ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA September 2024

STN	**Hodnotenie a prevádzkové skúšky pri spracovaní lekárskych obrazových informácií Časť 3-8: Preberacie skúšky a skúšky stálosti Zobrazovacie vlastnosti röntgenových prístrojov na rádiografiu a rádoskopiu**	**STN EN IEC 61223-3-8** 85 4012

Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging 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. 08/24

Obsahuje: EN IEC 61223-3-8:2024, IEC 61223-3-8:2024

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English Version

Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy (IEC 61223-3-8:2024)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-8: Essais d'acceptation et de constance - Performance d'imagerie des appareils à rayonnement X pour la radiographie et la radioscopie (IEC 61223-3-8:2024)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-8: Abnahme- und Konstanzprüfungen - Leistungsmerkmale zur Bildgebung von Röntgeneinrichtungen für Radiographie und Radioskopie (IEC 61223-3-8:2024)

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

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European foreword

The text of document 62B/1347/FDIS, future edition 1 of IEC 61223-3-8, 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 IEC 61223-3-8:2024.

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) 2025-01-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-04-30

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 61223-3-8:2024 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 60627:2013	NOTE	Approved as EN 60627:2015 (not modified)
IEC 61223-3-6:2020	NOTE	Approved as EN IEC 61223-3-6:2020 (not modified)
IEC 62220-1-1:2015	NOTE	Approved as EN 62220-1-1:2015 (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 62563-2:2021	NOTE	Approved as EN IEC 62563-2:2021 (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.

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 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		+ A2	2021
-	-		+ A13	2024
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
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
IEC 60601-2-43	2022	Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	EN IEC 60601-2-43	2023
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	-	-

EN IEC 61223-3-8:2024 (E)

IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 61674	2012	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	EN 61674	2013
IEC 61676	2023	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN IEC 61676	2023
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 61223-3-8

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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IEC 61223-3-8:2024-03(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-8: Acceptance and constancy tests – Imaging 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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 61223-3-8 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

Draft	Report on voting
62B/1347/FDIS	62B/1351/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/publications.

In this document, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type.
– explanations, advice, notes, general statements, exceptions and references: in smaller type.
– *test specifications: in italic type.*
– TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: IN SMALL CAPITALS.

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 A.

A list of all parts of the IEC 61223 series, published under the general title *Evaluation and routine testing in medical imaging departments,* 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, or
- revised.

NOTE The attention of the users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations might need a transitional period following publication of a new, amended or revised IEC publication in order to develop contractual specifications in accordance with the new test procedures and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The IEC 61223 series gives methods for ACCEPTANCE TESTS and CONSTANCY TESTS for diagnostic X-RAY EQUIPMENT.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 state that the MANUFACTURER provides ACCOMPANYING DOCUMENTS with instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. In this document, these instructions are referred to as a QUALITY CONTROL manual.

This part of IEC 61223 provides guidance on the content to be considered for inclusion in the QUALITY CONTROL manual for X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY, including INTERVENTIONAL X-RAY EQUIPMENT. The QUALITY CONTROL manual is intended to be used independently by the RESPONSIBLE ORGANIZATION to ensure safe and effective equipment performance during its EXPECTED SERVICE LIFE, without the need to consult IEC standards.

This document provides parameters to be evaluated, examples of test methods, recommended minimum frequencies of evaluation and tools intended to be used by the RESPONSIBLE ORGANIZATION on installed X-RAY EQUIPMENT within the scope of this document. For the parameters applicable to the specific X-RAY EQUIPMENT to be tested, specific acceptance criteria are supplied by MANUFACTURERS, which can be superseded with contractual criteria with the RESPONSIBLE ORGANIZATION and further superseded with locally applicable regulatory criteria.

A major purpose of this document is that of facilitating technical communication between stakeholders in the areas of ACCEPTANCE and CONSTANCY TESTING. The three major stakeholders responsible for assuring the safety and efficacy of X-RAY EQUIPMENT are the MANUFACTURER, the RESPONSIBLE ORGANIZATION and the regulatory authorities.

Generally, equipment installed in accordance with the MANUFACTURER'S QUALITY CONTROL PROCESS will comply with applicable IEC standards as well as meeting both local regulatory requirements and the MANUFACTURER'S general specifications and contractual specifications by the RESPONSIBLE ORGANIZATION.

The performance of installed equipment that is tested is assessed by the RESPONSIBLE ORGANIZATION and regulators using a wide variety of PROCESSES and tools. Acceptability criteria and PROCESSES can differ from those of equipment MANUFACTURERS.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray equipment for radiography and radioscopy

1 Scope and object

This part of IEC 61223 applies to evaluation of the imaging performance and related QUALITY CONTROL parameters of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY that conform to IEC 60601-2-54:2022 or IEC 60601-2-43:2022.

NOTE Cone-beam CT is a MODE OF OPERATION in INTERVENTIONAL X-RAY EQUIPMENT. This document discusses such MODE OF OPERATION in the informative Annex F.

This document applies to the evaluation of the imaging performance of the entire imaging chain from image acquisition, image processing and image display.

This document applies to ACCEPTANCE TESTS and CONSTANCY TESTS, which are part of the QUALITY ASSURANCE PROGRAM in medical imaging departments and are intended to be performed by or under the responsibility of the RESPONSIBLE ORGANIZATION. A detailed discussion of the position of these tests within the medical radiological equipment lifecycle is provided in Clause A.2. The methods included rely mainly on non-invasive measurements that use appropriate test equipment and are performed after the installation is completed in accordance with the MANUFACTURER'S installation instructions.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 require information to be provided to the RESPONSIBLE ORGANIZATION with respect to QUALITY CONTROL. This document provides guidance to MANUFACTURERS regarding the ACCEPTANCE and CONSTANCY TESTS for the X-RAY EQUIPMENT in a MANUFACTURER supplied QUALITY CONTROL manual. Annex G provides guidance for such a manual.

2 Normative references

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.

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

IEC 60601-2-43:2022, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

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 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

IEC 61674:2012, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676:2023, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

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