ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA November 2019

STN	**Zdravotnícke elektrické prístroje Časť 2-54: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti röntgenových prístrojov na skiagrafiu a skiaskopiu Zmena A2**	**STN EN 60601-2-54/A2** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/19

STN EN 60601-2-54 z augusta 2010 sa bez zmeny A2 môže používať do 24. 5. 2022.

Obsahuje: EN 60601-2-54:2009/A2:2019, IEC 60601-2-54:2009/AMD2:2018

129699

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-54:2009/A2

May 2019

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/A2:2018)

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 60601-2-54:2009/A2:2018)

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/A2:2018)

This amendment A2 modifies the European Standard EN 60601-2-54:2009; it was approved by CENELEC on 2018-08-03. 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 amendment 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.

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 60601-2-54:2009/A2:2019 E

EN 60601-2-54:2009/A2:2019 (E)

European foreword

The text of document 62B/1089/FDIS, future IEC 60601-2-54/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 60601-2-54:2009/A2:2019.

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) 2019-11-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-05-24

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.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009/A2:2018 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 62220-1-3:2008	NOTE Harmonized as EN 62220-1-3:2008 (not modified)
IEC 62563-1:2009	NOTE Harmonized as EN 62563-1:2010 (not modified)
IEC 60601-1-9	NOTE Harmonized as EN 60601-1-9

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.cenelec.eu.

Annex ZA of EN 60601-2-54:2009 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replacement				
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 62220-1-1	2015
Addition				
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

IEC 60601-2-54

Edition 1.0 2018-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

IEC 60601-2-54:2009-06/AMD2:2018-06(en-fr)

IEC 60601-2-54

Edition 1.0 2018-06

INTERNATIONAL STANDARD

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1089/FDIS	62B/1097/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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.

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INTRODUCTION TO AMENDMENT 2

The purpose of this second amendment to IEC 60601-2-54:2009 is to introduce changes which take the current state of the art into account. Therefore, X-RAY EQUIPMENT specified for DIRECT RADIOSCOPY is no longer in the scope of this document. The normative references were also updated in this amendment, and editorial clarifications and new terms and definitions were added. Provisions for QUALITY CONTROL PROCEDURES to be recommended by the MANUFACTURER are emphasized. Specific attention is paid to EXAMINATION PROTOCOLS in a new subclause which differentiate between adult and paediatric applications, in particular for X-RAY EQUIPMENT without an AUTOMATIC CONTROL SYSTEM. In addition, fixed periods for termination of LOADING after release of the RADIATION control by the OPERATOR are stipulated for RADIOSCOPY.

A new subclause on electronic documentation of EXAMINATION PROTOCOLS is introduced. It recommends providing access to electronic documentation containing relevant parameters of the PRE-PROGRAMMED EXAMINATION PROTOCOL. In another new subclause, the creation of basic documentation of the RADIATION DOSE STRUCTURED REPORT (RDSR) according to IEC 61910-1 is recommended. Furthermore, the subclause describing the LAST IMAGE HOLD RADIOGRAM has been revised and requires that the last image in RADIOSCOPY be displayed rather than provide just a means to display it.

This amendment recommends providing a graphical DISPLAY of the position of the BEAM LIMITING DEVICE blades on the IMAGE DISPLAY DEVICE in the subclause "Indication on the X-RAY EQUIPMENT".

Finally, the requirement for providing means to limit the FOCAL SPOT TO SKIN DISTANCES for radioscopic X-RAY EQUIPMENT differentiates between MOBILE and FIXED EQUIPMENT and extends, in the latter case, the minimum distance in possible clinical applications.

201.1.1 Scope

Replace, in the first paragraph, the first existing sentence by the following new sentence:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY.

Replace the second existing paragraph by the following new paragraph:

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography, dental or radiotherapy applications are excluded from the scope of this International Standard.

Delete the note.

201.1.3 Collateral standards

Replace the second paragraph, modified by IEC 60601-2-54:2009/AMD1:2015, by the following new paragraph:

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.2 Normative references

Replace the existing reference to IEC 62220-1:2003 by the following new reference:

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*

Add, to the existing list, the following new references:

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*