SLOVENSKI STANDARD
oSIST prEN IEC 61223-3-8:2022

01-oktober-2022

Vrednotenje in rutinsko preskušanje v medicinskih oddelkih za slikanje - 3-8. del: Preskusi sprejemljivosti in konstantnosti - Slikovni učinek rentgenske opreme za radiografijo in radioskopijo

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

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

Ta slovenski standard je istoveten z: **prEN IEC 61223-3-8:2022**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

oSIST prEN IEC 61223-3-8:2022 **en**

62B/1283/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61223-3-8 ED1**	
DATE OF CIRCULATION: **2022-07-15**	CLOSING DATE FOR VOTING: **2022-10-07**
SUPERSEDES DOCUMENTS: **62B/1240/CD, 62B/1253A/CC**	

IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT

SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62C	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☒ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2026

NOTE FROM TC/SC OFFICERS:

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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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-3-8 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62B/XX/FDIS	62B/XX/RVD

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

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

318 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC
319 Directives, Part 2. For the purposes of this standard, the auxiliary verb:

320 – “shall” means that compliance with a requirement or a test is mandatory for compliance with
321 this standard;
322 – “should” means that compliance with a requirement or a test is recommended but is not
323 mandatory for compliance with this standard;
324 – “may” is used to describe a permissible way to achieve compliance with a requirement or
325 test.

326 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title
327 indicates that there is guidance or rationale related to that item in Annex A.

328 A list of all parts of the IEC 61223 series, published under the general title *Evaluation and*
329 *routine testing in medical imaging departments,* can be found on the IEC website.

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

333 • reconfirmed,
334 • withdrawn,
335 • replaced by a revised edition, or
336 • amended.

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

342

INTRODUCTION

IEC 61223 (all parts) gives methods for ACCEPTANCE TESTS and CONSTANCY TESTS for diagnostic X-RAY EQUIPMENT.

IEC 60601-2-54 and IEC 60601-2-43 require 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 part of IEC 61223 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 standard. Acceptance criteria are supplied by MANUFACTURERS and (local) compliance criteria are given by the regulatory authorities.

A major purpose of this standard 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 need to be tested are assessed by the RESPONSIBLE ORGANIZATION and regulators using a wide variety of PROCESSES and tools. Similarly, acceptability criteria and PROCESSES often 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 performance of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY that conform to IEC 60601-2-54 or IEC 60601-2-43.

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

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

This standard applies to ACCEPTANCE TESTS and CONSTANCY TESTS, which are part of the QUALITY ASSURANCE PROGRAM in medical imaging departments and is 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 A.2 of Annex A. 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 and IEC 60601-2-43 require information to be provided to the RESPONSIBLE ORGANIZATION with respect to QUALITY CONTROL. This standard 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 detailed 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 60522-1:2020, *Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of quality equivalent filtration and permanent filtration*

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 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
IEC 60601-2-43:2010/AMD1:2017
IEC 60601-2-43:2010/AMD2:2019

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
IEC 60601-2-54:2010/AMD1:2015
IEC 60601-2-54:2010/AMD2:2018

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 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*
IEC 61676:2002/AMD1:2009

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*

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

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*
IEC 62563-1:2009/AMD1:2016
IEC 62563-1:2009/AMD2:2021

IEC 62563-2:2021, *Medical electrical equipment – Medical image display systems – Part 2: Acceptance and constancy tests*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions in IEC 60601-1, IEC 60601-1-3, IEC 60601-2-54, IEC 60601-2-43 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- IEC Glossary; available at http://std.iec.ch/glossary
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1.1
ACCEPTANCE TEST
ACCEPTANCE TESTING
test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with specifications

Note 1 to entry: The specifications could include contractual specifications, requirements enforced by legislation, the MANUFACTURER's specifications or requirements from standards, for example in the IEC 60601 series.

[SOURCE: IEC TS 61223-1:1993, 3.2.4, modified – contractual specifications replaced by specifications and note 1 to entry added]

3.1.2
ACTUAL FOCAL SPOT
area on the surface of the anode that intercepts the beam of accelerated particles

[SOURCE: IEC 60336:2020, 3.1 modified – target has been replaced by anode, note 1 to entry has been removed]

3.1.3
ANTI-SCATTER GRID
device to be placed before the IMAGE RECEPTION AREA in order to reduce the incidence of SCATTERED RADIATION upon that area and thus increase the contrast in the X-RAY PATTERN

[SOURCE: IEC 60627:2013, 3.1.1]

3.1.4
ARTEFACT(S)
apparent structure(s) visible in the image, which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

[SOURCE: IEC 61223-3-3:1996, 3.3.1, modified – artifact changed to ARTEFACT]

3.1.5
ASSOCIATED EQUIPMENT
in a RADIOLOGICAL INSTALLATION, ME EQUIPMENT other than those for the production and control of IONIZING RADIATION, but essential for its application

[SOURCE: IEC TR 60788:2004, rm-30-01, modified – equipment has been replaced by ME EQUIPMENT]

3.1.6
BASELINE VALUES
reference value of functional parameter, which is either:

- the value obtained for this parameter in the initial CONSTANCY TEST immediately following an ACCEPTANCE TEST, or
- where described in a corresponding particular standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following an ACCEPTANCE TEST

Note 1 to entry: The CONSTANCY TEST method can be different from the ACCEPTANCE TEST method. In case the methods are the same, the value obtained in the ACCEPTANCE TEST can be used.

[SOURCE: IEC 61223-3-6:2020, 3.1.5, modified – term status test replaced by ACCEPTANCE TEST and note 1 to entry added]

3.1.7
BASIC CHECK
a test that can be performed routinely and uses simple means and methods to enable the early detection of changes in the functional performance of equipment

Note 1 to entry: BASIC CHECKS are intended to be performed by the RESPONSIBLE ORGANIZATION frequently and without any measurement instruments (e.g., DOSIMETER, LUMINANCE meter).