

Medical electrical equipment —

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

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ICS 11.040.50

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The UK participation in its preparation was entrusted to Technical Committee CH/71, Diagnostic imaging equipment and accessories, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 39 and a back cover.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 April 2001

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ISBN 0 580 36434 8

Amendments issued since publication

Amd. No.	Date	Comments

Medical electrical equipment
Part 2-43: Particular requirements for the safety of X-ray equipment
for interventional procedures
(IEC 60601-2-43:2000)

Appareils électromédicaux
Partie 2-43: Règles particulières de
sécurité pour les appareils radiologiques
lors d'interventions
(CEI 60601-2-43:2000)

Medizinische elektrische Geräte
Teil 2-43: Besondere Festlegungen für
die Sicherheit von Röntgeneinrichtungen
für interventionelle Verfahren
(IEC 60601-2-43:2000)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62B/401/FDIS, future edition 1 of IEC 60601-2-43, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-43 on 2000-08-01.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2001-06-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-08-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annexes AA, EE, FF and ZA are normative and annexes BB, CC, DD and ZB are informative.

Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2000 was approved by CENELEC as a European Standard without any modification.

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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 ($\text{Gy}\cdot\text{m}^2$).

- DOSE AREA PRODUCT RATE, with the unit $\text{Gy}\cdot\text{m}^2\cdot\text{s}^{-1}$;
- 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 $\text{Gy}\cdot\text{m}^2$ may be expressed with a prefix e.g. as $\mu\text{Gy}\cdot\text{m}^2$ 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 operating parameters that affect the RADIATION QUALITY or the prevailing value of REFERENCE AIR KERMA (RATE) in NORMAL USE. This information shall include:

- 1) the values applying to the MODES OF OPERATION in RADIOSCOPY designated normal and low in accordance with 51.101.4;
- 2) details of all other MODES OF OPERATION, giving the default values and the available ranges of any factors that can be varied after the mode has been selected;
- 3) the values in RADIOSCOPY delivering the highest available REFERENCE AIR KERMA RATE;
- 4) the values in RADIOGRAPHY delivering the highest available REFERENCE AIR KERMA per frame;
- 5) one set of values typical of RADIOGRAPHY for distinctive types of procedure for which the EQUIPMENT is intended to be used.

NOTE This would, for example, include a typical vascular setting and a typical cardiac setting for EQUIPMENT intended to be used for both applications.

Compliance is determined by inspection, functional tests and measurements of REFERENCE AIR KERMA (RATE) as appropriate (see item cc) below).

cc) *RADIATION data*

For the MODES OF OPERATION and sets of values described in accordance with item bb) above, values of REFERENCE AIR KERMA (RATE) shall be given, based on measurement by the method described in annex EE.

In addition, for each of the available MODES OF OPERATION described in items bb) 1) and bb) 2), information shall be given, based on the use of the 20 cm PHANTOM, concerning the effect on the REFERENCE AIR KERMA(rate) of changing the following factors, if these factors are variable by the OPERATOR in the MODE OF OPERATION concerned:

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

Particulars shall be given of the configurations of the EQUIPMENT and the test geometries that can be used in the procedure described in annex EE to verify the values given.

Although it is required to provide details to enable verification by measurement in accordance with annex EE, 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 annex EE.

Compliance is determined by inspection, functional tests and examination of the INSTRUCTIONS FOR USE. The stated values of REFERENCE AIR KERMA (RATE) and statements concerning the variation of these values are verified by the method described in annex EE, using validated configurations and test geometries described in the INSTRUCTIONS FOR USE.

dd) *PROTECTIVE DEVICES and ACCESSORIES*

A list of PROTECTIVE DEVICES and ACCESSORIES for use when the EQUIPMENT is employed for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES shall be provided. 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 part of the EQUIPMENT.