APPAREIL EM et d'autres éléments fixes ou en mouvement pouvant se trouver à proximité.

La vérification est effectuée par l'examen des instructions d'utilisation.

201.9.2.2.5 Activation continue

Amendement:

Le mouvement de l'APPAREIL EM ou des parties de l'APPAREIL EM susceptible d'occasionner des dommages corporels au PATIENT ou à l'OPERATEUR en UTILISATION NORMALE doit exiger l'intervention permanente de l'OPERATEUR.

Les mouvements motorisés de l'APPAREIL EM ou des parties de l'APPAREIL EM susceptibles d'écraser le PATIENT ou l'OPERATEUR ou lui occasionner des dommages corporels, et dont l'arrêt, par action de l'OPERATEUR, sur une commande d'arrêt d'urgence, ne peut pas garantir que des dommages corporels soient évités, doivent être possibles uniquement par l'actionnement manuel continu de deux interrupteurs par l'OPERATEUR. Chaque interrupteur doit être capable d'interrompre de façon indépendante le mouvement.

Les deux interrupteurs peuvent être actionnés par un organe de commande unique et un interrupteur peut se trouver dans un circuit commun à tous les mouvements.

Ces interrupteurs doivent se trouver à un endroit d'où un dommage possible au PATIENT peut être observé par l'OPERATEUR. Au moins un jeu d'interrupteurs doit être localisé de manière à exiger la présence de l'OPERATEUR près du PATIENT afin d'observer les parties en mouvement de l'APPAREIL EM.

Il n'est pas exigé que les mouvements motorisés des parties de l'APPAREIL EM susceptibles d'occasionner indirectement des dommages corporels, tels qu'un mouvement d'angulation de la table pouvant faire tomber le PATIENT, soient commandés par deux interrupteurs.

En ce qui concerne les APPAREILS EM conçus pour être automatiquement enclenchés ou prépositionnés, une commande à action continue, qui arrête les mouvements mécaniques quand elle est relâchée, doit être disposée à un endroit où les mouvements peuvent être observés. Si la sécurité peut être obtenue par d'autres moyens et si cela est justifié dans le DOSSIER DE GESTION DES RISQUES, un actionnement continu n'est pas exigé.

Le FABRICANT doit identifier par la GESTION DES RISQUES les mouvements motorisés susceptibles de provoquer le DANGER.

La vérification est effectuée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.9.2.2.6 Vitesse du ou des mouvements

Addition:

Le dépassement de course d'un tel mouvement, qui intervient après l'actionnement d'une commande pour le stopper, ne doit pas dépasser 10 mm en UTILISATION NORMALE. Lorsque la sécurité peut être obtenue par d'autres moyens et lorsque cela est justifié dans le DOSSIER DE GESTION DES RISQUES, le dépassement de course peut être supérieur à 10 mm.

Sauf pour les APPAREILS EM MOBILES, lorsque le mouvement d'un APPAREIL EM motorisé vers le PATIENT est à moins de 300 mm du dessus de la table du PATIENT, ou de 100 mm du côté de la table, il convient que la vitesse soit limitée à la moitié de la vitesse maximale. Lorsque la sécurité peut être obtenue par d'autres moyens et lorsque cela est justifié dans le DOSSIER DE GESTION DES RISQUES, la limitation de vitesse n'est pas exigée.

La vérification est effectuée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels, ainsi que par mesurage.

201.9.2.3 Autres DANGERS MECANIQUES associés aux parties en mouvement

201.9.2.3.1 Mouvement non désiré

Addition:

Un moyen qui permet de réduire le plus possible la possibilité de mise en mouvement involontaire, lorsque cette mise en mouvement peut causer des dommages corporels au PATIENT ou à l'OPERATEUR, en UTILISATION NORMALE et en CONDITION DE PREMIER DEFAUT, doit être fourni. Ce qui suit doit être appliqué:

a) Lorsqu'une défaillance, par exemple, des contacts de relais soudés, risque de provoquer une mise en mouvement incontrôlée, des commandes redondantes ou d'autres protections de ce type doivent être mises en place. La défaillance de l'une des commandes redondantes doit être signalée à l'OPERATEUR, soit directement, soit par le biais d'un essai effectué conformément aux instructions d'utilisation.

b) Les éléments de commutation ne doivent pas être branchés sur la face reliée à la terre d'un circuit de commande de mise en mouvement.

La vérification est effectuée par examen du schéma de circuit, examen visuel et essais fonctionnels.

En ce qui concerne les APPAREILS EM INSTALLES DE FAÇON PERMANENTE ou les parties des APPAREILS EM INSTALLES DE FAÇON PERMANENTE, ce qui suit doit être appliqué:

Lorsque le placement ou le mouvement d'un objet ou du PATIENT contre une commande de mouvement risque d'actionner les deux commutateurs, un interrupteur qui permet de désactiver les commandes de mouvement doit être installé.

NOTE Cet interrupteur peut se trouver dans la salle d'examen et pas nécessairement à côté de la table. Il peut s'avérer utile pour l'OPERATEUR que l'interrupteur d'arrêt des commandes de mouvement soit placé à proximité de l'interrupteur d'arrêt de l'IRRADIATION.

Le fonctionnement en soi de l'interrupteur d'arrêt des commandes de mouvement ne doit pas permettre le déclenchement d'un mouvement.

Un témoin signalant l'état de l'interrupteur d'arrêt des commandes de mouvement doit se trouver à l'emplacement de travail de l'OPERATEUR.

L'emplacement, la fonction et le fonctionnement de l'interrupteur d'arrêt des commandes de mouvement doivent être décrits dans les instructions d'utilisation.

L'interrupteur d'arrêt des commandes de mouvement doit être distinct de l'interrupteur d'arrêt de l'IRRADIATION.

Il convient que l'interrupteur soit facilement accessible pour l'OPERATEUR et que sa conception réduise le plus possible le risque d'actionnement accidentel.

Les configurations doivent être prises en considération dans le PROCESSUS D'INGENIERIE D'APTITUDE A L'UTILISATION.

La vérification est effectuée par des essais fonctionnels et par l'examen des instructions d'utilisation et du DOSSIER D'INGENIERIE D'APTITUDE A L'UTILISATION.

Paragraphes complémentaires:

201.9.2.3.1.101 Mouvement involontaire pendant l'installation/le retrait du PATIENT

Un moyen doit être fourni pour empêcher un mouvement involontaire de l'APPAREIL EM ou de parties de l'APPAREIL EM pendant l'installation et le retrait du PATIENT, susceptible de causer des dommages corporels au PATIENT ou à l'OPERATEUR.

La vérification est effectuée par un essai fonctionnel qui tient compte du poids NOMINAL maximal du PATIENT.

201.9.2.3.101 Limitation de la pression et de la force

La pression ou la force qu'il est permis d'appliquer au PATIENT à des fins de diagnostic, doivent être analysées en fonction de la partie du corps qui peut entrer en contact avec l'APPAREIL EM, des exigences d'application et du risque de dommages corporels. D'une manière générale, il convient de limiter la pression exercée sur le PATIENT à 70 kPa au maximum et la force, à 200 N.

NOTE Des limites supérieures applicables aux DISPOSITIFS DE COMPRESSION peuvent être admises selon la réglementation du pays.

Pour les mouvements de compression motorisés, il doit être prévu un moyen qui limite la force exercée sur le PATIENT, en fonction des valeurs indiquées dans les instructions d'utilisation.

La vérification est effectuée par examen visuel, essai fonctionnel, mesurage et par examen des instructions d'utilisation.

201.9.2.3.102 VERROUILLAGE des mouvements des dispositifs de compression

Lorsqu'une force de compression est exercée sur le PATIENT et que les mouvements ne sont pas directement commandés par un OPERATEUR à proximité du PATIENT, les mouvements, susceptibles d'être dangereux pour le PATIENT et qui ne sont pas nécessaires à l'examen, doivent être verrouillés. Si une désactivation de ce VERROUILLAGE s'avère nécessaire pour l'examen en cours, cette désactivation peut se faire par l'intermédiaire d'une commande dédiée. Une indication visuelle doit être fournie à l'OPERATEUR tant que le VERROUILLAGE est désactivé.

Les instructions d'utilisation doivent comporter une mention qui avertit l'OPERATEUR des RISQUES possibles liés à la désactivation du VERROUILLAGE.

La vérification est effectuée par des essais fonctionnels et par l'examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.9.2.4 Dispositifs d'arrêt d'urgence

Paragraphe complémentaire:

201.9.2.4.101 Commandes

Tous les mouvements motorisés susceptibles d'occasionner des dommages corporels doivent être reliés à une commande d'arrêt d'urgence. En cas d'arrêt d'urgence, il doit être prévu un moyen qui permet l'accès et le retrait du PATIENT pendant que l'APPAREIL EM est neutralisé. Lorsque la sécurité peut être obtenue par d'autres moyens et lorsque cela est justifié dans le DOSSIER DE GESTION DES RISQUES, une commande d'arrêt d'urgence n'est pas exigée.

Lorsqu'en UTILISATION NORMALE, une partie de l'APPAREIL EM motorisée est destinée à ou susceptible d'entrer en contact avec le PATIENT, et lorsque cela convient à l'application prévue, il doit être prévu un moyen qui permet de détecter le contact avec le PATIENT et d'arrêter le mouvement si le contact risque de le blesser.

La vérification est effectuée par des essais fonctionnels et par examen du DOSSIER DE GESTION DES RISQUES.

201.9.8 DANGERS MECANIQUES associés aux systèmes de support

201.9.8.3.3 Forces dynamiques dues à la charge des personnes

Addition:

NOTE La masse est accélérée sur 150 mm, puis décélère pendant la compression de la mousse sur 60 mm, ce qui génère une force équivalent à 2 à 3 fois à la CHARGE DE FONCTIONNEMENT EN SECURITE.

Lorsqu'une analyse mécanique prouve que l'essai alternatif de charge statique produit des valeurs plus élevées que l'essai de charge dynamique spécifié dans l'IEC 60601-1, il est possible de renoncer à appliquer l'essai de charge dynamique fondé sur la GESTION DES RISQUES. Lorsque l'essai de charge dynamique a donné de bons résultats, l'essai de charge statique n'est pas nécessaire.

Avant de réaliser cet essai, un système de support/suspension PATIENT est placé horizontalement, dans sa position la plus défavorable en UTILISATION NORMALE.

En ce qui concerne la surface de support/suspension lorsque le PATIENT ou l'OPERATEUR peut s'asseoir, des multiples de masses adéquats (tels qu'ils sont définis à la Figure 33 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020) équivalents à une CHARGE DE FONCTIONNEMENT EN SECURITE, qui représentent le PATIENT ou l'OPERATEUR, comme cela est défini dans les instructions d'utilisation, sont appliqués à la surface pendant 1 min au moins. Toute perte de fonction ou dommage structurel susceptible de donner lieu à un RISQUE inacceptable constitue une défaillance.

201.9.8.4 Systèmes avec DISPOSITIFS DE PROTECTION MECANIQUE

Paragraphes complémentaires:

201.9.8.4.101 Dispositif de protection mécanique

Les cordes, chaînes ou courroies qui sont parallèles à d'autres cordes, chaînes ou courroies peuvent être considérées comme un DISPOSITIF DE PROTECTION MECANIQUE lorsqu'elles ne sont pas en charge au cours d'une UTILISATION NORMALE.

Les cordes, chaînes ou courroies utilisées comme un DISPOSITIF DE PROTECTION MECANIQUE doivent être accessibles pour effectuer un examen et les DOCUMENTS D'ACCOMPAGNEMENT doivent fournir des instructions appropriées concernant cet examen.

La vérification est effectuée par des essais fonctionnels et par l'examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.9.8.101 Dispositifs d'absorption des chocs

Un dispositif d'amortissement approprié doit être prévu pour les cas où une UTILISATION NORMALE induit de fortes charges dynamiques, par exemple au cours d'une accélération ou d'une décélération rapide.

La vérification est effectuée par des essais fonctionnels.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires et excessifs

L'Article 10 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, à l'exception du paragraphe 10.3 (Rayonnements à micro-ondes), qui ne s'applique pas.

NOTE La norme IEC 60601-1 fait référence à la norme collatérale IEC 60601-1-3, qui est traitée à l'Article 203 du présent document.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.11.1.1 Température maximale en UTILISATION NORMALE

Addition:

NOTE Les restrictions du Tableau 22 de l'IEC 60601-1:2005 relatives à la température maximale admissible des parties en contact avec de l'huile ne s'appliquent pas aux parties entièrement immergées dans l'huile.

201.11.8 Coupure de l'alimentation/du RESEAU D'ALIMENTATION vers l'APPAREIL EM

Remplacement du premier alinéa modifié par l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012:

L'APPAREIL EM doit être conçu de telle manière qu'une coupure et un rétablissement de l'alimentation ne doivent pas engendrer de perte de la SECURITE DE BASE et qu'un rétablissement de l'alimentation ne doive pas engendrer de perte des PERFORMANCES ESSENTIELLES.

Paragraphe complémentaire:

201.11.101 Protection contre les températures excessives des LIMITEURS DE FAISCEAU

Les LIMITEURS DE FAISCEAU qui incorporent un INDICATEUR DE CHAMP LUMINEUX doivent être équipés de l'un des dispositifs suivants afin de réduire l'élévation de température possible lorsque la lampe reste sous tension pendant que le LIMITEUR DE FAISCEAU est recouvert par des rideaux ou tout autre matériau, réduisant la dissipation normale de chaleur:

a) un COUPE-CIRCUIT THERMIQUE qui empêche la lampe de fonctionner lorsque la température maximale admissible, selon le paragraphe 11.1.1 de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD2:2020, de toute SURFACE ACCESSIBLE du LIMITEUR DE FAISCEAU est dépassée;

b) un dispositif de limitation de la durée qui empêche la lampe de fonctionner au-delà d'une période de 2 min suivant sa mise en service la plus récente par l'OPERATEUR;

c) une mention figurant dans les DOCUMENTS D'ACCOMPAGNEMENT, qui détaille l'interrupteur de limitation de la durée destiné à être connecté de l'extérieur et à remplir la fonction décrite au point b) ci-dessus.

La vérification est effectuée par des essais fonctionnels et par l'examen des DOCUMENTS D'ACCOMPAGNEMENT.

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

Addition:

NOTE Conformément au paragraphe 12.4.5 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020, les aspects de cette question qui sont liés à la dose sont traités au paragraphe 203.6.4.3 du présent document.

201.13 SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM

L'Article 13 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

L'Article 14 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de 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, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.16 SYSTEMES EM

L'Article 16 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.16.8 Interruption de l'alimentation électrique de parties d'un SYSTEME EM

Remplacement du premier alinéa modifié par l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012:

Un SYSTÈME EM doit être conçu de telle manière qu'une interruption et un rétablissement de l'alimentation pour le SYSTÈME EM dans son ensemble ou pour une partie quelconque du SYSTÈME EM ne doivent pas engendrer de perte de la SECURITE DE BASE et qu'un rétablissement de l'alimentation ne doit pas engendrer de perte des PERFORMANCES ESSENTIELLES.

201.17 Compatibilité électromagnétique des APPAREILS EM et des SYSTEMES EM

L'Article 17 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique.

202 Perturbations électromagnétiques – Exigences et essais

L'IEC 60601-1-2 :2014 et l'IEC 60601-1-2:2014/AMD1:2020 s'appliquent, avec les exceptions suivantes.

Article complémentaire:

202.101 *Essais d'immunité des PERFORMANCES ESSENTIELLES

Le FABRICANT peut réduire le plus possible les exigences d'essai applicables aux exigences supplémentaires relatives aux PERFORMANCES ESSENTIELLES potentielles énumérées dans le Tableau 201.101 à un niveau pratique au moyen du PROCESSUS DE GESTION DES RISQUES.

Lorsqu'il sélectionne les exigences à soumettre à l'essai, le FABRICANT doit prendre en compte la sensibilité à l'environnement CEM, la probabilité de l'état et de la GRAVITE liés à la CEM, la probabilité et la contribution à un RISQUE inacceptable au moyen du PROCESSUS DE GESTION DES RISQUES.

La précision des instruments d'essai utilisés pour évaluer l'immunité des APPAREILS EM ne doit pas être affectée par les conditions électromagnétiques de l'essai.

L'instrument d'essai ne doit pas influer sur l'immunité des APPAREILS EM.

Seuls des mesurages non invasifs doivent être réalisés.

L'APPAREIL EM soumis à l'essai ne doit pas être modifié pour réaliser cet essai d'immunité.

La vérification est effectuée par l'examen du DOSSIER DE GESTION DES RISQUES.

203 RADIOPROTECTION dans les APPAREILS A RAYONNEMENT X de diagnostic

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, avec les exceptions suivantes:

203.4 Exigences générales

203.4.1 Déclaration de conformité

Remplacement:

Lorsque la conformité d'un APPAREIL EM ou d'un sous-ensemble avec le présent document doit être déclarée, cette déclaration doit prendre la forme suivante:

APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE et la RADIOSCOPIE … ++) IEC 60601-2-54:2022

++) REFERENCE DU MODELE OU DU TYPE

Paragraphes complémentaires:

203.4.101 Conditions de qualification des termes définis

203.4.101.1 Puissance électrique

La puissance électrique dans le circuit haute tension, mentionnée dans le présent document au paragraphe 201.7.9.2.1.101, aux points c) et d), est calculée selon la formule suivante:

$$P = f\,U\,I$$

où

– *P* est la puissance électrique;

– *f* est le facteur dépendant de la forme d'onde de la HAUTE TENSION RADIOGENE, sélectionné comme suit et égal à

  a) 0,95 pour les APPAREILS EM qui comprennent un GENERATEUR RADIOLOGIQUE A SIX CRETES, ou

  b) 1,00 pour les APPAREILS EM qui comprennent un GENERATEUR RADIOLOGIQUE A DOUZE CRETES ou un GENERATEUR RADIOLOGIQUE A TENSION CONSTANTE; ou

  c) pour les autres APPAREILS EM, la valeur la plus appropriée, choisie en fonction de la forme d'onde de la HAUTE TENSION RADIOGENE, avec indication de la valeur choisie;

– *U* est la HAUTE TENSION RADIOGENE;

– *I* est le COURANT DANS LE TUBE RADIOGENE.

203.4.101.2 TAUX D'OSCILLATION dans les GENERATEURS RADIOLOGIQUES A TENSION CONSTANTE

Le TAUX D'OSCILLATION de la tension de sortie d'un APPAREIL EM avec GENERATEUR RADIOLOGIQUE A TENSION CONSTANTE ne doit pas dépasser 4 %.

NOTE Voir aussi le 7.2 de l'IEC 60601-1-3:2008.

203.4.101.3 TEMPS DE CHARGE

Le TEMPS DE CHARGE est mesuré comme l'intervalle de temps entre:

– le moment auquel la HAUTE TENSION RADIOGENE atteint pour la première fois une valeur égale à 75 % de sa valeur de crête; et

– le moment auquel elle retombe finalement au-dessous de cette même valeur.

Pour les APPAREILS EM dans lesquels l'APPLICATION D'UNE CHARGE est contrôlée par commutation électronique de la HAUTE TENSION au moyen d'une grille contenue dans un tube électronique ou dans le TUBE RADIOGENE, le TEMPS DE CHARGE peut être déterminé comme l'intervalle de temps entre le moment auquel l'INTEGRATEUR DE TEMPS envoie le signal de début de l'IRRADIATION et le moment auquel il envoie le signal de fin de l'IRRADIATION.

Pour les APPAREILS EM dans lesquels l'APPLICATION D'UNE CHARGE est contrôlée par commutation simultanée dans les circuits primaires, à la fois du circuit haute tension et de l'alimentation du chauffage du filament du TUBE RADIOGENE, le TEMPS DE CHARGE doit être déterminé comme l'intervalle de temps entre le moment auquel le COURANT DANS LE TUBE RADIOGENE dépasse pour la première fois 25 % de sa valeur maximale et le moment auquel il retombe finalement au-dessous de cette même valeur.

NOTE Voir aussi la définition 3.37 de l'IEC 60601-1-3:2008.

203.4.101.4 TEMPS MINIMAL D'IRRADIATION NOMINAL

Le TEMPS MINIMAL D'IRRADIATION NOMINAL est déterminé selon le 203.6.5.101 comme le TEMPS DE CHARGE minimal:

– pour l'application d'une CHARGE durant laquelle la valeur moyenne du KERMA DANS L'AIR atteinte ne diffère pas de plus de 20 % de celui atteint pour un TEMPS DE CHARGE au moins 50 fois supérieur, mesuré conformément à 203.6.3.2.103, et

– non inférieur au plus court TEMPS DE CHARGE pour lequel les exigences de constance en 203.6.3.2.102 c) 2) et les exigences de reproductibilité en 203.6.3.2.102 d) sont satisfaites.

203.5 Identification, marquage et documentation des APPAREILS EM

203.5.2.1 Références dans les paragraphes

Amendement:

Dans le Tableau 2 de l'IEC 60601-1-3:2008, la ligne relative aux protocoles cliniques du paragraphe 5.2.4.4 ne s'applique pas.

203.5.2.4 Instructions d'utilisation

203.5.2.4.4 Protocoles cliniques

Le paragraphe 5.2.4.4 de l'IEC 60601-1-3:2008 ne s'applique pas.

203.5.2.4.5 Effets déterministes

Paragraphes complémentaires:

203.5.2.4.5.101 Informations dosimétriques relatives aux APPAREILS A RAYONNEMENT X spécifiés pour la RADIOSCOPIE et/ou la SERIOGRAPHIE

a) Niveaux de dose à la peau

Les instructions d'utilisation doivent attirer l'attention sur les RISQUES d'effets déterministes (réactions tissulaires) liés aux niveaux de dose à la peau dans le cadre de l'UTILISATION PREVUE, en cas d'exposition répétée ou prolongée. L'effet des différents réglages possibles en RADIOSCOPIE et RADIOGRAPHIE sur la QUALITE DE RAYONNEMENT, le KERMA DANS L'AIR DE REFERENCE ou le DEBIT DE KERMA DANS L'AIR DE REFERENCE délivré doit être décrit.

La vérification est effectuée par l'examen des instructions d'utilisation.

b) Réglages possibles

Les instructions d'utilisation doivent indiquer les configurations possibles fournies par le FABRICANT, telles que les MODES DE FONCTIONNEMENT, les PARAMETRES DE CHARGE et d'autres paramètres de fonctionnement qui ont une incidence sur la QUALITE DE RAYONNEMENT ou la valeur applicable du (DEBIT DE) KERMA DANS L'AIR DE REFERENCE dans le cadre de l'UTILISATION PREVUE. Lorsque ces informations s'appliquent, elles doivent comprendre:

1) les MODES DE FONCTIONNEMENT en RADIOSCOPIE, désignés, par exemple, par résolution "normale", "faible", "élevée" ou "mode dose" normal, faible ou élevé;

2) les réglages pour un MODE DE FONCTIONNEMENT type, comme cela est décrit au point 1), qui mentionnent les valeurs par défaut et les plages possibles des facteurs variables après le choix du MODE DE FONCTIONNEMENT;

3) les PARAMETRES DE CHARGE et autres paramètres de fonctionnement en RADIOSCOPIE qui délivrent le DEBIT DE KERMA DANS L'AIR DE REFERENCE le plus élevé possible;

4) les PARAMETRES DE CHARGE et autres paramètres de fonctionnement en RADIOGRAPHIE qui délivrent le KERMA DANS L'AIR DE REFERENCE par image le plus élevé possible;

5) les réglages de la DISTANCE FOYER-RECEPTEUR D'IMAGE qui correspondent aux valeurs minimale et type du KERMA DANS L'AIR DE REFERENCE ou du DEBIT DE KERMA DANS L'AIR DE REFERENCE.

La vérification est effectuée par l'examen des instructions d'utilisation.

c) * données de RAYONNEMENT

Les instructions d'utilisation doivent spécifier, pour les MODES DE FONCTIONNEMENT et les ensembles de valeurs décrits selon les réglages au point b) ci-dessus, les valeurs représentatives du (DEBIT DE) KERMA DANS L'AIR DE REFERENCE, sur la base de mesurages effectués selon la méthode décrite en 203.5.2.4.5.102.

De plus, les instructions d'utilisation doivent spécifier, pour les MODES DE FONCTIONNEMENT et les ensembles de valeurs décrits selon les réglages en b) 1) et b) 2) du présent article, les valeurs représentatives du (DEBIT DE) KERMA DANS L'AIR DE REFERENCE, sur la base de mesurages effectués selon la méthode décrite en 203.5.2.4.5.102, et si ces valeurs sont ajustables par l'OPERATEUR dans le MODE DE FONCTIONNEMENT en question, pour deux réglages des paramètres suivants:

- les FILTRES ADDITIONNELS sélectionnables;
- la DIMENSION DU CHAMP D'ENTREE
- la fréquence de répétition des impulsions du RAYONNEMENT X.

Des informations doivent être fournies sur les configurations de l'APPAREIL EM et les géométries d'essai utilisables dans la PROCEDURE décrite en 203.5.2.4.5.102 pour vérifier les valeurs indiquées. Bien qu'il soit exigé de fournir des indications qui permettent de procéder à une vérification par mesurage selon 203.5.2.4.5.102, les valeurs déclarées peuvent être déterminées à l'origine par d'autres méthodes, y compris le calcul, qui produisent des valeurs conformes, soumises aux tolérances admises, lorsque la vérification est effectuée selon la méthode décrite en 203.5.2.4.5.102.

Les VALEURS MESUREES ne doivent pas s'écarter de plus de 50 % des valeurs déclarées.

NOTE 1 Les valeurs mesurées sont comparées aux valeurs déclarées dans les instructions d'utilisation. Par conséquent, un écart de 50 % est approprié.

La vérification est effectuée par des essais fonctionnels et par l'examen des instructions d'utilisation. Les valeurs spécifiées pour le (DEBIT DE) KERMA DANS L'AIR DE REFERENCE et les déclarations concernant la variation de ces valeurs sont vérifiées à l'aide de la méthode décrite en 203.5.2.4.5.102, en utilisant des configurations et les géométries d'essai décrites dans les instructions d'utilisation.

d) *POINT DE REFERENCE D'ENTREE PATIENT

Les instructions d'utilisation doivent décrire l'emplacement du POINT DE REFERENCE D'ENTREE PATIENT, comme cela est spécifié pour le type d'APPAREIL DE RADIOSCOPIE:

Le POINT DE REFERENCE D'ENTREE PATIENT se situe:

– à 1 cm au-dessus du SUPPORT PATIENT pour les APPAREILS A RAYONNEMENT X, l'ENSEMBLE RADIOGENE étant situé au-dessous du SUPPORT PATIENT;

– à 30 cm au-dessus du SUPPORT PATIENT pour les APPAREILS A RAYONNEMENT X, l'ENSEMBLE RADIOGENE étant situé au-dessus du SUPPORT PATIENT;

– à 15 cm de l'ISOCENTRE dans la direction du FOYER dans le cas des APPAREILS A RAYONNEMENT X à arceau ou

  - dans le cas des APPAREILS A RAYONNEMENT X à arceau sans ISOCENTRE, sur un point le long de l'AXE du FAISCEAU DE RAYONNEMENT X défini par le FABRICANT comme étant représentatif du point d'intersection de l'AXE du FAISCEAU DE RAYONNEMENT X avec la SURFACE DU PATIENT. Dans ce cas, la déclaration figurant dans les instructions d'utilisation doit inclure la justification du choix de la position par le FABRICANT ou
  - sur le point représentant la DISTANCE FOYER-PEAU minimale pour les APPAREILS A RAYONNEMENT X à arceau, avec une DISTANCE FOYER-RECEPTEUR D'IMAGE inférieure à 45 cm,

  NOTE 2 Pour le positionnement latéral de l'arceau, la même définition du POINT DE REFERENCE D'ENTREE PATIENT est utilisée en relation avec l'ISOCENTRE comme cela est décrit ci-dessus pour les arceaux.

– dans le cas d'APPAREILS A RAYONNEMENT X différents de ceux mentionnés ci-dessus, le POINT DE REFERENCE D'ENTREE PATIENT doit être spécifié par le FABRICANT.

La vérification est effectuée par l'examen des instructions d'utilisation.

203.5.2.4.5.102 *Essai relatif aux informations dosimétriques

Utiliser la PROCEDURE d'essai suivante pour déterminer les informations dosimétriques:

– *pour le FANTOME, utiliser un bloc rectangulaire en polyméthacrylate de méthyle (PMMA) de 20 cm d'épaisseur, avec des côtés supérieurs ou égaux à 25 cm. (Le FANTOME peut être fabriqué à partir de couches de matériau.);*

– *utiliser un DOSIMETRE avec un détecteur de mesure suffisamment petit pour ne pas couvrir plus de 80 % de la surface du FAISCEAU DE RAYONNEMENT X dans le plan de mesure;*

– *ajuster la DISTANCE FOYER-RECEPTEUR D'IMAGE à sa valeur minimale. Placer le FANTOME aussi près que possible du RECEPTEUR D'IMAGE RADIOLOGIQUE, en laissant autant de distance que possible entre l'ENSEMBLE RADIOGENE et la SURFACE D'ENTREE du FANTOME. (Ceci réduit le plus possible l'effet de RAYONNEMENT DIFFUSE sur les mesurages.)*

– *placer le détecteur de mesure:*

  - *au POINT DE REFERENCE D'ENTREE PATIENT (uniquement si le détecteur de mesure et le FANTOME sont distants d'au moins 20 cm)*

  ou

  - *en un point situé à mi-distance entre le FOYER et la SURFACE D'ENTREE du FANTOME. Dans ce cas, les VALEURS MESUREES comprennent une mise à l'échelle à la distance géométrique appropriée.*

  NOTE 1 Ce positionnement réduit le plus possible l'influence du rayonnement parasite dans la lecture.

– *mesurer le DEBIT DE KERMA DANS L'AIR pour les réglages radioscopiques pour lesquels une valeur de DEBIT DE KERMA DANS L'AIR de référence doit être déclarée en 203.5.2.4.5.101 c);*

– *mesurer le KERMA DANS L'AIR par image pour les réglages radioscopiques dont la déclaration est exigée en 203.5.2.4.5.101 c);*

  NOTE 2 Lorsque les mesurages impliquent des COMMANDES AUTOMATIQUES D'EXPOSITION, vérifier les PARAMETRES DE CHARGE qui s'appliquent sans le détecteur de mesure, puis effectuer les mesurages de dose en réglant ces PARAMETRES DE CHARGE en mode manuel.

– *pour chaque réglage, le (DEBIT DE) KERMA DANS L'AIR doit être mesuré, en utilisant le FANTOME décrit, pour deux réglages des paramètres suivants:*

  - *les FILTRES ADDITIONNELS sélectionnables*;
  - *les DIMENSIONS DU CHAMP D'ENTREE de l'OPERATEUR représentatives, qu'il est possible de sélectionner*;
  - *la fréquence de répétition des impulsions du* RAYONNEMENT X.

203.5.2.4.101 PROTOCOLES D'EXAMEN

Lorsque des PROTOCOLES D'EXAMEN sont proposés par le FABRICANT et sont préchargés sur l'APPAREIL, les instructions d'utilisation doivent indiquer s'ils constituent des recommandations à appliquer directement pour optimiser le fonctionnement ou s'ils ne sont que des exemples/des points de départ à remplacer par des protocoles plus spécifiques établis par l'ORGANISME RESPONSABLE.

La vérification est effectuée par l'examen des instructions d'utilisation.

203.6 Gestion des RAYONNEMENTS

203.6.1 Généralités

Paragraphes complémentaires:

203.6.1.101 Gestion du stockage d'images de RADIOSCOPIE

Il convient que les APPAREILS A RAYONNEMENT X spécifiés pour la RADIOSCOPIE soient capables de stocker la SEQUENCE DE REPETITION DE LECTURE D'IMAGES DE RADIOSCOPIE à des fins d'AFFICHAGE. Cette capacité peut être limitée au stockage d'images, comme suit:

- aux fréquences d'impulsion jusqu'à 10 impulsions par seconde, les 30 dernières secondes de la RADIOSCOPIE;
- pour les fréquences d'impulsion supérieures à 10 impulsions par seconde, les 300 dernières images;
- pour les RADIOSCOPIES continues, les 10 dernières secondes de la radioscopie.

La vérification est effectuée par des essais fonctionnels.

203.6.1.102 Gestion des PROTOCOLES D'EXAMEN

Lorsque les PROTOCOLES D'EXAMEN sont préchargés et que l'UTILISATION PREVUE des APPAREILS A RAYONNEMENT X couvre les applications sur les personnes adultes et les applications pédiatriques, la désignation de ces protocoles doit établir une distinction claire entre les applications sur les personnes adultes et les applications pédiatriques.

Pour les appareils sans SYSTEME DE COMMANDE AUTOMATIQUE:

– il convient que l'OPERATEUR ait le choix parmi au moins trois tailles de PATIENTS pour les PATIENTS adultes;
– dans le cas où l'UTILISATION PREVUE comprend les applications pédiatriques, il convient que l'OPERATEUR ait le choix parmi au moins trois tailles de PATIENTS pour les PATIENTS pédiatriques.

La vérification est effectuée par examen ou par les essais fonctionnels appropriés.

203.6.2 Déclenchement et arrêt de l'IRRADIATION

203.6.2.1 Déclenchement et arrêt normaux de l'IRRADIATION

Addition:

a) il ne doit pas être possible de déclencher une autre IRRADIATION ou, dans le cas de la SERIOGRAPHIE, une autre série, sans relâcher la commande qui a déclenché l'IRRADIATION précédente;

b) il doit être prévu un moyen permettant à l'OPERATEUR d'arrêter l'APPLICATION D'UNE CHARGE à tout moment avant sa fin prévue, sauf dans le cas de la SERIOGRAPHIE ou de l'APPLICATION D'UNE CHARGE unique pendant un TEMPS DE CHARGE de 0,5 s ou moins.

Pendant la SERIOGRAPHIE, l'OPERATEUR doit pouvoir arrêter les APPLICATIONS DE CHARGE à tout moment, mais des moyens peuvent être fournis pour permettre de terminer chaque APPLICATION DE CHARGE unique de la série en cours;

c) pour le fonctionnement en RADIOSCOPIE, lorsque la durée de l'IRRADIATION est déterminée par l'OPERATEUR pendant qu'elle se déroule, un INTEGRATEUR DE TEMPS doit être fourni, avertissant l'OPERATEUR par un signal sonore de la fin de périodes cumulées de l'APPLICATION D'UNE CHARGE. L'INTEGRATEUR DE TEMPS doit avoir les caractéristiques suivantes:

   1) il doit être possible de définir la durée de l'intégrateur de façon à permettre les APPLICATIONS DE CHARGE en une durée cumulative maximale de 5 min sans qu'un avertissement soit émis. Il peut également être prévu un dispositif qui permet de définir des durées inférieures à 5 min. Toute APPLICATION D'UNE CHARGE effectuée sans réglage du dispositif et toute APPLICATION D'UNE CHARGE effectuée après l'expiration de la période définie le plus récemment doit provoquer l'émission d'un avertissement sonore continu, audible pendant toute la durée de l'APPLICATION DE LA CHARGE;

   2) il doit être possible de réinitialiser le dispositif, sans empêcher ou interrompre l'APPLICATION D'UNE CHARGE, afin d'arrêter le signal et de permettre de cumuler d'autres périodes d'APPLICATION DE CHARGE, ne dépassant pas chacune 5 min, sans déclenchement d'un avertissement;

   3) toute commande de réglage ou de réinitialisation de la temporisation doit être séparée de toute COMMANDE D'IRRADIATION.

d) outre l'INTEGRATEUR DE TEMPS exigé au point c) ci-dessus, un système doit assurer l'arrêt automatique au cas où l'APPLICATION D'UNE CHARGE en RADIOSCOPIE se poursuit sans interruption pendant plus de 10 min. Si l'APPLICATION D'UNE CHARGE est arrêtée par l'intervention de ce dispositif en CONDITION NORMALE, il doit être possible de la reprendre en relâchant et en actionnant de nouveau la COMMANDE D'IRRADIATION;

e) * pour un EVENEMENT D'IRRADIATION DE RADIOSCOPIE de plus de 0,5 s, l'APPAREIL A RAYONNEMENT X doit mettre fin à l'APPLICATION D'UNE CHARGE en 0,1 s à partir de l'instant auquel l'OPERATEUR déclenche la commande (par exemple, en relâchant la pression sur une pédale). Le temps le plus court possible est souhaitable.

   Pour un EVENEMENT D'IRRADIATION DE RADIOSCOPIE de 0,5 s ou moins, l'APPAREIL A RAYONNEMENT X doit mettre fin à l'APPLICATION D'UNE CHARGE en 0,5 s à partir de l'instant auquel l'OPERATEUR déclenche la commande (par exemple, en relâchant la pression sur une pédale).

Les instructions d'utilisation doivent indiquer les durées d'EVENEMENT D'IRRADIATION DE RADIOSCOPIE pour lesquelles une RADIOSCOPIE peut continuer après le déclenchement de la commande, comme cela est décrit en 203.6.2.1 e), et la durée maximale pendant laquelle la RADIOSCOPIE peut continuer dans chacun des cas décrits.

La vérification est effectuée par examen et par les essais fonctionnels appropriés.

Paragraphes complémentaires:

203.6.2.1.101 VERROUILLAGE du mode de charge

Tout APPAREIL A RAYONNEMENT X MOBILE équipé d'un chargeur de batterie intégré doit comporter un système interdisant l'accès de personnes non autorisées aux commandes des mouvements motorisés et à l'émission de RAYONNEMENT X sans toutefois empêcher la charge des batteries.

NOTE Un exemple de dispositif qui permet de satisfaire à cette exigence est l'installation d'une commande à clé de telle sorte que les mouvements motorisés et l'émission de RAYONNEMENT X ne soient possibles qu'en présence de la clé, la batterie pouvant être chargée en l'absence de la clé.

La vérification est effectuée par examen.

203.6.2.1.102 Raccordements de VERROUILLAGES extérieurs

Les APPAREILS A RAYONNEMENT X, à l'exception des APPAREILS A RAYONNEMENT X MOBILES, doivent être équipés de raccordements pour dispositifs électriques extérieurs, distincts de l'APPAREIL EM, capables

– soit d'empêcher le GROUPE RADIOGENE de commencer à émettre un RAYONNEMENT X,

– soit de faire arrêter l'émission de RAYONNEMENT X par le GROUPE RADIOGENE,

– soit les deux.

Lorsque l'état des signaux émis par ces dispositifs électriques extérieurs n'est pas affiché sur le POSTE DE COMMANDE, les DOCUMENTS D'ACCOMPAGNEMENT doivent contenir des informations à l'intention de l'ORGANISME RESPONSABLE qui stipulent qu'il convient que l'état des signaux soit indiqué par des moyens visuels intégrés à l'installation.

NOTE Ce dispositif peut par exemple être utilisé pour garantir la présence d'une BARRIERE DE PROTECTION CONTRE LE FAISCEAU pendant la RADIOSCOPIE.

La vérification est effectuée par examen et par les essais fonctionnels appropriés.

203.6.2.2 Mesures de sécurité contre la défaillance de l'arrêt normal de l'IRRADIATION

Addition:

Dans le cas où la coupure normale dépend d'un mesurage du RAYONNEMENT

– la mesure de sécurité doit comprendre un système de coupure de l'IRRADIATION en cas de défaut de la coupure normale, et

– soit le produit de la HAUTE TENSION RADIOGENE, du COURANT DANS LE TUBE RADIOGENE et du TEMPS DE CHARGE doit être limité à 60 kWs par IRRADIATION, soit le PRODUIT COURANT TEMPS doit être limité à 600 mAs par IRRADIATION.

La vérification est effectuée par examen et par les essais fonctionnels appropriés.

203.6.3 Dose de RAYONNEMENT et qualité de RAYONNEMENT

203.6.3.1 Réglage de la dose de RAYONNEMENT et de la QUALITE DE RAYONNEMENT

Addition:

a) les systèmes de commande automatique des PARAMETRES DE CHARGE doivent permettre une plage de combinaisons adéquate de PARAMETRES DE CHARGE présélectionnables, de telle sorte que la commande automatique s'applique à des plages satisfaisant à l'exigence de la norme collatérale;

b) pour les systèmes de commande automatique des PARAMETRES DE CHARGE et/ou la FILTRATION ADDITIONNELLE à commande automatique en RADIOSCOPIE, il doit être considéré que l'exigence de la norme collatérale est satisfaite lorsque

– au moins deux niveaux convenablement différenciés de la quantité contrôlée peuvent être choisis; ou

– au moins deux niveaux convenablement différenciés pour un PARAMETRE DE CHARGE caractéristique et/ou une FILTRATION ADDITIONNELLE à commande automatique, ou des fonctions convenablement différenciées pour des PARAMETRES DE CHARGE interdépendants et/ou une FILTRATION ADDITIONNELLE à commande automatique peuvent être choisis; ou

– de façon complémentaire, une commande manuelle indépendante du SYSTEME DE COMMANDE AUTOMATIQUE est possible.

La vérification est effectuée par examen et par les essais fonctionnels appropriés.

203.6.3.2 Reproductibilité des CARACTERISTIQUES DE SORTIE DU RAYONNEMENT

Paragraphes complémentaires:

203.6.3.2.101 Reproductibilité des CARACTERISTIQUES DE SORTIE DU RAYONNEMENT en RADIOGRAPHIE

Le coefficient de variation des VALEURS MESUREES du KERMA DANS L'AIR ne doit pas être supérieur à 0,05 pour toute combinaison des PARAMETRES DE CHARGE.

La vérification est effectuée en adoptant la PROCEDURE d'essai suivante:

Effectuer 10 mesurages du KERMA DANS L'AIR en 1 h, dans les conditions d'essai conformes au paragraphe 203.6.3.2.103, pour chacun des paramétrages d'essai A, B, C et D conformes au Tableau 203.101.

Calculer le coefficient de variation pour chacune des séries de mesurages et le KERMA DANS L'AIR moyen pour les paramétrages d'essai C et D, afin de vérifier la conformité.

203.6.3.2.102 Linéarité et constance en RADIOGRAPHIE

a) La linéarité du KERMA DANS L'AIR sur des intervalles limités des PARAMETRES DE CHARGE

En ce qui concerne le fonctionnement en RADIOGRAPHIE, les quotients de la moyenne des VALEURS MESUREES du KERMA DANS L'AIR divisées par les valeurs présélectionnées ou les valeurs du PRODUIT COURANT TEMPS indiquées, ou le produit des valeurs du COURANT DANS LE TUBE RADIOGENE et du TEMPS DE CHARGE, obtenus

– pour deux réglages consécutifs du TEMPS DE CHARGE ou du COURANT DANS LE TUBE RADIOGENE ou du PRODUIT COURANT TEMPS

– ou à l'un des deux réglages des PARAMETRES DE CHARGE ci-dessus, lorsque la présélection est continue et que les valeurs présélectionnées diffèrent d'un facteur aussi proche que possible de 2, mais non supérieur à 2,

ne doivent pas différer de plus de 0,2 fois la valeur moyenne de ces quotients:

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{I_1 t_1} + \frac{\overline{K}_2}{I_2 t_2}}{2}$$

où

$\overline{K}_1$, $\overline{K}_2$ sont les moyennes des VALEURS MESUREES du KERMA DANS L'AIR;

Q_1 et Q_2 sont les PRODUITS COURANT TEMPS indiqués;

I_1 et I_2 sont les COURANTS DANS LE TUBE RADIOGENE indiqués;

t_1 et t_2 sont les TEMPS DE CHARGE indiqués.

La vérification est effectuée en adoptant la PROCEDURE d'essai suivante:

Effectuer 10 mesurages du KERMA DANS L'AIR en 1 h, dans les conditions d'essai conformes au paragraphe 203.6.3.2.103, pour chacun des paramétrages d'essai E et F conformes au Tableau 203.101.