BSI Standards Publication

Medical electrical equipment

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

bsi.

National foreword

This British Standard is the UK implementation of EN 60601-2-43:2010+A1:2018. It is identical to IEC 60601-2-43:2010, incorporating amendment 1:2018. It supersedes BS EN 60601-2-43:2010, which will be withdrawn on 18 May 2021.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment A1 is indicated by ⟨A1⟩ ⟨A1⟩.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2010.

Amendments/corrigenda issued since publication

Date	Text affected
31 October 2014	Implementation of CENELEC corrigendum July 2014: Supersession details amended
31 August 2018	Implementation of IEC amendment A1:2018 with CEN/CENELEC endorsement A1:2018

EUROPEAN STANDARD EN 60601-2-43:2010

NORME EUROPÉENNE

EUROPÄISCHE NORM

ICS 11.040.50; 37.040.25

English Version

Medical electrical equipment — Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010)

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)

Medizinische elektrische Geräte — Teil 2-43: Besondere Festlegungen für die Sicherheit und wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für interventionelle Verfahren (IEC 60601-2-43:2010)

This European Standard was approved by CENELEC on 20110-06-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-43:2010+A1:2018: E

European foreword

The text of document 62B/779/FDIS, future edition 2 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 approved by CENELEC as EN 60601-2-43:2010 on 2010-06-01.

This European Standard supersedes EN 60601-2-43:2000.

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 EN 60601-1:2006 and relevant collaterals. EN 60601-2-43:2010 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

The following dates are 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) 2011-03-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2013-06-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

[2]	IEC 60601-2-44	NOTE	Harmonized as EN 60601-2-44.
IEC 61000-2-4-14		NOTE	Harmonized as EN 61000-2-4-14:1999 (not modified).

Foreword to amendment A1

The text of document 62B/1012/CDV, future edition 2 of IEC 60601-2-43:2010+A1, 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 approved by CENELEC as EN 60601-2-43:2010+A1:2018.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2018-11-18
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-05-18

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010+A1:2017 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

***Annex ZA** of EN 60601-2-43:2010 applies, except as follows:*

Publication	Year	Title	EN/HD	Year
Amendment:				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
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	EN 60601-1-3	2008
IEC 60601-1-3:2008/AMD1	2013		EN 60601-1-3:20008+A1:20132013	
Addition:				
IEC 60580	-	Medical electrical equipment - Dose area product meters	EN 60580	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1:2005/AMD1	2012		EN 60601-1	2013
IEC 60601-2-54	2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of Xray equipment for radiography and radioscopy	EN 60601-2-54	2009

Publication	Year	Title	EN/HD	Year
IEC 60601-2-54:2009/AMD1	2015		EN 60601-2-54:2009/AMD1	2015
IEC 61910-1	2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy	EN 61910-1	2014
IEC 62220-1-1	2015	Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging	EN 62220-1	2015
IEC/TR 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	EN 62220-1	2004
IEC 60601-1-3:2008/AMD1	2013	requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3:2008/A1:2013	2013

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

Contents

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.

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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 constitutes a technical revision.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on the third edition of IEC 60601-1 and relevant collaterals. The present edition is extended to become a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES may subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT may be the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

Interventional procedures of the type envisaged are well established in clinical fields such as:

— invasive cardiology;

— interventional RADIOLOGY;

— interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

Medical electrical equipment —

Part 2: 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.

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1) The general standard is IEC 60601-1:2005 ⟦A1⟧ and IEC 60601-1:2005+A1:2012 ⟨A1⟩, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2) Figures in square brackets refer to the Bibliography.