BSI Standards Publication

# Medical electrical equipment

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

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# National foreword

This British Standard is the UK implementation of EN 60601-1-3:2008+A2:2021, incorporating corrigenda March 2010 and May 2014. It is derived from IEC 60601-1-3:2008, incorporating amendments 1:2013 and 2:2021. It supersedes BS EN 60601-1-3:2008+A11:2016, which is withdrawn.

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 to Technical Committee CH/62/2, Diagnostic imaging equipment.

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

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

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association and is intended to support essential requirements of the EU legislation detailed in the European foreword. Annex ZA/ZZ describes how the publication relates to the legislation.

For the Great Britain market (England, Scotland and Wales), if the UK Government has designated this publication for conformity with UKCA marking legislation and has not amended the essential requirements of that legislation, Annex ZA/ZZ and any references to EU law in the publication should be read in accordance with the designation as applying to UK legislation in the same way as to EU law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. References to EU legislation are therefore still valid.

More information on legislation can be found at www.gov.uk.


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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 30 September 2008.

| Date | Text affected |
|---|---|
| 31 July 2010 | Implementation of CENELEC corrigendum March 2010: date of withdrawal added to European foreword |
| 31 July 2013 | Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013 and Annex ZA updated |
| 30 June 2014 | Implementation of CENELEC corrigendum May 2014: date of withdrawal updated in the European foreword and foreword to amendment A1 |
| 31 December 2016 | Implementation of CENELEC amendment A11:2016: Annexes ZA and ZZ replaced |
| 31 March 2021 | Implementation of IEC amendment 2:2021 with CENELEC endorsement A2:2021 and Annex ZA updated |

EUROPEAN STANDARD EN 60601-1-3:2008



# EUROPÄISCHE NORM

March 2021

ICS 11.040.50; 13.280

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 (IEC 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.


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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**



Ref. No. EN 60601-1-3:2008/A2:2021 E

## European 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 |
| | (dow) | 2008-12-31 |

This European Standard supersedes EN 60601-1-3:1994. However, EN 60601-1-3:1994 remains valid until all the Parts 2 that are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting national standards (dow) has therefore been fixed. However, when Part 1-3 is used for appliances not covered by a Part 2, EN 60601-1-3:1994 is not to be used after 2009-09-12.

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.

## Endorsement notice

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

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

| | | |
|---|---|---|
| IEC 60601-2-7 | NOTE | Harmonized as EN 60601-2-7:1998 (not modified). |
| IEC 60601-2-28 | NOTE | Harmonized as EN 60601-2-28:1993 (not modified). |
| IEC 60601-2-29 | NOTE | Harmonized as EN 60601-2-29:1999 (not modified). |
| IEC 60601-2-32 | NOTE | Harmonized as EN 60601-2-32:1994 (not modified). |
| IEC 60601-2-43 | NOTE | Harmonized as EN 60601-2-43:2000 (not modified). |
| IEC 60601-2-44 | NOTE | Harmonized as EN 60601-2-44:2001 (not modified). |
| IEC 60601-2-45 | NOTE | Harmonized as EN 60601-2-45:2001 (not modified). |
| IEC 60580 | NOTE | Harmonized as EN 60580:2000 (not modified). |
| IEC 60627 | NOTE | Harmonized as EN 60627:2001 (not modified). |
| IEC 61262 | NOTE | Harmonized in EN 61262 series (not modified). |
| IEC 62220 | NOTE | Harmonized in EN 62220 series (not modified). |
| IEC 62220-1 | NOTE | Harmonized as EN 62220-1:2003 (not modified). |

## 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.

## Foreword to amendment A2

The text of document 62B/1176/CDV, future IEC 60601-1-3/A2, 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/A2:2021.

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) 2021–12–02
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024–03–02

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC 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.

### Endorsement notice

The text of the International Standard IEC 60601-1-3:2008/A2:2021 was approved by CENELEC as a European Standard without any modification.

(normative)

# Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.

| 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 |
| - | - | | + corrigendum Mar. | 2010 |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + A12 | 2014 |
| + A2 | 2020 | | - | - |
| 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 | | |