

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

This third edition cancels and replaces the second edition published in 2010, Amendment 1:2017 and Amendment 2:2019. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the changes in IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-54:2022. It also contains corrections and technical improvements. Significant technical changes with respect to the previous edition are as follows:

- a) a new specific term DOSIMETER is introduced to replace the general term DOSEMETER as in IEC 60601-2-54:2022;
- b) several terms and definitions that are moved from IEC TR 60788:2004 to 201.3 of IEC 60601-2-54:2022 are also referenced from IEC 60601-2-54:2022.

- c) the collateral standards IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are applicable if MANUFACTURER so declares;
- d) the former subclause 201.11.101 "Protection against excessive temperature of X-RAY TUBE ASSEMBLIES" is removed since covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017, and the former subclause 201.11.102 is renumbered as 201.11.101, as in IEC 60601-2-54:2022;
- e) to adopt changes in subclause 7.8.1 "Colours of indicator lights" in IEC 60601-1:2005/AMD2:2020, clarification of requirements is provided in 201.7.8.1 to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT, as in IEC 60601-2-54:2022;
- f) explanation of the term ESSENTIAL PERFORMANCE is provided in Annex AA to emphasize the performance of the clinical function under NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1297/FDIS	62B/1309/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

In this document, the following print types are used:

- requirements and definitions: normal 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

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

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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## INTRODUCTION

The purpose of this new edition is to introduce changes to reference the Amendment 2 (2020) to IEC 60601-1:2005 and some minor technical clarifications.

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES can 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 can 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 specialties.

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

## 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This document 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 document is recommended, are given in Annex AA.

NOTE 2 Specific requirements for magnetic resonance devices, and for the use of INTERVENTIONAL X-RAY EQUIPMENT in an operating room environment were not considered in this document; 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 document and not by IEC 60601-2-44 [1]<sup>1</sup>. No additional requirements for operation in cone-beam CT mode were identified for this document (see also Note 5 in 03.0.4.5).

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 document.

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 this is not the case, the clause or subclause applies both to INTERVENTIONAL X-RAY EQUIPMENT and to ME SYSTEMS, as relevant.

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

<sup>1</sup> Numbers in square brackets refer to the Bibliography.