BRITISH STANDARD

BS EN
60601-1-3:2008



*corrigenda*
*March 2010 and*
*May 2014*

# Medical electrical equipment —

## Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)

ICS 11.040.50; 13.280



BSI
British Standards

This British Standard is the UK implementation of EN 60601-1-3:2008+A11:2016, incorporating corrigenda March 2010 and May 2014. It is identical to IEC 60601-1-3:2008, incorporating amendment 1:2013. It supersedes BS EN 60601-1-3:2008+A1:2013, which will be withdrawn on 1 November 2019.

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 1 is indicated by [A1] ⟨A1⟩.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee 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.

**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 30 September 2008



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| Date | Comments |
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| 31 July 2010 | Implementation of CENELEC corrigendum March 2010. Date of withdrawal added to Foreword |
| 31 July 2013 | Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013. Annex ZA updated |
| 30 June 2014 | Implementation of CENELEC corrigendum May 2014: Date of withdrawal updated in the Foreword and Foreword to amendment A1 |
| 31 December 2016 | Implementation of CENELEC amendment A11:2016: Annexes ZA and ZZ updated |

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ICS 11.040.50; 13.280

Incorporating corrigenda March 2010 and May 2014

English version

# Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

(IEC 60601-1-3:2008)

Appareils électromédicaux - Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic
(CEI 60601-1-3:2008)

Medizinische elektrische Geräte - Teil 1-3: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Strahlenschutz von diagnostischen Röntgengeräten
(IEC 60601-1-3:2008)

This European Standard was approved by CENELEC on 2008-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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**



Ref. No. EN 60601-1-3:2008 E

## Foreword

The text of document 62B/673/FDIS, future edition 2 of IEC 60601-1-3, 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 60601-1-3 on 2008-03-01.

The following date was 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) | 2008-12-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2018-12-31 |

This European Standard supersedes EN 60601-1-3:1994.

This EN 60601-1-3 has been restructured and aligned to EN 60601-1:2006 and focussed on general requirements for RADIATION PROTECTION that apply to all diagnostic X-RAY EQUIPMENT. Requirements particular to specific equipment have been removed and will be covered in particular standards. For a description of the changes, see the mapping in Annex C.

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.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. RADIOLOGICAL equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in 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 COLLATERAL STANDARD OR AS NOTED: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the thirteen 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 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.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

Annexes ZA and ZZ have been added by CENELEC.

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## Endorsement notice

The text of the International Standard IEC 60601-1-3:2008 was approved by CENELEC as a European Standard without any modification.

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# Foreword to amendment A1

The text of document 62B/895/CDV, future amendment 1 to edition 2 of IEC 60601-1-3, 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 60601-1-3:2008/A1:2013.

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) | 2014-02-24 |
| • latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2018-12-31 |

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

## Endorsement notice

The text of the International Standard IEC 60601-1-3:2008/A1:2013 was approved by CENELEC as a European Standard without any modification.

## Foreword to amendment A11

This document (EN 60601-1-3:2008/A11:2016) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

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) 2017-11-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-11-01

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

# 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. However, for any use of this standard “within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| IEC 60336 | | Medical electrical equipment - X-ray tube assemblies for medical use - Characteristics of focal spots | EN 60336 | 2005 |
| IEC 60522 | 1999 | Determination of the permanent filtration of X-ray tube assemblies | EN 60522 | 1999 |
| IEC 60601-1 | 2005 | Medical electrical equipment Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| A1 | 2012 | | EN 60601-1/A1 | 2013 |
| | | | EN 60601-1/A12 | 2014 |
| IEC 60788 | 2004 | Medical electrical equipment - Glossary of defined terms | | |
| ISO 497 | | Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers | | |

(informative)

## Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

**General Guidance:**

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

**WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.**

**amended by 2007/47/EC, and Clauses and subclauses of this standard**

| No. | Essential Requirements | Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016 |
|---|---|---|
| **I.** | **GENERAL REQUIREMENTS** | |
| **1.** | General Guidance notes 1 to 6 shall be observed | |
| 1 | The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.<br>This shall include: | If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to general [1)] X-ray radiation-related aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to Clauses 4 to 13 of this collateral standard). |
| | - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and | Covered in respect of aspects contained in Clauses 5 and 6. |
| | - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | Covered in respect of aspects contained in 5.2.4 |
| **2.** | General Guidance notes 1, 2, 3, 4, 5, 6 shall be observed | |
| 2 | The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.<br><br>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: | 1st paragraph covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account.<br>2nd paragraph, including the following 3 bullets, are covered for radiation protection in x-ray equipment and in subassemblies of such equipment, where radiological images of a human patient are used for diagnosis, planning or guidance of medical procedures, .in respect to aspects contained in the Clauses 5 to 13, under the condition that the manufacturer implements<br>- EN ISO 14971 (2012) including its Annex ZA. |

1) This standard is intended to provide a set of general specifications to be complemented by existing particular/device specific standards, or by other means, such as risk management.

| | | |
|---|---|---|
| | | A1:2014 + A11:2016 |
| | - eliminate or reduce risks as far as possible (inherently safe design and construction), | |
| | - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, | |
| | - inform users of the residual risks due to any shortcomings of the protection measures adopted. | |
| 3 | The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. | Covered in respect of aspects contained in 6.7 |
| 4 | The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. | Not covered. |
| 11 | **Protection against radiation** | |
| General Guidance notes 1, 2, 3, 4, 5, 6 shall be observed | | |
| 11.1 | General | |
| 11.1.1 | Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. | Covered for X-ray equipment in respect to aspects contained in Clauses 5 to 13. |
| 11.2 | Intended radiation | |
| 11.2.1 | Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. | Covered for X-ray equipment with respect to aspects contained in Clause 6 |
| 11.2.2 | Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions. | Covered for X-ray equipment<br>with respect to aspects contained in 6.4 |

| | | |
|---|---|---|
| | | A1:2014 + A11:2016 |
| 11.3 | Unintended radiation | |
| 11.3.1 | Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. | Covered for X-ray equipment with respect to aspects contained in Clauses 5 to 13 |
| 11.4 | Instructions | |
| 11.4.1 | The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. | Covered in respect to aspects contained in 5.2.4 |
| 11.5 | Ionizing radiation | |
| 11.5.1 | Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use. | Covered for X-ray equipment with respect to aspects contained in Clauses 6 to 8 |
| 11.5.2 | Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. | Covered for X-ray equipment with respect to aspects contained in 6.7 |
| 11.5.3 | Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation. | Not covered. |
| 13 | **Information supplied by the manufacturer** | |
| 13.5 | Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. | Covered in respect to accessories, components and subassemblies of X-ray equipment in respect to Clause 5 |

CONTENTS

# INTRODUCTION

The requirements in this collateral Standard concern protective measures to be taken by the MANUFACTURER in the design and construction of medical diagnostic X-RAY EQUIPMENT and its subassemblies. They relate to the application of the X-RADIATION generated, both deliberately and incidentally, in fulfilling the medical purpose of the EQUIPMENT. Additional measures are necessary to regulate the generation processes themselves. These are described in the general requirements for safety, IEC 60601-1, and, where appropriate, in particular requirements for the EQUIPMENT concerned. The second edition of this collateral standard is focused on general requirements for RADIATION PROTECTION. The aim of the revision was to restrict to those requirements that apply to all diagnostic X-RAY EQUIPMENT. In consequence, most of the clauses have been reduced compared with the first edition of this standard, owing to the exclusion of content specific to projection RADIOGRAPHY and RADIOSCOPY. Implementation shall be considered in the RISK MANAGEMENT process or by using particular standards.

The recommended principles governing the use of RADIATION for medical purposes, as stated in Publication 60 of the International Commission on Radiological Protection (ICRP)[17][1)], Chapter 4, have been taken into account. The implementation of these principles is essentially determined in the prevailing circumstances at the point of use. It requires judgements to be made by the user and the establishment of measures and working practices part of which are connected with the construction of EQUIPMENT. The requirements in this collateral Standard are intended to be consistent with generally accepted good practice in the administration of X-RADIATION in medicine.

In some cases, the formulation of the requirements is deliberately designed to provide scope for accommodating local laws and regulations at the time of installation and commissioning. Several of the requirements include provisions for relevant technical information to be included in ACCOMPANYING DOCUMENTS.

RESPONSIBLE ORGANIZATIONS for medical diagnostic X-RAY EQUIPMENT should be aware that effective protection against IONIZING RADIATION requires the consideration of many aspects additional to the construction of the EQUIPMENT. Among these are the following:

- compatibility of components and correct installation of EQUIPMENT;
- the protective properties of rooms where X-RAY EQUIPMENT is installed;
- measures for monitoring and maintaining the safety and effectiveness of EQUIPMENT throughout its life, with particular attention to components that can deteriorate progressively with time and use;
- the need in appropriate circumstances for PROTECTIVE CLOTHING to be worn by staff and for suitable devices to be used to protect PATIENTS;
- the keeping of appropriate records concerning the usage of the EQUIPMENT and the results of tests, with systematic review and the application of corrective action when necessary;
- the training of staff in the principles of RADIATION PROTECTION and in the correct use of EQUIPMENT, including any PROTECTIVE DEVICES provided.

Further advice on these aspects can be found in ICRP Publications 33[15], 34[16], 60[17], 73[18], 85[21], 87[22] and 93[23].

Readers of this collateral standard are reminded that, in accordance with IEC 60601-1, Clause 5, all the test procedures described are TYPE TESTS, intended to be carried out in a dedicated testing environment in order to determine compliance. Tests to be carried out by MANUFACTURERS to ensure compliance during production or installation and tests for detecting non-compliance subsequently to delivery, are not included.

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1) Figures in square brackets refer to the Bibliography.

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

## 1 Scope, object and related standards

### 1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to X-RAY EQUIPMENT and to subassemblies of such equipment, where RADIOLOGICAL IMAGES of a human PATIENT are used for diagnosis, planning or guidance of medical procedures.

### 1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

The object of this collateral standard is to establish general requirements for protection against X-RADIATION in X-RAY EQUIPMENT, in order that the IRRADIATION of the human PATIENT, the OPERATOR, staff and members of the public can be kept as low as reasonably achievable, without jeopardizing the benefit of the RADIOLOGICAL procedure. Particular standards may specify their appropriate values and/or measures for general requirements specified in this collateral standard. The implementation of the general requirements or the reference to the particular standard instead, shall be justified in the RISK MANAGEMENT process.

This collateral standard considers RADIATION PROTECTION aspects related to X-RADIATION only.

Requirements for the control of the electrical energy used to generate X-RADIATION, which is also an important aspect of RADIATION PROTECTION, are included in IEC 60601-1 and in particular standards for the safety and ESSENTIAL PERFORMANCE of the EQUIPMENT concerned.

### 1.3 Related standards

#### 1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- ⟦A1⟩ “the general standard” designates IEC 60601-1:2005+A1:2012; ⟨A1⟧
- ⟦A1⟩ “this collateral standard” designates IEC 60601-1-3:2008+A1:2013; ⟨A1⟧
- "this standard" designates the combination of the general standard and this collateral standard.

#### 1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.