SLOVENSKI STANDARD
SIST EN IEC 60601-2-54:2024

01-november-2024

Medicinska električna oprema - 2-54. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za radiografijo in radioskopijo (IEC 60601-2-54:2022)

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2022)

Medizinische elektrische Geräte - Teil 2-54: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für Radiographie und Radioskopie (IEC 60601-2-54:2022)

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 (IEC 60601-2-54:2022)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-54:2024**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN IEC 60601-2-54:2024 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-54

September 2024

ICS 11.040.50

Supersedes EN 60601-2-54:2009; EN 60601-2-54:2009/A1:2015; EN 60601-2-54:2009/A2:2019

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 60601-2-54:2022)

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
(IEC 60601-2-54:2022)

Medizinische elektrische Geräte - Teil 2-54: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für Radiographie und Radioskopie
(IEC 60601-2-54:2022)

This European Standard was approved by CENELEC on 2024-07-31. 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 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye 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 IEC 60601-2-54:2024 E

European foreword

The text of document 62B/1285/FDIS, future edition 2 of IEC 60601-2-54, prepared by SC 62B "Medical imaging equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-54:2024.

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) 2025-05-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-07-31

This document supersedes EN 60601-2-54:2009 and all of its amendments and corrigenda (if any).

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2022 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 standard indicated:

IEC 60627	NOTE	Approved as EN 60627
IEC 61267:2005	NOTE	Approved as EN 61267:2006 (not modified)
ISO 4090:2001	NOTE	Approved as EN ISO 4090:2004 (not modified)
IEC 60601-2-28:2017	NOTE	Approved as EN IEC 60601-2-28:2019 (not modified)
IEC 60601-1-8	NOTE	Approved as EN 60601-1-8
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 60601-1-11:2015/A1:2020	NOTE	Approved as EN 60601-1-11:2015/A1:2021 (not modified)
IEC 60601-1-12:2014	NOTE	Approved as EN 60601-1-12:2015 (not modified)
IEC 60601-1-12:2014/A1:2020	NOTE	Approved as EN 60601-1-12:2015/A1:2020 (not modified)
IEC 60601-2-43:2010	NOTE	Approved as EN 60601-2-43:2010 (not modified)
IEC 60601-2-43:2010/A1:2017	NOTE	Approved as EN 60601-2-43:2010/A1:2018 (not modified)
IEC 60601-2-43:2010/A2:2019	NOTE	Approved as EN 60601-2-43:2010/A2:2020 (not modified)

IEC 62563-1:2009	NOTE	Approved as EN 62563-1:2010 (not modified)
IEC 62563-1:2009/A1:2016	NOTE	Approved as EN 62563-1:2010/A1:2016 (not modified)
IEC 62563-1:2009/AMD2:2021	NOTE	Approved as EN 62563-1:2010/A2:2021 (not modified)
IEC 60601-1-9	NOTE	Approved as EN 60601-1-9
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
IEC 62220-1-1:2015	NOTE	Approved as EN 62220-1-1:2015 (not modified)

Annex ZA
(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.cencenelec.eu.

Annex ZA of EN 60601-1:2006[1]*, applies, except as follows:*

Add:

Publication	Year	Title	EN/HD	Year
IEC 60336	2020	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	EN IEC 60336	2021
IEC 60580	2019	Medical electrical equipment - Dose area product meters	EN IEC 60580	2020
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60806	-	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis	EN IEC 60806	-

[1] As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

Publication	Year	Title	EN/HD	Year
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 62494-1	2008	Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography	EN 62494-1	2008

Replace:

Publication	Year	Title	EN/HD	Year
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
-	-		+ AC	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021

IEC 60601-2-54

Edition 2.0 2022-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

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.
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IEC 60601-2-54 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This second edition cancels and replaces the first edition published in 2009, Amendment 1:2015 and Amendment 2:2018. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the IEC 60601-1:2005/AMD2:2020. It also contains corrections and technical improvements. Significant technical changes with respect to the previous edition are as follows:

a) a new specific term DOSIMETER is introduced to replace the general term DOSEMETER;
b) terms and definitions taken exclusively from IEC TR 60788:2004 and which are specifically applicable in this document have been moved to 201.3;
c) the collateral standards IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are applicable if MANUFACTURER so declares;

d) the subclause 201.11.101 “Protection against excessive temperatures of X-ray tube assemblies” has been removed from this document as its requirements are sufficiently and clearly covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017;

e) to adopt changes which are introduced with respect to indicator lights in 7.8.1 of the IEC 60601-1:2005/AMD2:2020 clarification of requirements is provided to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT;

f) explanation of the term ESSENTIAL PERFORMANCE is provided in Annex AA to emphasize the performance of the clinical function under NORMAL and SINGLE FAULT CONDITIONS.

The text of this document is based on the following documents:

Draft	Report on voting
62B/1285/FDIS	62B/1293/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– “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 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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