SLOVENSKI STANDARD
SIST EN 60601-2-54:2009/A2:2019

01-julij-2019

Medicinska električna oprema - 2-54. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za radiografijo in radioskopijo - Dopolnilo A2 (IEC 60601-2-54:2009/A2:2018)

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)

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)

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)

Ta slovenski standard je istoveten z: **EN 60601-2-54:2009/A2:2019**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-54:2009/A2:2019 **en**

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)

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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

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

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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

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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.

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*

201.3 Terms and definitions

Add, after the existing definition 201.3.209, the following new terms and definitions:

201.3.210
EXAMINATION PROTOCOL
full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and DISPLAY

201.3.211
EXAMINATION PROTOCOL SELECTION CONTROL
control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.212
LAST-IMAGE HOLD RADIOGRAM
LIH RADIOGRAM
single image obtained by sampling or temporal processing of one or more images from the end of a radioscopic IRRADIATION

Note 1 to entry: This note applies to the French language only.

201.3.213
PRE-PROGRAMMED EXAMINATION PROTOCOL
single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.214
RADIOSCOPY REPLAY IMAGE SEQUENCE
series of the most recent images of the most recent RADIOSCOPY IRRADIATION-EVENT

201.7.9.1 General

*Replace the first paragraph after "*Addition:*" by the following new paragraph and note:*

The ACCOMPANYING DOCUMENTS shall contain instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria for each test and frequency for each test.

NOTE The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

Replace the first dash in the second paragraph by the following new dash:

– an identification of adjustable or selectable image processing settings applied to ORIGINAL DATA including the version number or how to determine it;

Add, before the compliance statement at the end of this subclause, the following new paragraph:

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

Replace, at the end of the item a), the colon by a semicolon.

201.9.8 HAZARDS associated with support systems

Replace the existing title of this subclause by the following new title:

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.3 Dynamic forces due to loading from persons

*Replace the paragraph starting with "*Where mechanical analysis…*" by the following new paragraph:*

Where mechanical analysis proves that the following alternate static load test is more severe than the dynamic load test specified in the general standard, it is possible to waive the dynamic load test based on RISK MANAGEMENT. If the dynamic load test is passed, the static test may not be necessary.

201.10 Protection against unwanted and excessive radiation HAZARDS

Replace the existing text of this clause by the following new text:

Clause 10 of the general standard applies, except Subclause 10.3 (Microwave radiation), which does not apply.

201.11 Protection against excessive temperatures and other HAZARDS

Add, before the instruction "Additional subclauses", the following new subclauses:

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

NOTE Restrictions on allowable maximum temperature in Table 22 of the general standard for parts in contact with oil shall not apply to parts wholly immersed in oil.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Replacement of the first paragraph modified by IEC 60601-1:2005/AMD1:2012:

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace the existing text of this clause by the following new text:

Clause 12 of the general standard applies, except as follows:

Addition:

NOTE According to subclause 12.4.5 of the general standard, the dose related aspects of this question are addressed under 203.6.4.3 of this document.

201.16 ME SYSTEMS

Replace the existing text of this clause by the following new text:

Clause 16 of the general standard applies, except as follows:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Replacement of the first paragraph modified by IEC 60601-1:2005/AMD1:2012:

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in the loss of BASIC SAFETY and that restoration of the power shall not result in the loss of ESSENTIAL PERFORMANCE.