SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-43:2022

01-februar-2022

Medicinska električna oprema - 2-43. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za interventne postopke

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

Ta slovenski standard je istoveten z: prEN IEC 60601-2-43:2021

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
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62B/1264/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

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IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☒ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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TITLE:

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

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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International standard IEC 60601-2-43 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition constitutes a technical revision.

This particular standard has been revised to introduce changes to reference the second amendment:2020 to IEC 60601-1:2005. The present edition remains a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "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 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The purpose of this new edition is to introduce changes to reference the second amendment:2020 to IEC 60601-1:2005 and some minor technical clarifications.

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES may subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT may be the occurrence of deterministic injury when RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

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. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT;
– dental X-RAY EQUIPMENT.

NOTE 1 Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of INTERVENTIONAL X-RAY EQUIPMENT complying with this standard is recommended, are given in Annex AA.

NOTE 2 Specific requirements for magnetic navigation devices, and for the use of INTERVENTIONAL X-RAY EQUIPMENT in an operating room environment were not considered in this particular standard; therefore no specific requirements have been developed for these devices or uses. In any case, such devices or uses remain under the general clause requirements.

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).

INTERVENTIONAL X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.

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

NOTE 4 See also 4.2 of the general standard.

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.

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1) The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2) Figures in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The object of this particular standard is:

- to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the design and manufacture of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, as defined in 201.3.205.
- to specify information which is to be provided with such INTERVENTIONAL X-RAY EQUIPMENT for the assistance of the RESPONSIBLE ORGANIZATION and OPERATOR in managing the RADIATION RISK and equipment failure RISK arising from these RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES which could affect PATIENTS or staff.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and Clause 203 respectively. IEC 60601-1-8[3)], IEC 60601-1-9[4)], IEC 60601-1-10[5)], IEC 60601-1-11[6)] and IEC 60601-1-12[7)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard 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 the general standard.

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

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral

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3) 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*

4) 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*

5) 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*

6) 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*

7) 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*

standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

NOTE Informative references are listed in the Bibliography beginning on page 54.

Amendment:

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

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

IEC 60601-1-8 does not apply.

Addition:

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 60601-2-54:20xx, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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

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*

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 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3/AMD1:2013 and IEC 60601-1-3/AMD2:2021, IEC 60601-2-54:20xx, IEC TR 60788:2004, IEC 61910-1:2014, IEC 62220-1-1:2015 and the following apply.

NOTE 1 An index of defined terms is found beginning on page 56.

Addition:

201.3.201
DOSE MAP
representation of the spatial distribution of a RADIATION dose quantity

201.3.202
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

201.3.203
*** IMAGE DISPLAY DELAY**

during RADIOSCOPY or RADIOGRAPHY, time delay between an event captured during an X-ray LOADING used to create an image and the DISPLAY of this event on the image

201.3.204
INTERVENTIONAL X-RAY EQUIPMENT
X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

201.3.205
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
RGI PROCEDURE

invasive procedure (involving the introduction of a device, such as a needle or a catheter into the PATIENT) using RADIOSCOPY as the principal means of guidance, and intended to effect treatment or diagnosis of the medical condition of the PATIENT

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 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Subclause 201.4.3 of IEC 60601-2-54:20xx, except as follows:

Addition:

NOTE Subclause 203.6.4.3.104.2 (Accuracy of LOADING FACTORS in automatic control mode) of IEC 60601-2-54 specifies a limitation in applying subclause 203.6.4.3.104.3 (Accuracy of X-RAY TUBE VOLTAGE) and 203.6.4.3.104.4 (Accuracy of X-RAY TUBE CURRENT). This limitation is also valid for the ESSENTIAL PERFORMANCE list.

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

Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis

Requirement	Subclause
Recovery management	201.4.101
RADIATION dose documentation	201.4.102

201.4.10.2 SUPPLY MAINS FOR ME EQUIPMENT and ME SYSTEMS

Subclause 201.4.10.2 of IEC 60601-2-54:20xx applies.

Additional subclauses:

201.4.101 * Recovery management

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 20xx;
– 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

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.

The data elements shall be populated with the specified data.

Compliance is checked by appropriate inspection and functional test.

201.5 General requirements for testing of ME EQUIPMENT

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

388 **201.5.7 Humidity preconditioning treatment**

389 *Addition:*

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

394 *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*

395 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

396 Clause 6 of the general standard applies.

397 **201.7 ME EQUIPMENT identification, marking and documents**

398 Clause 7 of the general standard applies, except as follows:

399 **201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**

400 **201.7.2.7 Electrical input power from the SUPPLY MAINS**

401 Subclause 201.7.2.7 of IEC 60601-2-54:20xx applies.

402 **201.7.2.15 Cooling conditions**

403 Subclause 201.7.2.15 of IEC 60601-2-54:20xx applies.

404 *Additional subclauses:*

405 **201.7.2.101 BEAM LIMITING DEVICE**

406 Subclause 201.7.2.101 of IEC 60601-2-54:20xx applies.

407 **201.7.2.102 * PATIENT SUPPORT load**

408 The PATIENT SUPPORT shall be marked with the maximum permissible mass in kilograms for
409 NORMAL USE, excluding use for cardiopulmonary resuscitation (CPR).

410 This maximum permissible mass shall be the SAFE WORKING LOAD minus the CPR loading (see
411 201.9.8.3.1 for CPR loading value).

412 **201.7.2.103 Cardiopulmonary resuscitation (CPR)**

413 The PATIENT SUPPORT shall be marked with abbreviated instructions on configuring the
414 INTERVENTIONAL X-RAY EQUIPMENT for CPR.

415 **201.7.2.104 Marking of compliance**

416 If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be marked on the
417 outside of the INTERVENTIONAL X-RAY EQUIPMENT, the marking shall be made in combination
418 with the MODEL OR TYPE REFERENCE as follows:

419 INTERVENTIONAL X-RAY EQUIPMENT [model or type reference] IEC 60601-2-43:20xx.