

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**

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REDLINE VERSION

VERSION REDLINE



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-43 edition 2.2 contains the second edition (2010-03) [documents 62B/779/FDIS and 62B/792/RVD], its amendment 1 (2017-05) [documents 62B/1012/CDV and 62B/1037/RVC] and its amendment 2 (2019-10) [documents 62B/1137/FDIS and 62B/1146/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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 second edition constitutes a technical revision.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on the third edition of IEC 60601-1 and relevant collaterals. The present edition is extended to become 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,
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INTRODUCTION

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 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.

Interventional procedures of the type envisaged are well established in clinical fields such as:

- invasive cardiology;
- interventional RADIOLOGY;
- interventional neuroradiology.

These 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.

INTRODUCTION to Amendment 1

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.

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 radiology 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 radiology 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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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 standard¹⁾ 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 in cross-sectional imaging mode (sometimes described as CT-like mode or cone-beam CT) for cone-beam CT mode, is covered by this particular standard and not by IEC 60601-2-44 [2]²⁾. No additional requirements for operation in CT-like mode or cone-beam CT mode were not considered in the present 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.

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*.

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 201.3.203.
- 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 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 60601-1-8³⁾, IEC 60601-1-9⁴⁾, IEC 60601-1-10⁵⁾, IEC 60601-1-11⁶⁾ and IEC 60601-1-12⁷⁾ 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

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*