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Incorporating corrigendum April 2010

BSI Standards Publication

Medical electrical equipment

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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This British Standard is the UK implementation of EN 60601-2-54:2009+A1:2015. It is identical to IEC 60601-2-54:2009, incorporating amendment 1:2015. It supersedes BS EN 60601-2-54:2009 which will be withdrawn on 22 May 2018.

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.

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

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Amendments/corrigenda issued since publication

Date	Text affected
30 April 2010	Supersession details amended
31 July 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015. Annex ZA amended

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

ICS 11.040.50

English version

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

(IEC 60601-2-54:2009+A1:2015)

Appareils électromédicaux -
Partie 2-54: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils à rayonnement X utilisés
pour la radiographie et la radioscopie
(CEI 60601-2-54:2009)

Medizinische elektrische Geräte -
Teil 2-54: Besondere Festlegungen
für die Sicherheit und die wesentlichen
Leistungsmerkmale
von Röntgeneinrichtungen
für Radiographie und Radioskopie
(IEC 60601-2-54:2009)

This European Standard was approved by CENELEC on 2009-08-01. 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: Avenue Marnix 17, B - 1000 Brussels

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Ref. No. EN 60601-2-54:2009 E

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Foreword

The text of document 62B/735/FDIS, future edition 1 of IEC 60601-2-54, 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 60601-2-54 on 2009-08-01.

EN 60601-2-54 was developed for use with EN 60601-1:2006.

This European Standard supersedes EN 60601-2-7:1998, EN 60601-2-32:1994 and EN 60601-2-28:1993 (partially).

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)	2010-05-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-08-01

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 MDD (93/42/EEC). See Annex ZZ.

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.

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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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009 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:

[1] IEC 60627	NOTE	Harmonized as EN 60627:2001 (not modified).
[2] IEC 61267	NOTE	Harmonized as EN 61267:2006 (not modified).
[3] ISO 4090	NOTE	Harmonized as EN ISO 4090:2004 (not modified).
[10] IEC 60601-2-7	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
[11] IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
[12] IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
[13] IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8:2007 (not modified).
[14] IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10:2008 (not modified).
[15] IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43:2000 (not modified).

Foreword to amendment A1

The text of document 62B/929/CDV, future IEC 60601-2-54:2009/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 60601-2-54:2009/A1:2015.

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) 2016-02-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-05-22

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 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-54:2009.

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Endorsement notice

The text of the International Standard IEC 60601-2-54:2009/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-54:2009, **replace** notes [1] and [15] by the following notes:

[1]	IEC 60627	NOTE	Harmonized as EN 60627.
[15]	IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43.

In the Bibliography of EN 60601-2-54:2009, the following notes have to be **added** for the standards indicated:

[16]	IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
[17]	IEC 60601-1-12	NOTE	Harmonized as EN 60601-1-12.