

# CONSOLIDATED VERSION

# VERSION CONSOLIDÉE



**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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## CONTENTS

FOREWORD .....	4
INTRODUCTION .....	7
INTRODUCTION to Amendment 1 .....	7
INTRODUCTION to Amendment 2 .....	7
201.1 Scope, object and related standards .....	9
201.2 Normative references .....	11
201.3 Terms and definitions .....	12
201.4 General requirements .....	13
201.5 General requirements for testing of ME EQUIPMENT .....	15
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	15
201.7 ME EQUIPMENT identification, marking and documents .....	15
201.8 Protection against electrical HAZARDS from ME EQUIPMENT .....	20
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS .....	20
201.10 Protection against unwanted and excessive radiation HAZARDS .....	22
201.11 Protection against excessive temperatures and other HAZARDS .....	22
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	24
201.13 HAZARDOUS SITUATIONS and fault conditions .....	27
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	27
201.15 Construction of ME EQUIPMENT .....	27
201.16 ME SYSTEMS .....	28
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	28
202 Electromagnetic <del>compatibility</del> disturbances – Requirements and tests .....	28
203 Radiation protection in diagnostic X-ray equipment .....	29
Annexes .....	42
Annex AA (informative) Particular guidance and rationale .....	43
Annex BB (normative) Distribution maps of STRAY RADIATION .....	55
Annex CC (informative) Mapping between this Edition 2 of IEC 60601-2-43 and Edition 1 .....	58
Bibliography .....	60
Index of defined terms used in this particular standard .....	63
Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration .....	56
Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration .....	57
Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis .....	13
Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS .....	20
Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS .....	29
Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible .....	43
Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely .....	44

Table AA.3 – Examples of isodose boundaries and colour codes for SKIN DOSE MAP and air kerma map.....	53
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**This Consolidated version of IEC 60601-2-43 bears the edition number 2.2. It consists of 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]. The technical content is identical to the base edition and its amendments.**

**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,
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- replaced by a revised edition, or
- amended.

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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;