

FANTOME .....	IEC 60601-1-3:2008, 3.46
FENETRE .....	IEC 60601-1-3:2008, 3.54
FILTRE ADDITIONNEL .....	IEC 60601-1-3:2008, 3.2
FILTRE EN COIN .....	IEC TR 60788:2004, rm-35-10
FOYER .....	IEC TR 60788:2004, rm-20-13s
GESTION DES RISQUES .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.107
GRAVITE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.114
GRILLE ANTIDIFFUSANTE .....	IEC TR 60788:2004, rm-32-06
HAUTE TENSION NOMINALE .....	IEC 60601-1-3:2008, 3.42
HAUTE TENSION RADIOGENE .....	IEC 60601-1-3:2008, 3.88
INSTALLE DE FAÇON PERMANENTE .....	IEC 60601-1:2005, 3.84
INTERVENTION GUIDEE PAR RADIOSCOPIE .....	201.3.203
IRRADIATION .....	IEC 60601-1-3:2008, 3.30
ISOCENTRE .....	IEC TR 60788:2004, rm-37-32
KERMA DANS L'AIR DE REFERENCE .....	IEC 60601-1-3:2008, 3.70
KERMA DANS L'AIR .....	IEC 60601-1-3:2008, 3.4
(DEBIT DE) KERMA DANS L'AIR .....	IEC 60601-1-3:2008, 3.5 +
MAÎTRISE DU RISQUE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.105
MODE DE FONCTIONNEMENT .....	IEC 60601-1-3:2008, 3.40
OPERATEUR .....	IEC 60601-1:2005, 3.73
ORGANISME RESPONSABLE .....	IEC 60601-1:2005, 3.101
OUTIL .....	IEC 60601-1:2005, 3.127
PARAMETRE DE CHARGE .....	IEC 60601-1-3:2008, 3.35
PARTIE APPLIQUEE .....	IEC 60601-1:2005, 3.8
PATIENT .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.76
PERFORMANCE ESSENTIELLE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.27
PLAN DU RECEPTEUR D'IMAGE .....	IEC TR 60788:2004, rm-37-15
POINT DE REFERENCE D'ENTREE PATIENT .....	IEC 60601-1-3:2008, 3.43
PORTIQUE .....	IEC TR 60788:2004, rm-30-04
PROCÉDURE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.88
PROCESSUS .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.89
PRODUIT EXPOSITION-SURFACE .....	IEC 60601-2-54:2009, 201.3.203
(DEBIT DE) PRODUIT EXPOSITION-SURFACE .....	IEC 60601-2-54:2009, 201.3.203+
PROTECTION RADIOLOGIQUE .....	IEC TR 60788:2004, rm-60-03
QUALITE DE RAYONNEMENT .....	IEC 60601-1-3:2008, 3.60

RADIOMETRE DE PRODUIT EXPOSITION-SURFACE.....	IEC 60580	3.8
RADIOGRAPHIE DIRECTE .....	IEC 60601-2-54:2009,	201.3.201
RADIOGRAPHIE INDIRECTE .....	IEC 60601-2-54:2009,	201.3.205
RADIOGRAPHIE.....	IEC 60601-1-3:2008,	3.64
RADIOLOGIE.....	IEC TR 60788:2004,	rm-40-01
RADIOPROTECTION .....	IEC 60601-1-3:2008,	3.59
RADIOSCOPIE DIRECTE .....	IEC 60601-2-54:2009,	201.3.202
RADIOSCOPIE.....	IEC 60601-1-3:2008,	3.69
RADIOSCOPIE D'URGENCE.....		201.3.204
RADIOTHERAPIE .....	IEC TR 60788:2004,	rm-40-05
RAPPORT STRUCTURÉ DE DOSE DE RAYONNEMENT (RDSR) .....	IEC 61910-1:2014,	3.3
RAYONNEMENT DIFFUSE.....	IEC 60601-1-3:2008,	3.73
RAYONNEMENT PARASITE .....	IEC 60601-1-3:2008,	3.75
RAYONNEMENT X.....	IEC 60601-1-3:2008,	3.53
RAYONNEMENT .....	IEC 60601-1-3:2008,	3.53
RECEPTEUR D'IMAGE RADIOLOGIQUE .....	IEC 60601-1-3:2008,	3.81
REFERENCE DU MODELE OU DU TYPE.....	IEC 60601-1:2005,	3.66
RESEAU D'ALIMENTATION .....	IEC 60601-1:2005,	3.120
RISQUE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012,	3.102
SECURITE DE BASE .....	IEC 60601-1:2005,	3.10
SERIOGRAPHIE.....	IEC 60601-2-54:2009,	201.3.209
SITUATION DANGEREUSE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012,	3.40
SUPPORT PATIENT .....	IEC TR 60788:2004,	rm-30-02
SURFACE D'ENTREE.....	IEC 60601-1-3:2008,	3.21
SURFACE DU PATIENT .....	IEC TR 60788:2004,	rm-37-18
SURFACE RECEPTRICE DE L'IMAGE EFFICACE.....	IEC 60601-1-3:2008,	3.20
SURFACE RECEPTRICE DE L'IMAGE .....	IEC 60601-1-3:2008,	3.28
SYSTEME ELECTROMEDICAL (SYSTEME EM) .....	IEC 60601-1:2005,	3.64
TEMPS D'IRRADIATION.....	IEC 60601-1-3:2008,	3.32
TEMPS DE CHARGE .....	IEC 60601-1-3:2008,	3.37
TOMODENSITOMETRIE .....	IEC TR 60788:2004,	rm-41-20
TRANSMISSION DE FIN DE PROCÉDURE DU RDSR.....	IEC 61910-1:2014,	3.5
UTILISATION NORMALE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012,	3.71
UTILISATION PREVUE .....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012,	3.44
VALEUR MESUREE .....	IEC 60601-1-3:2008,	3.38
VERROUILLAGE .....	IEC 60601-2-54:2009,	201.3.207
VETEMENT DE PROTECTION RADIOLOGIQUE .....	IEC 60601-1-3:2008,	3.50

ZONE DE PIÉGEAGE .....	IEC 60601-1:2005, 3.131
ZONE PROTEGEE .....	IEC 60601-1-3:2008, 3.48
ZONE SIGNIFICATIVE D'OCCUPATION .....	IEC 60601-1-3:2008, 3.74

---



# FINAL VERSION

# VERSION FINALE

**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**

This is a preview. [Click here to purchase the full publication.](#)

## CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
INTRODUCTION to the Amendment .....	6
201.1 Scope, object and related standards .....	7
201.2 Normative references .....	9
201.3 Terms and definitions.....	10
201.4 General requirements.....	10
201.5 General requirements for testing of ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	12
201.7 ME EQUIPMENT identification, marking and documents.....	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	17
201.10 Protection against unwanted and excessive radiation HAZARDS.....	18
201.11 Protection against excessive temperatures and other HAZARDS.....	18
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	20
201.13 HAZARDOUS SITUATIONS and fault conditions .....	23
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	24
201.15 Construction of ME EQUIPMENT .....	24
201.16 ME SYSTEMS.....	24
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	24
202 Electromagnetic disturbances – Requirements and tests.....	24
203 Radiation protection in diagnostic X-ray equipment.....	25
Annexes .....	35
Annex AA (informative) Particular guidance and rationale.....	36
Annex BB (normative) Distribution maps of STRAY RADIATION.....	44
Annex CC (informative) Mapping between this Edition 2 of IEC 60601-2-43 and Edition 1 .....	48
Bibliography.....	50
Index of defined terms used in this particular standard.....	52
 Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration .....	46
Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration.....	47
 Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis.....	11
Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS .....	16
Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible .....	36
Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely .....	37

## 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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

#### **DISCLAIMER**

**This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.**

**This Consolidated version of IEC 60601-2-43 bears the edition number 2.1. It consists of the second edition (2010-03) [documents 62B/779/FDIS and 62B/792/RVD] and its amendment 1 (2017-05) [documents 62B/1012/CDV and 62B/1037/RVC]. The technical content is identical to the base edition and its amendment.**

**This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted 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 amendment 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.

## 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 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.

## 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<sup>1)</sup> applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of 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) is covered by this particular standard and not by IEC 60601-2-44 [2]<sup>2)</sup>. Additional requirements for operation in CT-like mode or cone-beam CT were not considered in the present standard.

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.

<sup>1)</sup> 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*.

<sup>2)</sup> Figures in square brackets refer to the Bibliography.