IEC 60601-2-54

Edition 1.0 2018-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

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

IEC 60601-2-54:2009-06/AMD2:2018-06(en-fr)

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ICS 11.040.50 ISBN 978-2-8322-5758-6

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1089/FDIS	62B/1097/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION TO AMENDMENT 2

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

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

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

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

201.1.1 Scope

Replace, in the first paragraph, the first existing sentence by the following new sentence:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY.

Replace the second existing paragraph by the following new paragraph:

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

Delete the note.

201.1.3 Collateral standards

Replace the second paragraph, modified by IEC 60601-2-54:2009/AMD1:2015, by the following new paragraph:

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.2 Normative references

Replace the existing reference to IEC 62220-1:2003 by the following new reference:

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

Add, to the existing list, the following new references:

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*

201.3 Terms and definitions

Add, after the existing definition 201.3.209, the following new terms and definitions:

201.3.210
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

201.3.211
EXAMINATION PROTOCOL SELECTION CONTROL
control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.212
LAST-IMAGE HOLD RADIOGRAM
LIH RADIOGRAM
single image obtained by sampling or temporal processing of one or more images from the end of a radioscopic IRRADIATION

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

201.3.213
PRE-PROGRAMMED EXAMINATION PROTOCOL
single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.214
RADIOSCOPY REPLAY IMAGE SEQUENCE
series of the most recent images of the most recent RADIOSCOPY IRRADIATION-EVENT

201.7.9.1 General

*Replace the first paragraph after "*Addition:*" by the following new paragraph and note:*

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.

Replace the first dash in the second paragraph by the following new dash:

– an identification of adjustable or selectable image processing settings applied to ORIGINAL DATA including the version number or how to determine it;

Add, before the compliance statement at the end of this subclause, the following new paragraph:

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.

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

Replace, at the end of the item a), the colon by a semicolon.

201.9.8 HAZARDS associated with support systems

Replace the existing title of this subclause by the following new title:

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.3 Dynamic forces due to loading from persons

*Replace the paragraph starting with "*Where mechanical analysis…*" by the following new paragraph:*

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

201.10 Protection against unwanted and excessive radiation HAZARDS

Replace the existing text of this clause by the following new text:

Clause 10 of the general standard applies, except Subclause 10.3 (Microwave radiation), which does not apply.

201.11 Protection against excessive temperatures and other HAZARDS

Add, before the instruction "Additional subclauses", the following new subclauses:

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

NOTE Restrictions on allowable maximum temperature in Table 22 of the general standard for parts in contact with oil shall 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/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.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace the existing text of this clause by the following new text:

Clause 12 of the general standard applies, except as follows:

Addition:

NOTE According to subclause 12.4.5 of the general standard, the dose related aspects of this question are addressed under 203.6.4.3 of this document.

201.16 ME SYSTEMS

Replace the existing text of this clause by the following new text:

Clause 16 of the general standard applies, except 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/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.

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Replace the existing title of this subclause by the following new title:

202.101 *Immunity testing of ESSENTIAL PERFORMANCE

203.5 ME EQUIPMENT identification, marking and documents

Add, before the existing 203.5.2.4.5, the following new text:

203.5.2.1 References in subclauses

Amendment:

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

203.5.2.4 Instructions for use

203.5.2.4.4 Clinical protocols

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

Additional subclause:

203.5.2.4.101 EXAMINATION PROTOCOLS

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

Compliance is checked by inspection of the instructions for use.

203.6 Radiation management

Add, after the existing title of 203.6, the following new subclauses:

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 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.

203.6.2.1 Normal initiation and termination of the IRRADIATION

Add, at the end of the existing list, the following new item:

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.

203.6.3.2.102 Linearity and constancy in RADIOGRAPHY

Replace the existing item b) by the following new item b):

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 subclause 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 one hour. Calculate the coefficient of variation of AIR KERMA.

II) Compliance of variation of optical density, see test PROCEDURE subclause c).

Replace the existing item d) by the following new item d):

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 one hour. 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.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

203.6.4.3.101 General requirements for the indication of LOADING FACTORS

Add, after the last dash, the following new text:

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.

203.6.4.3.104.3 Accuracy of X-RAY TUBE VOLTAGE

Replace the existing first paragraph by the following new paragraph:

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 %.

Replace the first sentence of the existing third paragraph (without modifying items a) and b) by the following new sentence:

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

Add, after the existing 203.6.4.3.105, the following new subclause:

203.6.4.3.106 *Electronic documentation of EXAMINATION PROTOCOLS

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

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

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

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

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

NOTE Additional equipment may be required (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.

203.6.4.5 Dosimetric indications

Add, after the last dash of the existing third paragraph, the following new item:

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

Add, after the existing 203.6.4.5, the following new text:

Additional subclause:

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. The RDSR 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.

203.6.5 AUTOMATIC CONTROL SYSTEM

Add, after the last paragraph, the following new paragraph:

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.

203.6.6 SCATTERED RADIATION reduction

Add, after the last sentence of the existing first paragraph, the following new sentence:

If the ANTI-SCATTER GRID is removable, it shall be possible to remove and replace it without the use of TOOLS.

Replace the existing second paragraph by the following new paragraph:

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

203.6.7.101 DISPLAY of last image hold (LIH)

Replace the existing subclause, including its title, by the following new 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 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.