SVENSK STANDARD SS-EN IEC 61223-3-6

Fastställd	Utgåva	Sida	Ansvarig kommitté
2020-10-21	1	1 (1+55)	SEK TK 62BC

Utvärdering och rutinprovning i avdelningar för medicinsk bildframställning – Del 3-6: Leverans- och konstansprovning – Bildkvalitet hos röntgenutrustning för avbildning med mammografisk tomosyntes

Evaluation and routine testing in medical imaging departments – Part 3-6: Acceptance and constancy tests – Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation

Som svensk standard gäller europastandarden EN IEC 61223-3-6:2020. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61223-3-6:2020.

Nationellt förord

Europastandarden EN IEC 61223-3-6:2020

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61223-3-6, First edition, 2020 - Evaluation and routine testing in medical imaging departments - Part 3-6: Acceptance and constancy tests - Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation**

utarbetad inom International Electrotechnical Commission, IEC.

ICS 11.040.50

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61223-3-6

April 2020

ICS 11.040.50

English Version

Evaluation and routine testing in medical imaging departments - Part 3-6: Acceptance and constancy tests - Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation (IEC 61223-3-6:2020)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-6: Essais d'acceptation et de constance - Performance d'imagerie des appareils de mammographie à rayonnement X utilisés en mode tomosynthèse en mammographie (IEC 61223-3-6:2020)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-6: Abnahmeprüfungen und Konstanzprüfungen – Leistungsmerkmale zur Bildgebung im mammographischen Tomosynthese-Betrieb von Röntgen-Mammographiegeräten (IEC 61223-3-6:2020)

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 61223-3-6:2020 E

European foreword

The text of document 62B/1127/CDV, future edition 1 of IEC 61223-3-6, 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 61223-3-6:2020.

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) 2020-12-13
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-03-13

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 61223-3-6:2020 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 60806:1984	NOTE	Harmonized as EN 60806:2004 (not modified)
IEC 62220-1-2:2007	NOTE	Harmonized as EN 62220-1-2:2007 (not modified)
IEC 61223-3-4:2000	NOTE	Harmonized as EN 61223-3-4:2000 (not modified)
IEC 60544-1:2013	NOTE	Harmonized as EN 60544-1:2013 (not modified)
IEC 62132-1:2015	NOTE	Harmonized as EN 62132-1:2016 (not modified)
IEC 60601-2-44:2009	NOTE	Harmonized as EN 60601-2-44:2009 (not modified)
IEC 62220-1-1:2015	NOTE	Harmonized as EN 62220-1-1:2015 (not modified)
IEC 62464-1:2018	NOTE	Harmonized as EN IEC 62464-1:2019 (not modified)
IEC 61223-3-5:2019	NOTE	Harmonized as EN IEC 61223-3-5:2019 (not modified)
IEC 60601-1-3:2008	NOTE	Harmonized as EN 60601-1-3:2008 (not modified)
IEC 62563-1	NOTE	Harmonized as EN 62563-1
IEC 60627	NOTE	Harmonized as EN 60627
IEC 60601-2-28	NOTE	Harmonized as EN IEC 60601-2-28
IEC 61223-3-4:2000	NOTE	Harmonized as EN 61223-3-4:2000 (not modified)
IEC 60601-2-64:2014	NOTE	Harmonized as EN 60601-2-64:2015 (not modified)
IEC 61675-2:2015	NOTE	Harmonized as EN 61675-2:2015 (not modified)
IEC 80601-2-59:2017	NOTE	Harmonized as EN IEC 80601-2-59:2019 (not modified)
IEC 60730-1:2013	NOTE	Harmonized as EN 60730-1:2016 (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.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60601-2-45	2011	Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices	EN 60601-2-45	2011
+ A1	2015		+ A1	2015
IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment	EN 61223-3-2	2008
IEC 61674	2012	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	EN 61674	2013

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-6: Acceptance and constancy tests – Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation

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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International Standard IEC 61223-3-6 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:

CDV	Report on voting
62B/1127/CDV	62B/1148/RVC

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:

– requirements, compliance with which can be tested, and definitions: in roman type.

– explanations, advice, notes, general statements, exceptions and references: in smaller 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.

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 "http://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.

NOTE The attention of the users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements 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 publication 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

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

This part of IEC 61223 describes test methods for the ACCEPTANCE and CONSTANCY TESTS of MAMMOGRAPHIC X-RAY EQUIPMENT used in a MAMMOGRAPHIC TOMOSYNTHESIS MODE OF OPERATION.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-6: Acceptance and constancy tests – Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation

1 Scope and object

This part of IEC 61223 applies to the performance of MAMMOGRAPHIC X-RAY EQUIPMENT when used in MAMMOGRAPHIC TOMOSYNTHESIS modes of operation, with respect to image quality and dose.

Excluded from the scope of this document are:

– MAMMOGRAPHIC X-RAY EQUIPMENT modes of operation other than MAMMOGRAPHIC TOMOSYNTHESIS;
– 2D images synthesised from the tomosynthesis images;
– reconstructive TOMOGRAPHY other than MAMMOGRAPHIC TOMOSYNTHESIS;
– CT SCANNERS covered by IEC 61223-3-5.

This document defines:

a) the essential parameters which describe the acceptability criteria of MAMMOGRAPHIC TOMOSYNTHESIS modes of operation of MAMMOGRAPHIC X-RAY EQUIPMENT with regard to image quality and dose,
b) the methods of testing whether measured quantities related to those parameters comply with specified tolerances, and
c) CONSTANCY TEST frequency when required.

This document is intended to be applied along with the acceptability criteria included in IEC 61223-3-2 or equivalent protocol for 2D mammography which are also relevant for MAMMOGRAPHIC TOMOSYNTHESIS modes of operation.

These methods mainly rely on non-invasive measurements that use appropriate test equipment and are performed during or after the installation. Signed statements covering steps in the installation procedure can be used as part of the ACCEPTANCE TEST. Tests required by a higher level of compliance take precedence over similar tests with a lower level of compliance.

When the results of the ACCEPTANCE TEST are in compliance with the expected values, the BASELINE VALUES for the subsequent CONSTANCY TESTS are established.

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 60601-2-45:2011, *Medical electrical equipment – Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices*
IEC 60601-2-45:2011/AMD1:2015

IEC 61223-3-2:2007, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment*

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