

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**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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 ($\text{Gy}\cdot\text{m}^2$)

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 radioscopy 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 $\pm 2\%$ 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 $1 \Omega \text{ m}^{-1}$, 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 kW s 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:

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

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

where

$\bar{K}_1, \bar{K}_2$ 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 <i>or</i> 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 RADIOLOGY

ME EQUIPMENT designed for RADIOLOGY shall be provided with means for the available combinations of LOADING FACTORS in RADIOLOGY 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 RADIOLOGY 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 $\pm (10 \% + 1 \text{ ms})$.

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 $\pm (10 \% + 0,2 \text{ mAs})$.

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 $\pm 35\%$ 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 $\text{Gy}\cdot\text{m}^2$ with appropriate SI prefixes. The overall uncertainty in the displayed values of the cumulative DOSE AREA PRODUCT above $5\ \mu\text{Gy}\cdot\text{m}^2$ 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 cm².

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.

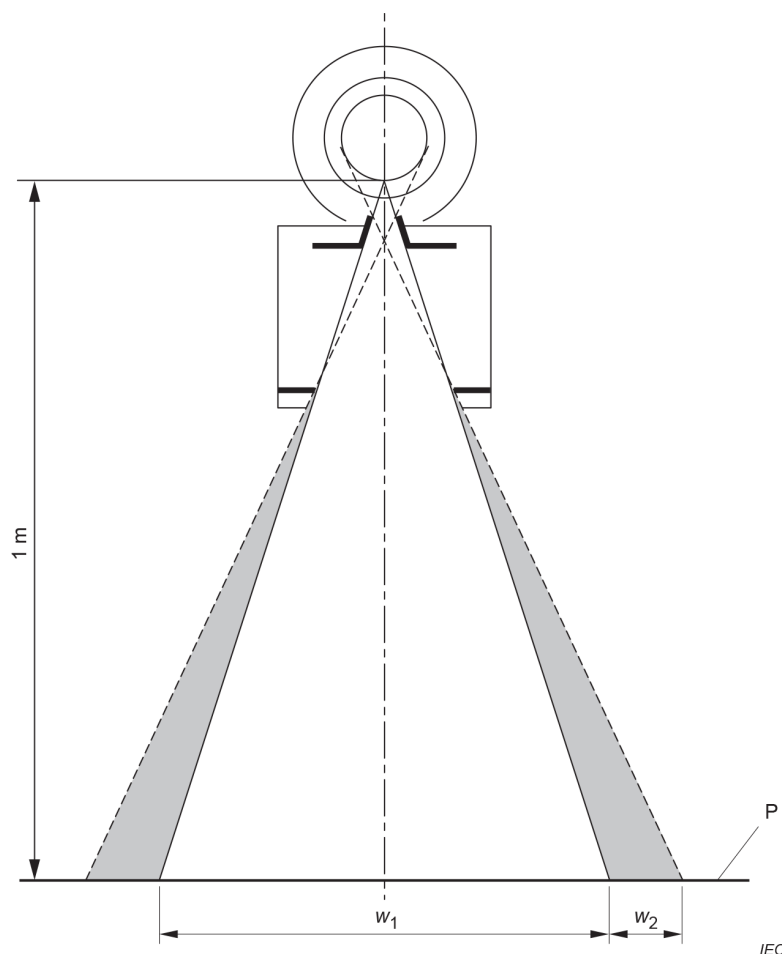


Figure 203.101 – Zone of EXTRA-FOCAL RADIATION

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.