IEC 60601-2-43

Edition 2.0 2017-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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/AMD1:2017-05(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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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:

CDV	Report on voting
62B/1012/CDV	62B/1037/RVC

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- withdrawn,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 the Amendment

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

– refer to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its applicable collateral standards;
– refer to IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 and consequent subclause adaptations;
– include a requirement to have a maximum time of 10 min to recover all functions after a recoverable failure in 201.4.101;
– include several aspects from IEC 61910-1:2014 and remove the reference to IEC PAS 61910-1:2007 in 201.4.102;
– include an alternative way of testing in 201.11.6.5.103;
– include a clarification for tableside controls in 201.12.4.106.

In addition, a number of technical errors have been corrected.

201.1 Scope, object and related standards

Replace the text of the existing footnote by the following:

1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

201.1.3 Collateral standards

Replace the existing second sentence of the second paragraph by the following:

IEC 60601-1-8, IEC 60601-1-10[1)], IEC 60601-1-11[2)] and IEC 60601-1-12[3)] do not apply.

201.2 Normative references

Replace, under "Amendment", *the existing references to IEC 60601-1-2 and to IEC 60601-1-3 as follows:*

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

Add, under "Addition", *the following new references:*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

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

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

Replace, under "Addition", *the existing references to IEC 60601-2-54 and to IEC 60788 as follows:*

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

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1) 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*

2) 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*

3) 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*

201.3 Terms and definitions

Replace the introductory paragraph by the following new paragraph:

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

Add, after 201.3.203, the following new term and definition:

201.3.204
EMERGENCY RADIOSCOPY
RADIOSCOPY with availability of a limited set of functions (emergency functions), for use during recovery from a recoverable failure of the INTERVENTIONAL X-RAY EQUIPMENT

201.4.3 ESSENTIAL PERFORMANCE

*Replace, in the first sentence, "*IEC 60601-2-54:2009*" by "*IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015*".*

Delete the first sentence of the addition (sentence starting with 'The list in Table…').

201.4.101 * Recovery management

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

The time to recover all of the functions necessary for performing EMERGENCY RADIOSCOPY, after a failure recoverable automatically or by the OPERATOR shall be as short as reasonably practicable. The RISK MANAGEMENT shall take into account the availability of emergency power supply in the determination of the recovery time.

When the recovery is complete, a reinitiation of IRRADIATION shall be required to produce further IRRADIATION.

The time to recover all functions, after a failure recoverable automatically or by the operator, shall be as short as reasonably practicable.

In case of a manually recoverable failure, the time to recover all functions shall not exceed 10 min from the time the OPERATOR has initiated the recovery to the time the INTERVENTIONAL X-RAY EQUIPMENT has all functions available.

In case of an automatically detected and automatically recoverable failure, the time to recover all functions shall not exceed 10 min from the time of the failure of the INTERVENTIONAL X-RAY EQUIPMENT to the time the INTERVENTIONAL X-RAY EQUIPMENT has all functions available.

INTERVENTIONAL X-RAY EQUIPMENT may have both recovery modes.

NOTE Less than 1 min is a desirable value for the time to recover all functions for performing EMERGENCY RADIOSCOPY. Less than 3 min is a desirable value to recover all functions.

The instructions for use shall indicate:

– the time necessary to get all functions for EMERGENCY RADIOSCOPY operable;
– the time to restore all functions of the INTERVENTIONAL X-RAY EQUIPMENT;
– for failures recoverable by the OPERATOR, the required procedure which the OPERATOR must follow to perform this recovery.

When the system is in the EMERGENCY RADIOSCOPY mode, this mode shall be indicated at the working position of the OPERATOR.

The functions necessary for performing EMERGENCY RADIOSCOPY shall include, at minimum:

– RADIOSCOPY MODE OF OPERATION, in priority order:
  - RADIOSCOPY in the MODE OF OPERATION that was used at the time of the recoverable equipment failure;
  - or, if this is not possible, RADIOSCOPY in the MODE OF OPERATION as close as possible to the one which was used at the time of the recoverable equipment failure;
– normal operation of the PATIENT SUPPORT;
– normal operation of the gantry;
– normal operation of tableside controls for all functions described above;
– normal operation of the irradiation disabling switch (see 203.6.103);
– normal operation of the motion disabling switch (see 201.9.2.3.1 in IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015);
– normal operation of anti-collision functions (see 201.9.2.4).

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

201.4.102 * RADIATION dose documentation

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

The INTERVENTIONAL X-RAY EQUIPMENT shall create RADIATION DOSE STRUCTURED REPORTS (RDSR) and shall have the ability to perform RDSR END OF PROCEDURE TRANSMISSION.

The RDSR shall contain the data elements that are required ('shall') in 5.1.2 and 5.1.3 of IEC 61910-1:2014.

The RDSR should contain the data elements that are recommended ('should') in 5.1.2 and 5.1.3 of IEC 61910-1:2014.

NOTE The conditional statements associated with the data elements in IEC 61910-1:2014 are considered to be part of these data elements.

If the INTERVENTIONAL X-RAY EQUIPMENT does not have means to determine GANTRY angulations, the RDSR need not contain the data elements related to positioner angles.

Compliance is checked by functional test.

201.7.2.101 Beam limiting device

*Replace the reference to "*IEC 60601-2-54:2009*" by "*IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015*".*

201.7.2.105 * Protection against ingress of liquids

Add, after the existing Note 2, the following new note:

NOTE 3 Parts that are IPX0 need not be marked.

201.7.9.2.12 * Cleaning, disinfection and sterilization

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

201.7.9.2.17 ME EQUIPMENT emitting radiation

Subclause 201.7.9.2.17 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 applies.

201.9.2 HAZARDS associated with moving parts

Replace the existing title of this subclause by the following:

201.9.2 MECHANICAL HAZARDS associated with moving parts

Add, before the existing 201.9.2.2.4, the following new title:

201.9.2.2 TRAPPING ZONE

201.9.2.2.4 GUARDS and protective measures

Replace the existing title and text of this subclause by the following:

201.9.2.2.4 GUARDS and other RISK CONTROL measures

Subclause 201.9.2.2.4 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 applies.

201.9.2.3 Other HAZARDS associated with moving parts

Replace the existing title and text of this subclause by the following:

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

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

201.11.6.5.101 Footswitches

Replace, in the second paragraph, "a saline solution of at least 0.9 %" *by* "a saline solution of at least 0,9 % weight to volume of sodium chloride in water".

201.11.6.5.103 * ENCLOSURES

Replace the third dash by the following new dash:

– PATIENT SUPPORT should have a minimum degree of protection of IPX2 or should be protected against spraying water at any angle up to 15° from the vertical.

Renumber the existing Note as NOTE 1, and add, after this note, the following new note:

NOTE 2 For the PATIENT SUPPORT test, the PATIENT SUPPORT can be placed on a 15° slope.

201.11.101 Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES

*Replace the reference to "*IEC 60601-2-54:2009*" by "*IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015*".*

201.12 Accuracy of controls and instruments and protection against hazardous output

201.12.4 * Protection against hazardous output

Add, after the title of this subclause, the following new subclause:

201.12.4.5.2 Diagnostic X-ray equipment

Replacement:

INTERVENTIONAL X-RAY EQUIPMENT shall comply with IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 as modified by this particular standard.

Compliance is checked as specified in IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 as modified by this particular standard.

201.12.4.106 * Tableside controls

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

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

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

– IRRADIATION SWITCHES (other than footswitches);

– collimation blade control (not including WEDGE FILTER control).

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

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

Compliance is checked by inspection and by functional tests.

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

202 Electromagnetic compatibility – Requirements and tests

Replace the existing clause title by the following:

202 Electromagnetic disturbances – Requirements and tests

*Replace "*IEC 60601-1-2:2007*" by "*IEC 60601-1-2:2014*".*

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Replace the existing text of this subclause by the following sentence:

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

203 Radiation protection in diagnostic X-ray equipment

*Replace, in the first paragraph, "*IEC 60601-1-3:2008 applies*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply".

203.4.1 Statement of compliance

Replace the existing text after "Replacement" *and before* "Additional subclause" *by the following:*

If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be stated, the statement shall be made with the following content:

– model or type reference;

– IEC 60601-2-43:2010.

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

*In item d), last dash, replace "*shall by specified*" by "*shall be specified*".*

203.6.4.5 * Dosimetric indications

*Replace, in the note, "*IEC 60601-2-54:2009*" by "*IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015*".*

Replace, in the third paragraph, the second, third and fourth dashes by the following:

– 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 correction to the fifth paragraph starting with "*The instructions…*" applies to the French text only.*

203.7 RADIATION QUALITY

*Replace the reference to "*IEC 60601-2-54:2009*" by "*IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015*".*

Annex AA

Subclause 201.4.101 – Recovery management

*Delete the third and fourth paragraphs (both starting with "*Less than …*").*

Bibliography

Delete the reference [23] to DICOM and the reference [24] to IEC/PAS 61910-1:2007.

Index of defined terms used in this particular standard

*Replace, in the existing list, all references to "*IEC 60788:2004*" by references to "*IEC TR 60788:2004*".*

Replace the following references as follows:

CLEARLY LEGIBLE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.15
ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.27
HARM ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.38
HAZARD ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.40
INTENDED USE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.44
MANUFACTURER ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.55
NORMAL USE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.71
ORIGINAL DATA .....IEC 62220-1-1:2015, 3.13
PATIENT..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76
PROCEDURE..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.88
PROCESS..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.89
RISK..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.102
RISK MANAGEMENT ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.107
RISK MANAGEMENT FILE..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.108
SEVERITY..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.114
SINGLE FAULT CONDITION ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.116

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

EMERGENCY RADIOSCOPY 201.3.204
GUARD .....IEC 60601-1:2005, 3.36
MECHANICAL HAZARD.....IEC 60601-1:2005, 3.61
RADIATION DOSE STRUCTURED REPORT (RDSR).....IEC 61910-1:2014, 3.3
RDSR END OF PROCEDURE TRANSMISSION .....IEC 61910-1:2014, 3.5
RISK CONTROL..... IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.105
TRAPPING ZONE.....IEC 60601-1:2005, 3.131

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