INTERNATIONAL STANDARD

IEC 60601-2-43

First edition
2000-06

Medical electrical equipment –

Part 2-43:
Particular requirements for the safety of X-ray equipment for interventional procedures

Appareils électromédicaux –

Partie 2-43:
Règles particulières de sécurité pour les appareils radiologiques lors d'interventions

Reference number
IEC 60601-2-43:2000(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

INTERNATIONAL STANDARD

IEC 60601-2-43

First edition
2000-06

Medical electrical equipment –

Part 2-43:
Particular requirements for the safety of X-ray equipment for interventional procedures

Appareils électromédicaux –

Partie 2-43:
Règles particulières de sécurité pour les appareils radiologiques lors d'interventions

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE W

For price, see current catalogue

CONTENTS

Page

FOREWORD 4

INTRODUCTION 6

SECTION 1: GENERAL

Clause

1 Scope and object 7

1.1 Scope 7

1.2 Object 7

1.3 Particular standards 8

2 Terminology and definitions 8

6 Identification, marking and documents 9

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts 9

6.8.2 INSTRUCTIONS FOR USE 10

6.8.3 Technical description 12

6.8.101 Statement of compliance 13

SECTION 2: ENVIRONMENTAL CONDITIONS

10 Environmental conditions 13

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

21 Mechanical strength 13

22 Moving parts 14

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29 X-RADIATION 15

29.201.2 HALF-VALUE LAYERS in X-RAY EQUIPMENT 15

29.201.4 FILTRATION in X-RAY SOURCE ASSEMBLIES 16

29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA 16

29.208.3 Designated SIGNIFICANT ZONES OF OCCUPANCY 16

29.208.101 Isokerma maps 16

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures 17

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection 18

44.1 General 18

44.6 Ingress of fluids 18

44.6.101 Footswitches 18

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

51 Protection against hazardous output 18

51.101 Control features 19

51.102 Information to the OPERATOR 20

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

59 Construction and layout 22

59.101 Configuration for cardiopulmonary resuscitation (CPR) 22

59.102 Attachment of protective drapes 22

Annexes

L References - Publications mentioned in this standard 23

AA Terminology – Index of defined terms 24

BB Indications for the need to use EQUIPMENT complying with this standard 26

CC The INTERVENTIONAL REFERENCE POINT 28

DD Cleaning and disinfection 29

EE Procedure for measuring REFERENCE AIR KERMA (RATE) 30

FF Distribution maps of STRAY RADIATION 33

Figures

101 Example of isokerma map at 100 cm height 35

102 Example of isokerma map at 150 cm height 36

Tables

101 Subclauses containing normative references to the ACCOMPANYING DOCUMENTS 12

102 Addition to Table Xa in IEC 60601-1 17

BB.1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible 26

BB.2 Examples of RADIOSCOPICALLY guided procedures for which deterministic effects are unlikely 27

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

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

FDIS	Report of voting
62B/401/FDIS	62B/408/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.

Annexes AA, EE and FF form an integral part of this standard.

Annexes BB, CC and DD are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;

– *test specifications: italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC 60788 OR IN THIS STANDARD: SMALL CAPITALS.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

In recent years, there have been major developments in the use of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. These procedures may involve prolonged IRRADIATIONS and may subject PATIENTS and OPERATORS to higher levels of risk than those which normally prevail.

A consequence is the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas on the PATIENT. Another consequence is the large contribution to the stochastic risk for the RADIATION induced cancers etc. collectively to the PATIENT.

This Particular Standard deals with these additional risks and thereby complements the General Standard with special provisions for this particular domain. 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 safety of X-ray equipment for interventional procedures

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard applies to X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT.

NOTE 1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of EQUIPMENT complying with this standard is recommended, are given in annex BB.

NOTE 2 The particular requirements of this standard are not essential for EQUIPMENT used in all RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Examples of procedures, for which the use of EQUIPMENT complying with this standard is considered not to be essential, are given in annex BB.

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.

1.2 Object

Replacement:

The object of this standard is:

– to establish safety requirements for the design and manufacture of X-RAY EQUIPMENT for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES;
– to specify information which is to be provided with such EQUIPMENT for the assistance of the USER and OPERATOR in managing the RADIATION risk arising from these procedures which could affect PATIENTS and staff.

1.3 Particular standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety,* its amendments 1 (1991) and 2 (1995), and all Collateral Standards.

The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. 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 is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition before 2.1:

An index of defined terms used in this standard is given in annex AA.

In this standard, terms printed in small capitals are used in accordance with their definitions in the General Standard, in this standard, in IEC 60788 or in other IEC standards referenced in annex AA.

NOTE Attention is drawn to the fact that where some terms, although listed in annex AA, are not printed in small capitals, the concept addressed is not strictly confined to the formal definition.

In this standard, unless otherwise indicated:

– the values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;

– the values of X-RAY TUBE CURRENT refer to average values;

– qualifying conditions for certain defined terms, as listed in 2.202.1 to 2.202.5 of IEC 60601-1-3, apply.

Additional definitions:

2.101
RADIOSCOPICALLY GUIDED INVASIVE PROCEDURE
invasive procedure (involving the introduction of a device, such as a needle or a catheter into the body of the PATIENT) using RADIOSCOPIC imaging as the principal means of guidance

2.102
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
RADIOSCOPICALLY GUIDED INVASIVE PROCEDURE indented to effect treatment on the medical condition of the PATIENT

2.103
INTERVENTIONAL X-RAY EQUIPMENT
X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

2.104
INTERVENTIONAL REFERENCE POINT
for INTERVENTIONAL X-RAY EQUIPMENT, specified point on the REFERENCE AXIS used as a reference location for the indication of PATIENT-incident AIR KERMA and AIR KERMA RATE

2.105
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the Gray square metre ($Gy \cdot m^2$).

– DOSE AREA PRODUCT RATE, with the unit $Gy \cdot m^2 \cdot s^{-1}$;

– DOSE AREA PRODUCT (RATE), used for brevity where either DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE apply, according to the context.

NOTE The SI unit $Gy \cdot m^2$ may be expressed with a prefix e.g. as $\mu Gy \cdot m^2$ to retain earlier used numeric dimensions of values displayed to the OPERATOR.

2.106
REFERENCE AIR KERMA
AIR KERMA of the primary X-RAY BEAM measured under specific conditions and expressed as an equivalent value at the INTERVENTIONAL REFERENCE POINT

– REFERENCE AIR KERMA RATE, AIR KERMA RATE expressed as above

– REFERENCE AIR KERMA (RATE), used for brevity where either REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE apply, according to the context.

2.107
MODE OF OPERATION
for INTERVENTIONAL X-RAY EQUIPMENT, the technical state defined by a configuration of several predetermined LOADING FACTORS, technique factors or other settings for RADIOSCOPY or RADIOGRAPHY, selectable simultaneously by the operation of a single control

NOTE 1 Selection of a particular mode does not necessarily define the values of all the parameters affecting its use.

NOTE 2 Values defined by selection of a particular mode are not necessarily invariable during its use.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Additional items:

aa) *PATIENT SUPPORT load*

The PATIENT SUPPORT shall be marked with the maximum permissible mass (“load”) in kilograms for NORMAL USE, other than use for cardiopulmonary resuscitation.

bb) *Cardiopulmonary resuscitation (CPR)*

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

cc) *Marking of compliance*

If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be marked on the outside of the 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 60601-2-43:2000.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

Add the following sentence to the first dash (as created in amendment 2 of the General Standard):

The statement shall mention that the EQUIPMENT is intended for procedures in which skin dose levels can be high enough in NORMAL USE to constitute a risk of deterministic effects.

d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

Amendment:

Replace "or, where necessary, identify suitable sterilization agents," with "shall identify suitable agents for these purposes,".

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT the scope of this information shall include details concerning the cleaning and disinfection of all parts that, although not necessarily in direct contact with the PATIENT, can become soiled or contaminated, especially with body fluids, in NORMAL USE.

NOTE 1 It is advisable for MANUFACTURERS to ensure that the information given is sufficient 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 EQUIPMENT concerned.

NOTE 2 General information concerning the importance of cleaning and disinfection of INTERVENTIONAL X-RAY EQUIPMENT is given in annex DD.

Additional items:

aa) *Skin dose levels*

The instructions shall draw attention to the need to manage the risk of skin dose levels being high enough in NORMAL USE to cause deterministic effects and to the availability of several selectable settings in both RADIOSCOPY and RADIOGRAPHY having a considerable effect on the RADIATION QUALITY, the delivered AIR KERMA or AIR KERMA RATE and the image quality.

bb) *Available settings*

Information shall be provided as delivered from the MANUFACTURER concerning available configurations, MODES OF OPERATION, settings of LOADING FACTORS, technique factors and