IEC 60601-2-43

Edition 2.0 2019-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 2
AMENDEMENT 2

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

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

IEC 60601-2-43:2010-03/AMD2:2019-10(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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/1137/FDIS	62B/1146/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- withdrawn,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.

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INTRODUCTION to Amendment 2

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

– scope clarification with regards to MOBILE X-ray equipment and applicability of IEC 60601-2-54 subclauses;
– reference to IEC 60601-2-54:2009/AMD2:2018 for common subclauses;
– alignment of 201.7.9.1 with IEC 60601-2-54:2009/AMD2:2018 – 201.7.9.1 is no longer modified;
– inclusion of adapted requirements or recommendations from IEC 60601-2-54:2009/AMD2:2018 for
  - management of radioscopy image storage in 203.6.1.101,
  - display of last image hold (LIH RADIOGRAM) in 203.6.7.101, and
  - graphical indication of the boundaries of the X-RAY FIELD in 203.8.102.2;
– inclusion of a recommendation for protection of gantry enclosures in 201.11.6.5.103;
– inclusion of a requirement for X-RADIATION pulse repetition frequency during radioscopy in 203.6.3.103;

– inclusion of a recommendation for a DOSE MAP in 203.6.4.5 with additional definitions in 201.3;

– inclusion of a requirement for display unit of dose area product in 203.6.4.5;

– addition of a number of technical clarifications.

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201.1.1 Scope

Replace the first sentence of the first existing paragraph by the following new sentence:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of both FIXED and MOBILE X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, hereafter referred to as INTERVENTIONAL X-RAY EQUIPMENT.

Replace the third existing note, including the footnote, by the following new note and footnote:

NOTE 3 INTERVENTIONAL X-RAY EQUIPMENT, when used for cone-beam CT mode, is covered by this standard and not by IEC 60601-2-44 [2][2]. No additional requirements for operation in cone-beam CT mode were identified for this standard (see also Note 4 in 203.6.4.5).

_____

2) Figures in square brackets refer to the Bibliography.

Add, after the fourth existing note, the following new paragraph:

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

201.1.3 Collateral standards

Replace, in the second existing paragraph, the second sentence, including its corresponding footnotes, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new sentence and footnotes:

IEC 60601-1-8[6], IEC 60601-1-9[7], IEC 60601-1-10[8], IEC 60601-1-11[9], IEC 60601-1-12[10] do not apply.

_____

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

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

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

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

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

201.2 Normative references

Add, immediately after the instruction "Amendment", the following new reference:

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

Replace, under "Addition", the existing reference to IEC 60580 and the one to IEC 60601-2-54, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new references:

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

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

201.3 Terms and definitions

Replace the first existing paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new paragraph:

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

Add, after the existing definition 201.3.204, added by IEC 60601-2-43:2010/AMD1:2017, the following new terms and definitions:

201.3.205
DOSE MAP
representation of the spatial distribution of a RADIATION dose quantity

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

201.3.207
SKIN DOSE MAP
DOSE MAP of the SKIN DOSE

201.4.102 RADIATION dose documentation

Add, at the end of the paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, but before the compliance statement, the following new paragraph:

The data elements shall be populated with the specified data.

Replace the existing compliance statement by the following new compliance statement:

Compliance is checked by appropriate inspection and functional test.

201.5 General requirements for testing of ME EQUIPMENT

Replace the existing text by the following new text:

Clause 5 of the general standard applies, except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

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

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.2.104 Marking of compliance

Replace, in the second existing paragraph, the reference "IEC 60601-2-43:2010" *by* "IEC 60601-2-43:2010, IEC 60601-2-43:2010/AMD1:2017, IEC 60601-2-43:2010/AMD2:2019".

201.7.2.105 Protection against ingress of liquids

Replace, in the existing paragraph, the reference "IEC 60529" *by* "IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013".

201.7.9.1 General

Replace the existing text by the following new text:

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

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS

Add, after the last row, the following new rows:

201.5.7	Humidity preconditioning treatment
201.11.6.5.103	ENCLOSURES
203.5.2.4.102	EXAMINATION PROTOCOLS
203.6.4.5	Dosimetric indications

Add, after Table 201.102, the following new note:

NOTE While Table 201.C.102 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018 lists the following subclauses "203.6.4.5 Dosimetric indications" and "203.5.2.4.5.101 Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY", the corresponding requirements for statements in ACCOMPANYING DOCUMENTS are located in this standard and not in IEC 60601-2-54:2009 and its amendments.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

*Delete the sentence: "*Clause 8 of the general standard applies, except as follows:*"*

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, in the existing paragraph, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

201.10 Protection against unwanted and excessive radiation HAZARDS

Replace the existing paragraph, excluding the note, by the following new paragraph:

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

201.11 Protection against excessive temperatures and other HAZARDS

201.11.6.5.103 ENCLOSURES

Add, in the first existing paragraph, the following new sentence to the third dash, modified by IEC 60601-2-43:2010/AMD1:2017:

For the PATIENT SUPPORT test, testing may be considered sufficient by angulating the PATIENT SUPPORT 15° from the horizontal position.

Add, in the first existing paragraph, the following item to the dash list:

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

Replace, in the second paragraph, the reference "IEC 60529" *by* "IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013".

Replace "NOTE 1" *by* "NOTE".

Delete the second note.

Add, after 201.11.6.5.103, the following new text:

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

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

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace, in the note, the reference "under 203.6.4.3 of IEC 60601-2-54:2009" *by* "under 203.6.4.3 of this document".

201.16 ME SYSTEMS

Replace the existing text 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:

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

203.4.1 Statement of compliance

Replace, in the existing paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, the reference "IEC 60601-2-43:2010" *by* "IEC 60601-2-43:2010, IEC 60601-2-43:2010/AMD1:2017 and IEC 60601-2-43:2010/AMD2:2019".

Add, after the existing 203.4.101, the following new text:

203.5.2.1 References in subclauses

Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Amendment:

The row about Clinical protocols, Subclause 5.2.4.4, does not apply.

203.5.2.4 Instructions for use

Add, after the existing 203.5.2.4, the following new subclause:

203.5.2.4.4 Clinical protocols

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

203.5.2.4.5.102 Test for dosimetric information

Replace, in the last paragraph, "NOTE 2" *by* "NOTE".

Add, after the existing 203.5.2.4.101, the following new subclause:

203.5.2.4.102 EXAMINATION PROTOCOLS

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

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

Add, after the existing 203.6, the following new text:

203.6.1 General

Additional subclauses:

203.6.1.101 Management of RADIOSCOPY image storage

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

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

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

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

Compliance is checked by functional test.

203.6.1.102 Management of EXAMINATION PROTOCOLS

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

203.6.2 Initiation and termination of the IRRADIATION

Replace, in the existing paragraph, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.2 Reproducibility of the RADIATION output

Replace, in the existing paragraph, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

Add, after the existing 203.6.3.102, the following new subclause:

203.6.3.103 * X-RADIATION pulse repetition frequency during RADIOSCOPY

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

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Replace, in the existing paragraph, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

203.6.4.5 * Dosimetric indications

Replace the existing note by the following new note:

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

Add, in the third existing paragraph after the note, the following dashed item to the list:

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

Add, in the fourth paragraph after the note, the following new text after the third sentence:

Means shall be provided to the RESPONSIBLE ORGANIZATION to allow configuring the unit for display of DOSE AREA PRODUCT at least among all the following:

– $Gy \cdot cm^2$;
– $\mu Gy \cdot m^2$ or $cGy \cdot cm^2$;
– $mGy \cdot cm^2$.

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

Delete, in the fourth paragraph after the note, the last sentence.

Add, after the fourth paragraph after the note, the following new paragraph:

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

Add, before the compliance statement, the following new text:

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

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

NOTE 3 A SKIN DOSE MAP is preferred over other DOSE MAPS. An example of a DOSE MAP can be obtained by cumulating the values of REFERENCE AIR KERMA over ranges of the available parameters that influence the location of the X-RAY BEAM relative to the PATIENT. When the INTERVENTIONAL X-RAY EQUIPMENT cannot determine the orientation of the X-RAY BEAM AXIS, creation of a DOSE MAP is not practical. Mapping head, chest, abdomen and pelvic anatomy is of primary value; mapping extremities is of secondary value due to smaller body part thickness and their variability in position on the PATIENT SUPPORT.

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

NOTE 4 Dosimetric indications apply also for operation in cone-beam CT mode. This provides a means to combine the RADIATION dose for all MODES OF OPERATIONS.

203.6.5 AUTOMATIC CONTROL SYSTEM

Replace, in the existing paragraph, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

203.6.6 SCATTERED RADIATION reduction

Replace, in the first sentence of the subclause, the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".

203.6.7 Imaging performance

Replace the existing paragraph by the following new text:

Additional subclause:

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

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

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

Compliance is checked by inspection and functional tests.

203.7 RADIATION QUALITY

Replace, in the existing paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, the reference "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015" *by* "IEC 60601-2-54:2009, IEC 60601-2-54:2009/AMD1:2015 and IEC 60601-2-54:2009/AMD2:2018".

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

Replace the existing paragraph by the following new text:

Additional subclauses:

203.8.102.1 General

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

203.8.102.2 Indication on the X-RAY EQUIPMENT

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

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

203.8.102.3 Indication in the instructions for use

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

203.8.102.4 Accuracy of marked and written indications

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

203.8.103 Interception of the X-RAY BEAM in RADIOSCOPY

Replace the reference "IEC 60601-2-54:2009" *by* "IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018".