IEC 60601-2-43

Edition 2.0 2010-03

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

IEC 60601-2-43:2010

IEC Central Office
3, rue de Varembé
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 It also gives information on projects, withdrawn and replaced publications.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

IEC 60601-2-43

Edition 2.0 2010-03

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

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 standard[1)] 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 QUIPMENT 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.