

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



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2010 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch
Tél.: +41 22 919 02 11
Fax: +41 22 919 03 00

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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XA

ICS 11.40.50; 37.040.25

ISBN 978-2-88910-223-5

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions.....	9
201.4 General requirements.....	10
201.5 General requirements for testing of ME EQUIPMENT.....	11
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.....	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	16
201.10 Protection against unwanted and excessive radiation HAZARDS.....	17
201.11 Protection against excessive temperatures and other HAZARDS.....	17
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	19
201.13 HAZARDOUS SITUATIONS and fault conditions.....	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	22
201.15 Construction of ME EQUIPMENT	22
201.16 ME SYSTEMS	23
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	23
202 Electromagnetic compatibility – Requirements and tests	23
203 Radiation protection in diagnostic X-ray equipment.....	24
Annexes	34
Annex AA (informative) Particular guidance and rationale.....	35
Annex BB (normative) Distribution maps of STRAY RADIATION.....	43
Annex CC (informative) Mapping between this Edition 2 of IEC 60601-2-43 and Edition 1	47
Bibliography.....	49
Index of defined terms used in this particular standard.....	51
Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration	45
Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration.....	46
Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis.....	10
Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS	15
Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible	35
Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely	36

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.

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 cancels and replaces the first edition published in 2000. This 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.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/779/FDIS	62B/792/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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 this publication 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.

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 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]². 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.

¹⁾ The general standard is IEC 60601-1:2005, *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 60601-1-8 and IEC 60601-1-10 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 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 50.

Amendment:

IEC 60601-1-2:2007 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

Addition:

IEC 60580, *Medical electrical equipment – Dose area product meters*

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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

IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE 1 An index of defined terms is found beginning on page 51.

NOTE 2 The reference point labelled as ‘interventional reference point’ in Edition 1 is replaced by PATIENT ENTRANCE REFERENCE POINT in this edition.

Addition:

201.3.201

*** 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

201.3.202

INTERVENTIONAL X-RAY EQUIPMENT

X-RAY EQUIPMENT FOR RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

201.3.203

RADIOSCOPICALLY GUIDED INTERVENTIONAL 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

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Subclause 201.4.3 of IEC 60601-2-54:2009 applies, except as follows:

Addition:

The list in Table 201.101 of IEC 60601-2-54 is a list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis.

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 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 60601-2-54:2009 applies.

Additional subclauses:

201.4.101 * Recovery management

The time to recover a minimum set of functions for performing emergency RADIOSCOPY, after a failure recoverable 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 procedure shall be required to further produce IRRADIATION.

The time to recover all functions, after a failure recoverable by the operator, shall be as short as reasonably practicable. The RISK MANAGEMENT shall determine means of realization with definition of the transition timing.

In case of failure recoverable by the OPERATOR, the instructions for use shall describe the required procedure, which the OPERATOR must follow, to perform this recovery. The instructions for use shall indicate:

- the time necessary to get the minimum set of functions for emergency RADIOSCOPY operable;
- the time to get all the functions of the INTERVENTIONAL X-RAY EQUIPMENT operable.

When the system is in the emergency RADIOSCOPY mode, this mode shall be indicated at the working position of the OPERATOR.

The minimum set of functions necessary for performing emergency RADIOSCOPY are called “emergency functions” and include:

- RADIOSCOPY MODE OF OPERATION, in priority order:
 - RADIOSCOPY in the MODE OF OPERATION which 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 subclause 201.9.2.3.1 in IEC 60601-2-54);
- 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.

NOTE 3 This item is an addition compared to the first edition of IEC 60601-2-43:2000.

201.4.102 * RADIATION dose documentation

INTERVENTIONAL X-RAY EQUIPMENT shall provide RADIATION dose structured reports (RDSR).

NOTE The Radiation Dose Structured Report (RDSR) is defined in the DICOM standard [23].

RDSR should be created and handled by the INTERVENTIONAL X-RAY EQUIPMENT according to IEC/PAS 61910-1:2007 [24].

The method for testing the performance/accuracy of the RSDR shall be stated in the RISK MANAGEMENT FILE.

Compliance is checked by functional test and the RISK MANAGEMENT FILE, if applicable.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

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

201.7.2.7 Electrical input power from the SUPPLY MAINS

Subclause 201.7.2.7 of IEC 60601-2-54:2009 applies.

201.7.2.15 Cooling conditions

Subclause 201.7.2.15 of IEC 60601-2-54:2009 applies.

Additional subclauses:

201.7.2.101 Beam limiting device

Subclause 201.7.2.101 of IEC 60601-2-54:2009 applies.

201.7.2.102 * PATIENT SUPPORT load

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

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

201.7.2.103 Cardiopulmonary resuscitation (CPR)

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

201.7.2.104 Marking of compliance

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

INTERVENTIONAL X-RAY EQUIPMENT [model or type reference] IEC 60601-2-43:2010.

201.7.2.105 * Protection against ingress of liquids

Specific parts of the INTERVENTIONAL X-RAY EQUIPMENT, which are located in the PATIENT vicinity (or around the PATIENT), shall be marked with the degree of protection as defined in IEC 60529. When an ACCESSORY is required for protection against ingress of liquids, this shall be stated in the instructions for use.

NOTE 1 This is an addition compared to the first edition of IEC 60601-2-43:2000.

NOTE 2 See also 201.11.6.5.103.

201.7.8.1 Colours of indicator lights

The indication of X-RAY related states shall be excluded from subclause 7.8 in the general standard. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the INTERVENTIONAL X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria and frequency for the tests.

Additionally for INTERVENTIONAL X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

- the identification of the version of image processing applied to ORIGINAL DATA;
NOTE Information displayed on the user interface can be considered to satisfy this requirement.
- a description of the file transfer format of the images acquired with this unit and of any data associated with these images;

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Subclause 201.7.9.2.1 of IEC 60601-2-54:2009 applies.

201.7.9.2.12 * Cleaning, disinfection and sterilization

Addition:

NOTE In order to satisfy subclause 11.6.6 of the general standard, the information given has to exclude commonly used but possibly corrosive substances, such as sodium hypochlorite, if the use of such substances would present a risk of damage to the parts of the INTERVENTIONAL X-RAY EQUIPMENT concerned.

Additional subclauses:

201.7.9.2.101 PROTECTIVE DEVICES and ACCESSORIES

A list shall be provided of PROTECTIVE DEVICES and ACCESSORIES recommended when the INTERVENTIONAL X-RAY EQUIPMENT is employed for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. There may be different lists for different types of procedures. The listing may include PROTECTIVE DEVICES such as PROTECTIVE CLOTHING, recommended for use but not forming part of the INTERVENTIONAL X-RAY EQUIPMENT.

201.7.9.2.102 * Provisions for CPR

Instructions shall be given for at least one method of configuring the INTERVENTIONAL X-RAY EQUIPMENT to permit CPR including the use of any necessary ACCESSORIES provided with the INTERVENTIONAL X-RAY EQUIPMENT. These instructions shall not call for the use of ACCESSORIES that are not provided with the INTERVENTIONAL X-RAY EQUIPMENT.

If instructions differ between NORMAL USE and in cases of SINGLE FAULT CONDITIONS, the instructions shall be given for all appropriate cases.

NOTE This last sentence is an addition compared to the first edition of IEC 60601-2-43:2000.

201.7.9.2.103 * Emergency instructions

Emergency instructions shall be provided in non-electronic form, resistant to manipulation, water damage and cleaning.

Emergency instructions shall contain only instructions related to emergency functions and situations.

At minimum, emergency instructions shall include instructions for:

- configuring the INTERVENTIONAL X-RAY EQUIPMENT for CPR (only for INTERVENTIONAL X-RAY EQUIPMENT including a PATIENT SUPPORT) (201.7.9.2.102);
- the re-starting procedure in case of recoverable failure by the OPERATOR (201.4.101);
- the re-starting procedure for the INTERVENTIONAL X-RAY EQUIPMENT in the event of failure of SUPPLY MAINS(201.7.9.2.104);
- the re-starting procedure for the INTERVENTIONAL X-RAY EQUIPMENT in the case of the use of an emergency power supply requiring such actions (201.7.9.2.104);
- the location, function and operation of the IRRADIATION disabling switch (203.5.2.4.101);
- the location, function and operation of the motion disabling switch (see 201.9.2.3.1 of IEC 60601-2-54);
- the list of emergency functions, as defined in 201.4.101;
- if the complete instructions for use are only available in electronic form, instructions for accessing the complete instructions for use.

NOTE This is an addition compared to the first edition of IEC 60601-2-43:2000.

201.7.9.2.104 Failure of supply mains

The instructions for use shall describe the functional response and re-starting procedure for the INTERVENTIONAL X-RAY EQUIPMENT in the event of failure of the SUPPLY MAINS. Details shall be given of the possibilities for provisions being made in the installation of emergency power supply for the following cases:

- for the preservation of stored images only;
- for emergency RADIOSCOPY (as described in 201.4.101);
- for minimum equipment motion (limited motion of GANTRY, table and source-to-image motion as determined by the MANUFACTURER);
- for all functions for performing RADIOSCOPY and RADIOGRAPHY.
- for placing the INTERVENTIONAL X-RAY EQUIPMENT in CPR position in case of the failure of SUPPLY MAINS, if placing the INTERVENTIONAL X-RAY EQUIPMENT IN CPR configuration requires electrical power.

This information is necessary so that the RESPONSIBLE ORGANIZATION is able to decide on an appropriate level of protection to be provided against such failures.

Compliance is determined by inspection of the instructions for use.

NOTE See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.12.4.108 for requirements on operation of the emergency power supply.

201.7.9.2.105 Description of the protection against ingress of liquids

The instructions for use shall explain the IPXY marking used on the INTERVENTIONAL X-RAY EQUIPMENT.

NOTE 1 See also 201.7.2.105.

NOTE 2 This is an addition compared to the first edition of IEC 60601-2-43:2000.

201.7.9.3 Technical Description

Additional subclauses:

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

Subclause 201.7.9.3.101 of IEC 60601-2-54:2009 applies.

201.7.9.3.102 Installation

For PERMANENTLY INSTALLED INTERVENTIONAL X-RAY EQUIPMENT, the technical description shall contain the following recommendations concerning the installation of the INTERVENTIONAL X-RAY EQUIPMENT:

- INTERLOCKS must not be present on the doors of the room containing the INTERVENTIONAL X-RAY EQUIPMENT. No other measures, whether or not employed for RADIATION PROTECTION, should be able to cause the interruption of IRRADIATION or any other disturbance of a procedure in progress, unless the OPERATOR has the means to prevent such action from occurring during the procedure;
- all emergency stop controls in the system must be protected against accidental actuation;
- sufficient space must be available around the PATIENT SUPPORT for the unimpeded conduct of CPR;
- one or more warning lights must be present in order to indicate the LOADING STATE to persons at all positions in the room containing the INTERVENTIONAL X-RAY EQUIPMENT; see also requirement of 203.13.4
- appropriate warning lights to indicate the LOADING STATE must be present adjacent to doors opening into the procedure room when warning lights within the procedure room are not visible.

NOTE This list is a set of information for the RESPONSIBLE ORGANIZATION, therefore the verb 'must' is used to clearly distinguish these from requirements on the INTERVENTIONAL X-RAY EQUIPMENT itself.

Additional subclauses:

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Additional requirements for statements in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Annex C Table 201.C.102 of IEC 60601-2-54:2009 and in Table 201.102 of this particular standard.

Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS

Subclause	Heading
201.4.101	Recovery management
201.7.2.105	Protection against ingress of liquids
201.9.8.3.1	Strength of PATIENT or OPERATOR support or suspension systems – General
201.11.6.1	Overflow, spillage, etc. – General
201.11.6.5.102	Sources of dust and other particles
201.12.4.101.2	Management of image storage capacity

Subclause	Heading
201.12.4.102	IMAGE DISPLAY DELAY
201.12.4.107	Measuring functions
201.15.102	Attachment of sterile drapes
203.5.2.4.5	Deterministic effects
203.5.2.4.101	IRRADIATION disabling switch
203.6.4.2	Indication of LOADING STATE
203.13.4	Designated SIGNIFICANT ZONES OF OCCUPANCY

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

Replacement:

Clause 201.8 of IEC 60601-2-54:2009 applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2 HAZARDS associated with moving parts

201.9.2.2.4 GUARDS and protective measures

Subclause 201.9.2.2.4 of IEC 60601-2-54:2009 applies.

201.9.2.2.5 Continuous activation

Subclause 201.9.2.2.5 of IEC 60601-2-54:2009 applies.

201.9.2.2.6 Speed of movement(s)

Subclause 201.9.2.2.6 of IEC 60601-2-54:2009 applies.

201.9.2.3 Other HAZARDS associated with moving parts

Subclause 201.9.2.3 of IEC 60601-2-54:2009 applies.

201.9.2.4 * Emergency stopping devices

Addition:

aa) In order to prevent HAZARDS arising from the unintended interruption of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, the operation of anti-collision devices in INTERVENTIONAL X-RAY EQUIPMENT shall not automatically switch off IRRADIATION and shall not impair other functions of the INTERVENTIONAL X-RAY EQUIPMENT, except movements connected with the potential collision. Means shall be provided for any movement disabled by the actuation of an anti-collision device to be caused to recover from collision within 5 s after a positive action taken at the working position of the OPERATOR.

Additional subclause:

201.9.2.4.101 Controls

Subclause 201.9.2.4.101 of IEC 60601-2-54:2009 applies.

201.9.8 HAZARDS associated with support systems**201.9.8.3 Strength of patient or operator support or suspension systems****201.9.8.3.1 General**

Addition:

In INTERVENTIONAL X-RAY EQUIPMENT, the load for which the PATIENT SUPPORT is designed shall be the normal load imposed by the PATIENT (as specified and marked, or otherwise as required in this subclause), with the addition of a mass of not less than 50 kg to provide for additional load imposed in the performance of CPR. This additional load shall be assumed to be applied uniformly over a length of 1 500 mm from the head-end of the PATIENT SUPPORT, or over the whole length if it is less than 1 500 mm, when the INTERVENTIONAL X-RAY EQUIPMENT is configured for CPR in accordance with the instructions for use, including the fitting of any ACCESSORIES specified for use in CPR.

Addition to the description of the compliance test:

For INTERVENTIONAL X-RAY EQUIPMENT, the test shall be carried out in the least favourable position other than when configured for CPR, and also in the least favourable position when configured for CPR. When configured for CPR, the test shall include the application of additional weight evenly over the portion of the PATIENT SUPPORT from the head-end up to a length of 1 500 mm or the maximum available length if less than 1 500 mm. This additional weight shall be applied after an interval of 1 min or more subsequent to the application of the testing weight representing the normal load.

For a test of INTERVENTIONAL X-RAY EQUIPMENT in the CPR configuration, the system shall be free from flexing or resonance effects that would impede the conduct of CPR.

201.9.8.3.3 Dynamic forces due to loading from persons

Subclause 201.9.8.3.3 of IEC 60601-2-54:2009 applies.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Subclause 201.9.8.4 of IEC 60601-2-54:2009 applies.

Additional subclause:

201.9.8.101 Shock absorbing means

Subclause 201.9.8.101 of IEC 60601-2-54:2009 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies

NOTE See Clause 203.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 * Maximum temperature during NORMAL USE

Addition:

Table 24 of the general standard shall be used for INTERVENTIONAL X-RAY EQUIPMENT parts which can, in NORMAL USE, have prolonged contact with the PATIENT.

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.1 * General

Addition:

All components which can come into contact with PATIENTS' secretions, excretions, other body fluids, or other fluids shall be constructed so that:

- covers or drapes can be employed to divert these fluids away from the INTERVENTIONAL X-RAY EQUIPMENT, and
- the INTERVENTIONAL X-RAY EQUIPMENT surfaces over which the fluids can flow are suitable for cleaning and disinfection.

Guidance shall be provided for the use of the cleaning and disinfecting agents listed in the ACCOMPANYING DOCUMENTS.

Surfaces of the INTERVENTIONAL X-RAY EQUIPMENT likely to be exposed to specified cleaning and disinfecting agents shall be designed so that they are protected from, or are otherwise tolerant, of the agents concerned.

It should be assumed that all external surfaces of the X-RAY SOURCE ASSEMBLY, the GANTRY, the X-RAY IMAGE RECEPTOR assembly, the PATIENT SUPPORT and the tableside controls may be contaminated by PATIENTS' body fluids in the course of NORMAL USE.

NOTE 1 This subclause is modified compared to the first edition of IEC 60601-2-43:2000.

NOTE 2 Attention is drawn to the additional requirements in 201.7.9.2.12 concerning cleaning and disinfection.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Additional subclauses:

201.11.6.5.101 Footswitches

The footswitches of INTERVENTIONAL X-RAY EQUIPMENT, that are located at the table side, shall be operable even if the floor is covered with 25 mm of a saline solution.

NOTE Attention is drawn to the limitation of operating voltage imposed by 8.10.4 in the general standard.

Compliance is determined by mechanically actuating and releasing the footswitch (with no electrical power source connected) 900 times in 25 mm depth of a saline solution of at least 0.9% over a period of 1 h; then checking its functionality and electrical safety in accordance with the general standard. In addition there shall be no evidence of fluid having reached mechanical parts that might deteriorate if they remain wet indefinitely.

Tableside connections of footswitch cable should be at least 25 mm above floor level.

Compliance is determined by inspection.

NOTE This subclause is modified compared to the first edition of IEC 60601-2-43:2000.

201.11.6.5.102 * Sources of dust and other particles

Sources of dust or other particles due to the INTERVENTIONAL X-RAY EQUIPMENT shall not be directed towards the PATIENT.

Parts of the INTERVENTIONAL X-RAY EQUIPMENT mounted above the patient shall be designed to minimize the accumulation of dust, which could otherwise fall onto the PATIENT.

The instructions for use shall specify the procedure for removal of dust from parts of the INTERVENTIONAL X-RAY EQUIPMENT that are mounted above the patient.

Compliance is checked by inspection.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.11.6.5.103 * ENCLOSURES

The degree of protection without ACCESSORIES is as follows:

- Footswitches shall have a minimum degree of protection of IPX7.
- Tableside control should have a minimum degree of protection of IPX3.
- PATIENT SUPPORT should have a minimum degree of protection of IPX2.
- Image monitor may be IPX0 (i.e. no marking required)

There shall be no ingress of water under the specified test conditions of IEC 60529.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

Additional subclauses:

201.11.101 Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES

Subclause 201.11.101 of IEC 60601-2-54:2009 applies.

201.11.102 Protection against excessive temperatures of BEAM LIMITING DEVICES

Subclause 201.11.102 of IEC 60601-2-54:2009 applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

NOTE In accordance with subclause 12.4.5 of the general standard, the dose related aspects of this topic are addressed under 203.6.4.3 of IEC 60601-2-54:2009.

201.12.4 * Protection against hazardous output

Additional subclauses:

201.12.4.101 Information to the OPERATOR

201.12.4.101.1 * PATIENT data

Information shall be available on the DISPLAY concerning the identity of the PATIENT and the medical procedure to which displayed images relate.

In the case of emergency interventions, this requirement is exempted.

Compliance is determined by inspection and functional tests.

201.12.4.101.2 Management of image storage capacity

In the instructions for use, the need to check regularly the available storage capacity and secure/archive important records shall be stated.

Upon completion of entry of the PATIENT data at the beginning of a new case, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate the available image storage capacity.

When the operating parameters have been entered, prior to acquiring any run, the INTERVENTIONAL X-RAY EQUIPMENT shall indicate if there is insufficient storage space to store the run completely under the programmed conditions or shall state the number of frames possible or the acquisition time available, at the frame rate and resolution selected.

When there is not sufficient storage space, it shall be indicated at the working position of the OPERATOR.

In the event of the INTERVENTIONAL X-RAY EQUIPMENT reaching a zero storage space condition, RADIOGRAPHY either shall not be possible or be stopped, unless data has been stored elsewhere and the INTERVENTIONAL X-RAY EQUIPMENT has a means to determine that data has been stored successfully elsewhere.

NOTE This subclause is modified compared to the first edition of IEC 60601-2-43:2000.

Compliance is determined by inspection and functional tests.

201.12.4.101.3 * Image DISPLAYS

During RADIOSCOPY, the live image shall always occupy the same DISPLAY location. The status of all displayed images, in particular whether they are currently live or stored and, if stored, whether they are "last-image-hold" images or previously stored reference images, shall be indicated at their relevant DISPLAY locations.

Compliance is determined by inspection and functional tests.

201.12.4.101.4 Indications of emergency power supply

For PERMANENTLY INSTALLED INTERVENTIONAL X-RAY EQUIPMENT, if an emergency power supply is provided with the INTERVENTIONAL X-RAY EQUIPMENT, a visual indicator shall be displayed in the event of failure of the SUPPLY MAINS indicating that the INTERVENTIONAL X-RAY EQUIPMENT is operating on the emergency power supply.

This indicator shall be visible at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

NOTE 1 See also 201.7.9.2.104 for requirements on ACCOMPANYING DOCUMENTS. See also 201.12.4.108 for requirements on operation of the emergency power supply.

NOTE 2 This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.102 * IMAGE DISPLAY DELAY

IMAGE DISPLAY DELAY during RADIOSCOPY shall be as short as reasonably practicable. The appropriate limit shall be determined in the RISK MANAGEMENT FILE.

The instructions for use shall state that, if the RADIOGRAPHY mode is misused on purpose by the OPERATOR for real-time imaging, the IMAGE DISPLAY DELAY may be longer than in RADIOSCOPY.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by appropriate functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.103 * Documentation of image orientation

If it is possible for the OPERATOR to change the image orientation, the INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the image orientation on both the displayed and stored images.

The INTERVENTIONAL X-RAY EQUIPMENT shall have means to document the patient orientation.

Compliance is checked by functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.104 * Availability of RADIOSCOPY during networking activities

Networking activities shall not have an impact on the availability of RADIOSCOPY.

Compliance is checked by functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.105 * Appropriate mask location for subtracted images

When automatic subtraction means are provided for imaging modes where several mask images are acquired at different equipment positions, for any given image to be subtracted, the corresponding mask image shall be selected so that the difference between the position of the equipment at which this mask image was acquired and the position of the equipment for the image to be subtracted with this mask is minimized.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.106 * Tableside controls

For tableside controls, as a minimum, the following user interface controls, requiring operation by touch, shall be individually and unambiguously identifiable both by touch alone and also by sight alone:

- GANTRY and PATIENT SUPPORT motions controls (not including motion controls for preselecting INTERVENTIONAL X-RAY EQUIPMENT positions);
- IRRADIATION SWITCHES;
- collimation blade control (not including WEDGE FILTER control).

The other tableside controls shall be identifiable under all lighting conditions, when covered by sterile transparent protective means and if such means are needed.

Compliance is checked by inspection and by functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.107 * Image measuring functions

The instructions for use shall describe the image measuring functions, their units and their related inaccuracies with regards to the INTENDED USE.

The errors in image measuring functions introduced by the INTERVENTIONAL X-RAY EQUIPMENT shall be as small as reasonably practicable depending on the MODE OF OPERATION and INTENDED USE.

For measurements displayed by the INTERVENTIONAL X-RAY EQUIPMENT having a measuring function, each value shall be displayed together with its unit.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and appropriate inspection and functional tests.

NOTE This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.12.4.108 Provision for emergency power supply

The requirements in this subclause apply only for INTERVENTIONAL X-RAY EQUIPMENT that is PERMANENTLY INSTALLED and that is provided with an emergency power supply. For such INTERVENTIONAL X-RAY EQUIPMENT, the return to the SUPPLY MAINS in case of power failure shall be as follows:

- a) If RADIOSCOPY is currently being performed,
 - in the case of automated return to SUPPLY MAINS, the SUPPLY MAINS return shall be performed without interruption of RADIOSCOPY;
 - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS, to allow for initiating the switching back to SUPPLY MAINS by the OPERATOR. This indicator shall be visible at the working positions of the OPERATOR.
- b) If RADIOSCOPY is currently not being performed,
 - in the case of automated return to SUPPLY MAINS, there shall be no interruption in the availability of RADIOSCOPY;
 - in the case of manually controlled SUPPLY MAINS return, there shall be an indication of the state of SUPPLY MAINS. This indicator shall be visible at the working positions of the OPERATOR. An immediate switching back by the OPERATOR shall be possible when the SUPPLY MAINS is indicated to be available.

Compliance is checked by functional tests.

NOTE 1 See 201.12.4.101.4 for requirements on indications of emergency power supply mode. See also 201.7.9.2.104 for requirements on ACCOMPANYING DOCUMENTS.

NOTE 2 This subclause is an addition compared to the first edition of IEC 60601-2-43:2000.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

Additional subclauses:

201.15.101 * Configuration for cardiopulmonary resuscitation (CPR)

In NORMAL CONDITION, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can be placed in a configuration designated for CPR within 15 s. This period may be increased by 1 s for each 15° of tilt that the current working position of the PATIENT SUPPORT deviates from the CPR position.

In SINGLE FAULT CONDITIONS excluding SUPPLY MAINS failure, the INTERVENTIONAL X-RAY EQUIPMENT shall be so constructed that it can either comply with the CPR configuration time in NORMAL USE or shall be able to release or properly position the PATIENT within a time as low as reasonably practicable.

Compliance is determined by inspection of the RISK MANAGEMENT FILE and by appropriate functional tests.

In case of SUPPLY MAINS failure, the requirement for the NORMAL CONDITION applies.

Compliance is checked by disconnecting the INTERVENTIONAL X-RAY EQUIPMENT from the SUPPLY MAINS and verifying that the EQUIPMENT can be placed in CPR conditions.

NOTE This subclause is modified compared to the first edition of IEC 60601-2-43:2000.

201.15.102 Attachment of sterile drapes

Means shall be provided, and described in the instructions for use, for allowing sterile drapes to be attached to the INTERVENTIONAL X-RAY EQUIPMENT or its ACCESSORIES to enable procedures to be conducted with an appropriate level of sterility.

Compliance is determined by inspection of the INTERVENTIONAL X-RAY EQUIPMENT and the instructions for use.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows:

Additional clause:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional ESSENTIAL PERFORMANCE listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER needs to take into account the sensitivity to the EMC environment, probability of EMC condition and severity, and probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the INTERVENTIONAL X-RAY EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the INTERVENTIONAL X-RAY EQUIPMENT.

Only non-invasive measurements shall be performed.

INTERVENTIONAL X-RAY EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by the inspection of RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 applies, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be stated, the statement shall be made in the following form:

INTERVENTIONAL X-RAY EQUIPMENT *) IEC 60601-2-43:2010, or

.... **) *) IEC 60601-2-43:2010.

*) MODEL OR TYPE REFERENCE

**) Name of the INTERVENTIONAL X-RAY EQUIPMENT

Additional subclause:

203.4.101 Qualifying conditions for defined terms

Clause 203.4.101 of IEC 60601-2-54:2009 applies.

203.5.2.4 Instructions for use

203.5.2.4.5 Deterministic effects

Additional subclauses:

203.5.2.4.5.101 * Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY

NOTE Differences related to the same subclause in IEC 60601-2-54 include: point b): item 1), item 2) and item 5); point c): the variations due to selectable ADDED FILTERS, etc are to be given for all settings and not for only two settings.

a) Skin dose levels

The instructions for use shall draw attention to the RISK of local skin dose levels that cause tissue reactions under the INTENDED USE in the case of repetitive or prolonged exposure. The effect of the various selectable settings available in both RADIOSCOPY and RADIOGRAPHY on the RADIATION QUALITY, the delivered REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE shall be described.

Compliance is checked by inspection of the instructions for use.

b) Available settings

In the instructions for use, information shall be provided on the available configurations delivered by the MANUFACTURER such as MODES OF OPERATION, settings of LOADING FACTORS and other operating parameters that affect the RADIATION QUALITY or the prevailing value of REFERENCE AIR KERMA (RATE) in the INTENDED USE. If applicable this information shall include:

- 1) the values of the REFERENCE AIR KERMA (RATE) applying to the MODES OF OPERATION in RADIOSCOPY designated normal and low in accordance with 203.6.101;
- 2) details of all other MODES OF OPERATION, giving the default values of the REFERENCE AIR KERMA (RATE), and the available ranges for any factor that can be varied after the MODE OF OPERATION has been selected;
- 3) the settings of LOADING FACTORS and other operating parameters in RADIOSCOPY delivering the highest available REFERENCE AIR KERMA RATE;
- 4) the settings of LOADING FACTORS and other operating parameters in RADIOGRAPHY delivering the highest available REFERENCE AIR KERMA per frame;
- 5) one set of REFERENCE AIR KERMA (RATE) values typical of RADIOGRAPHY for distinctive types of procedure for which the INTERVENTIONAL X-RAY EQUIPMENT is intended to be used.

Compliance is checked by inspection of the instructions for use.

c) RADIATION data

In the instructions for use, for the MODES OF OPERATION and sets of values described in accordance with the settings in b) above, representative values of REFERENCE AIR KERMA (RATE) shall be given, based on measurement by the method described in 203.5.2.4.5.102.

In addition, representative values of REFERENCE AIR KERMA (RATE) based on measurement by the method described in 203.5.2.4.5.102 shall be given in the instructions for use, for respectively the MODES OF OPERATION and sets of values described in accordance with the settings in b) 1) and b) 2) of this subclause, and if they are adjustable by the OPERATOR in the MODE OF OPERATION concerned, for all settings of the following factors:

- selectable ADDED FILTERS;
- ENTRANCE FIELD SIZE;
- X-RADIATION pulse repetition frequency.

Information shall be given on the configurations of the INTERVENTIONAL X-RAY EQUIPMENT and the test geometries that can be used in the procedure described in 203.5.2.4.5.102 to verify the values given. Although it is required to provide details to enable verification by measurement in accordance with 203.5.2.4.5.102, the stated values may be determined originally by other methods, including calculation, leading to values that are in compliance, subject to the permitted tolerances, when verified by the method given in 203.5.2.4.5.102.

Measured values shall not deviate from stated values by more than 50%.

Compliance is checked by functional tests and inspection of the instructions for use. The stated values REFERENCE AIR KERMA (RATE) and statements concerning the variation of these values are verified by the method described in 203.5.2.4.5.102, using configurations and test geometries and settings described in the instructions for use.

d) PATIENT ENTRANCE REFERENCE POINT

In the instructions for use, the location of the PATIENT ENTRANCE REFERENCE POINT shall be described as specified for the type of INTERVENTIONAL X-RAY EQUIPMENT:

The PATIENT ENTRANCE REFERENCE POINT is located:

- 1 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT;
- 30 cm above the PATIENT SUPPORT for INTERVENTIONAL X-RAY EQUIPMENT with the X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT;
- 15 cm from the ISOCENTRE in the direction of the FOCAL SPOT for C-arm INTERVENTIONAL X-RAY EQUIPMENT or
 - for C-arm INTERVENTIONAL X-RAY EQUIPMENT without an ISOCENTRE, a point along the X-RAY BEAM AXIS defined by the MANUFACTURER as being representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT SURFACE. In this case, the statement in the instructions for use shall include the rationale for the choice of position made by the MANUFACTURER or
 - at the point representing the minimum FOCAL SPOT TO SKIN DISTANCE for C-arm INTERVENTIONAL X-RAY EQUIPMENT with FOCAL SPOT TO IMAGE RECEPTOR DISTANCE less than 45 cm,
- for INTERVENTIONAL X-RAY EQUIPMENT not listed above the PATIENT ENTRANCE REFERENCE POINT shall be specified by the MANUFACTURER.

Compliance is checked by inspection of the instructions for use

203.5.2.4.5.102 * Test for dosimetric information

a) Relevant parameters

It is required in 203.5.2.4.5.101 to provide, in the instructions for use, a description of the configurations and test geometries applying to the stated values of REFERENCE AIR KERMA (RATE). The following are examples of factors that need to be referenced, when relevant to the INTERVENTIONAL X-RAY EQUIPMENT settings concerned.

i) Equipment configuration

- 1) Orientation of the X-RAY BEAM
- 2) PATIENT SUPPORT *in or out*
- 3) ANTI-SCATTER GRID *in or out*
- 4) Appropriate ENTRANCE FIELD SIZE *selected*

ii) Operating settings (representative of NORMAL USE)

- 1) Technical details of parameters included in each MODE OF OPERATION
- 2) Frame rate
- 3) Selectable ADDED FILTERS *automatically applied*
- 4) Selectable ADDED FILTERS *manually applied*

iii) Test geometry

- 1) FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
- 2) Distance of FOCAL SPOT to measuring detector
- 3) RADIATION FIELD *size at the measuring detector*
- 4) Positioning of PHANTOM (see item c) below)
- 5) Positioning of measuring detector (see item c) below)

b) Checking the test conditions

Before any dosimetric measurements are made, verify that the particulars of the INTERVENTIONAL X-RAY EQUIPMENT settings under test and the associated measuring arrangements given in the instructions for use are in compliance with 203.5.2.4.5.101.

c) *Measurements and test conditions:*

- Use a 20 cm polymethyl-methacrylate (PMMA) PHANTOM (the PHANTOM may be fabricated from layers of material) comprising of rectangular blocks with sides equal to or exceeding 25 cm. Area density of the nominal 20 cm PHANTOM: 23,5 g/cm², with a relative tolerance of ± 5 %.
- Use a DOSEMETER with a measuring detector small enough to cover not more than 80 % of the area of the X-RAY BEAM in the plane of measurement, and the area of its surface perpendicular to the source-detector axis shall not exceed 30 cm².
- The PHANTOM is placed near the image receptor, leaving as much of the available distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM.
- Position the measuring detector at a point that is either:
 - the PATIENT ENTRANCE REFERENCE POINT (only if there is at least 20 cm distance between the measuring detector and the PHANTOM)
 or
 - half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM. In that case, the readings are to be corrected to the appropriate distance.
- Measure the AIR KERMA RATE for the RADIOSCOPY settings for which a value of REFERENCE AIR KERMA RATE is required to be stated in 203.5.2.4.5.101c).
- Measure the AIR KERMA per image for RADIOGRAPHY settings as required to be stated in 203.5.2.4.5.101 c).
- For each setting required in 203.5.2.4.5.101, measure the AIR KERMA (RATE) using the PHANTOM described:
 - for all representative OPERATOR selectable ENTRANCE FIELD SIZES;
 - for all representative OPERATOR selectable ADDED FILTERS;
 - for all representative OPERATOR selectable pulse repetition frequencies
- The surface of the PHANTOM shall be aligned perpendicular to the X-RAY BEAM AXIS within ± 2 degrees in all directions.

NOTE 2 This item about PHANTOM alignment is an addition compared to the first edition of IEC 60601-2-43:2000.

*Additional subclause:***203.5.2.4.101 Instruction for use of the IRRADIATION disabling switch**

The instructions for use shall recommend that the IRRADIATION disabling switch be used at all times, except when a procedure is in progress, to prevent the possibility of RADIATION being emitted through the inadvertent actuation of an IRRADIATION SWITCH.

203.6 RADIATION management**203.6.2 Initiation and termination of the IRRADIATION**

Subclause 203.6.2 of IEC 60601-2-54:2009 applies.

203.6.3 RADIATION dose and RADIATION QUALITY**203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY**

Subclause 203.6.3.1 of IEC 60601-2-54:2009 applies except that the additional manual control without the use of the AUTOMATIC CONTROL SYSTEM in subclause 203.6.3.1 b) of IEC 60601-2-54:2009 is not possible.

203.6.3.2 Reproducibility of the RADIATION output

Subclause 203.6.3.2 of IEC 60601-2-54:2009 applies.

Additional subclauses:

203.6.3.101 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

Subclause 203.6.3.101 of IEC 60601-2-54:2009 applies.

203.6.3.102 High-level control (HLC)

Subclause 203.6.3.102 of IEC 60601-2-54:2009 applies.

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

The LOADING STATE shall be indicated by a yellow indicator on the CONTROL PANEL.

At the initiation of IRRADIATION a brief audible signal shall be indicated at the working position of the OPERATOR. The audible signal shall be different for RADIOSCOPY and for RADIOGRAPHY. Means shall be provided to adjust or inactivate these audible signals and shall be described in the ACCOMPANYING DOCUMENTS. All of these requirements do not apply to high-level control (HLC) RADIOSCOPY.

NOTE This item is an addition compared to the first edition of IEC 60601-2-43:2000.

Compliance is checked by inspection.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Subclause 203.6.4.3 of IEC 60601-2-54:2009 applies.

203.6.4.4 Indication of automatic modes

Subclause 203.6.4.4 of IEC 60601-2-54:2009 applies.

203.6.4.5 * Dosimetric indications

Addition:

NOTE Differences related to the same subclause in IEC 60601-2-54:2009 include: the 1st dash of 3rd paragraph is applicable also to SERIAL RADIOGRAPHY; in the 4th paragraph, the minimal value is 2,5 Gy·cm² instead of 5 μGy·m² i.e. is 50 times larger, and the recommended unit for displaying the DOSE AREA PRODUCT is Gy·cm²; additional requirements and recommendations are present after the requirement about DOSE AREA PRODUCT METERS; and also unlike in IEC 60601-2-54, there is no specific requirement for INDIRECT RADIOGRAPHY and DIRECT RADIOGRAPHY.

The ACCOMPANYING DOCUMENTS shall provide information on the performance of the dosimetric indications and describe the operations required to maintain this performance within specification.

Means shall be provided to reset to zero the values of all the cumulative dosimetric indications prior to the commencement of a new examination or PROCEDURE.

INTERVENTIONAL X-RAY EQUIPMENT specified for either RADIOSCOPY or RADIOSCOPY and RADIOGRAPHY shall satisfy the following requirements.

- The value of the mean REFERENCE AIR KERMA RATE shall be displayed during RADIOSCOPY and during SERIAL RADIOGRAPHY in mGy/min together with this unit. This value shall be continuously displayed at the working position of the OPERATOR during the actuation of the IRRADIATION SWITCH and updated at least once every second.
- The value of the cumulative REFERENCE AIR KERMA resulting from RADIOSCOPY and RADIOGRAPHY since the last reset operation shall be continuously displayed at the working position of the OPERATOR in mGy together with this unit and updated at least once every 5 seconds.
- The values for the cumulative REFERENCE AIR KERMA shall be displayed within the 5 seconds following the interruption or termination of LOADING in RADIOSCOPY or RADIOGRAPHY.
- During RADIOSCOPY, the values for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be displayed simultaneously while remaining clearly distinguishable from each other.
- The REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall not deviate from their respective displayed values by more than $\pm 35\%$ over the range of 6 mGy/min and 100 mGy to the maximum values.

INTERVENTIONAL X-RAY EQUIPMENT shall be provided with an indication of the cumulative DOSE AREA PRODUCT resulting from RADIOGRAPHY and from RADIOSCOPY since the last reset operation. The DOSE AREA PRODUCT may be measured or calculated. The value should be expressed in Gy·cm². The overall uncertainty of the displayed values of the cumulative DOSE AREA PRODUCT above 2,50 Gy·cm² shall not exceed 35 %.

This DOSE AREA PRODUCT indication need not be provided at the working position of the OPERATOR.

If part of the INTERVENTIONAL X-RAY EQUIPMENT, DOSE AREA PRODUCT METERS shall comply with IEC 60580.

The indications of cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE shall be CLEARLY LEGIBLE 2,5 meter from the DISPLAY in the procedure room. This display may be included on an image monitor or it may be a separate device.

The display label for the cumulative REFERENCE AIR KERMA and REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT shall not be designated as “skin dose” and “skin dose rate” respectively.

When the cumulative REFERENCE AIR KERMA displayed on the INTERVENTIONAL X-RAY EQUIPMENT exceeds a threshold expected to produce skin injury, the INTERVENTIONAL X-RAY EQUIPMENT should display a visual warning to the OPERATOR. When such a DISPLAY is provided, the threshold value shall be adjustable.

Compliance is checked by inspection and by the appropriate functional tests. The tests for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be performed with a LOADING STATE of duration longer than 3 s.

During RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, indications of one or more of the following items should be made available:

- cumulative LOADING TIME of RADIOSCOPY for the whole procedure;
- cumulative LOADING TIME of RADIOSCOPY for at least one part of the procedure determined by the OPERATOR;
- cumulative number of IRRADIATIONS from RADIOGRAPHY for the whole procedure;
- cumulative number of IRRADIATIONS from RADIOGRAPHY for at least one part of the procedure determined by the OPERATOR;

- cumulative REFERENCE AIR KERMA for at least one part of the procedure determined by the OPERATOR.

Additional subclause:

203.6.4.101 Indication of READY STATE

Subclause 203.6.4.101 of IEC 60601-2-54:2009 applies.

203.6.5 AUTOMATIC CONTROL SYSTEM

Subclause 203.6.5 of IEC 60601-2-54:2009 applies.

203.6.6 SCATTERED RADIATION reduction

Subclause 203.6.6 of IEC 60601-2-54:2009 applies, except as follows:

Addition:

INTERVENTIONAL X-RAY EQUIPMENT specified for paediatric applications shall have means to easily remove the ANTI-SCATTER GRID without the use of TOOLS.

Compliance is determined by inspection and functional tests.

203.6.7 Imaging performance

Subclause 203.6.7 of IEC 60601-2-54:2009 applies.

Additional subclauses:

203.6.101 Range of AIR KERMA RATES in RADIOSCOPY

For RADIOSCOPY the MODES OF OPERATION provided for NORMAL USE shall include two modes, designated normal and low respectively, producing different REFERENCE AIR KERMA RATES, such that the value for the low mode does not exceed 50 % of the value for the normal mode. Additional MODES OF OPERATION may be provided, with REFERENCE AIR KERMA RATES less or greater than the values for the normal and low modes.

A control for the selection of any of these MODES OF OPERATION shall not also perform the function of an IRRADIATION SWITCH.

An indication of the selected MODE OF OPERATION shall be provided at the working position of the OPERATOR.

The INTERVENTIONAL X-RAY EQUIPMENT shall not default to a setting with a REFERENCE AIR KERMA RATE higher than that of the normal setting, when the INTERVENTIONAL X-RAY EQUIPMENT is being prepared for the commencement of a procedure.

Compliance is determined by inspection and functional tests and also by the test procedure given in 203.5.2.4.5.102 using the 20 cm polymethyl-methacrylate (PMMA) PHANTOM in order to verify the ratio of the REFERENCE AIR KERMA RATES at the designated normal and low MODES OF OPERATION.

203.6.102 * Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

Means to switch between RADIOSCOPY and RADIOGRAPHY shall be provided at the working positions of the OPERATOR.

Compliance is determined by inspection and functional tests.

203.6.103 IRRADIATION disabling switch

A switch shall be provided to disable/enable the LOADING STATE without affecting any other functions of the INTERVENTIONAL X-RAY EQUIPMENT. The operation of this switch shall not, in itself, be capable of initiating the LOADING STATE.

The state of the IRRADIATION disabling switch shall be displayed at the working position of the OPERATOR. The switch should be configured to minimize the likelihood of accidental operation.

Compliance is determined by inspection and functional tests.

203.6.104 * Last-image-hold (LIH)

For RADIOSCOPY sequences that have not been stored, the INTERVENTIONAL X-RAY EQUIPMENT shall be equipped with means to store the LIH RADIOGRAM with other stored images.

NOTE 1 Storage of the LIH RADIOGRAM is subject to 201.12.4.101.2.

NOTE 2 This item is an addition compared to the first edition of IEC 60601-2-43:2000. The requirement for having a last-image-hold can be found in subclause 203.6.7.101 of IEC 60601-2-54.

Compliance is determined by inspection and functional tests.

203.6.105 Limitation of RADIATION output

In the case of SINGLE FAULT CONDITIONS, there shall be no unwanted IRRADIATIONS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests

NOTE This item is an addition compared to the first edition of IEC 60601-2-43:2000.

203.7 RADIATION QUALITY

Subclause 203.7 of IEC 60601-2-54:2009 applies.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Subclause 203.8.4 of IEC 60601-2-54:2009 applies.

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 * Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Subclause 203.8.5.3 of IEC 60601-2-54:2009 applies, except as follows:

Addition:

Regardless of the shape of the IMAGE RECEPTION AREA (circular and non-circular shape), when the X-RAY BEAM is perpendicular to the IMAGE RECEPTOR PLANE, the maximum area of the X-RAY FIELD shall conform to the following requirements:

- a) at least 80 % of the area of the X-RAY FIELD shall overlie the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION AREAS smaller than 10 cm in diameter or less than 10 cm in length on any side are exempted;

- b) the X-RAY FIELD measured from the centre of the IMAGE RECEPTION AREA in the direction of greatest misalignment with the IMAGE RECEPTION AREA shall not extend beyond the boundary of the effective IMAGE RECEPTION AREA by more than 2 cm.

The additional requirement is applicable for all magnification steps and for minimum and maximum positions of the source to image receptor distance and for horizontal and vertical positions of the GANTRY.

Compliance is checked by inspection and testing of the equipment by measurement of the X-RAY FIELDS. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, in order for the automatic mechanism to complete any adjustment occurring during the tests (see Annex AA).

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Subclause 203.8.5.4 of IEC 60601-2-54:2009 applies.

Additional subclauses:

203.8.101 Boundary and dimensions of the X-RAY FIELD

Subclause 203.8.101 of IEC 60601-2-54:2009 applies.

203.8.102 Methods of beam limitation in X-RAY EQUIPMENT

Subclause 203.8.102 of IEC 60601-2-54:2009 applies.

203.8.103 Interception of the X-RAY BEAM in RADIOLOGY

Subclause 203.8.103 of IEC 60601-2-54:2009 applies.

203.8.104 Positioning of the X-RAY BEAM AXIS

Subclause 203.8.104 of IEC 60601-2-54:2009 applies.

203.9 FOCAL SPOT TO SKIN DISTANCE

Subclause 203.9 of IEC 60601-2-54:2009 applies.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Subclause 203.10 of IEC 60601-2-54:2009 applies.

203.11 Protection against RESIDUAL RADIATION

Subclause 203.11 of IEC 60601-2-54:2009 applies.

203.12 Protection against LEAKAGE RADIATION

Subclause 203.12 of IEC 60601-2-54:2009 applies.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Subclause 203.13.2 of IEC 60601-2-54:2009 applies.