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## **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.

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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)

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## **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

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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](http://www.cenelec.eu).

| <u>Publication</u> | <u>Year</u> | <u>Title</u>                                                                                                                                                                         | <u>EN/HD</u>  | <u>Year</u> |
|--------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------|
| 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        |

## CONTENTS

|                                                                              |    |
|------------------------------------------------------------------------------|----|
| FOREWORD.....                                                                | 6  |
| INTRODUCTION.....                                                            | 8  |
| 1 Scope and object.....                                                      | 9  |
| 2 Normative references .....                                                 | 9  |
| 3 Terms, definitions, symbols and abbreviated terms.....                     | 10 |
| 3.1 Terms and definitions.....                                               | 10 |
| 3.2 Symbols and abbreviated terms .....                                      | 13 |
| 4 General aspects of the ACCEPTANCE TEST.....                                | 13 |
| 4.1 Levels of requirements.....                                              | 13 |
| 4.1.1 Local regulatory.....                                                  | 13 |
| 4.1.2 Contractual.....                                                       | 13 |
| 4.1.3 General .....                                                          | 13 |
| 4.2 General conditions in test procedures .....                              | 13 |
| 4.3 Documents and data for the tests.....                                    | 14 |
| 4.4 Test conditions .....                                                    | 14 |
| 4.5 Scope of tests.....                                                      | 15 |
| 4.6 Test equipment.....                                                      | 15 |
| 4.6.1 General .....                                                          | 15 |
| 4.6.2 Analysis software .....                                                | 16 |
| 4.6.3 DOSIMETER.....                                                         | 16 |
| 4.7 Evaluating the test results.....                                         | 16 |
| 5 General aspects of CONSTANCY TESTS .....                                   | 17 |
| 5.1 Establishment of BASELINE VALUES.....                                    | 17 |
| 5.2 Frequency of CONSTANCY TESTS .....                                       | 17 |
| 6 Summary of tests for MAMMOGRAPHIC TOMOSYNTHESIS equipment .....            | 17 |
| 7 Inventory and initial tests for MAMMOGRAPHIC TOMOSYNTHESIS equipment ..... | 18 |
| 7.1 Requirements .....                                                       | 18 |
| 7.2 Test method.....                                                         | 19 |
| 7.3 CONSTANCY TESTING .....                                                  | 19 |
| 7.3.1 Test method .....                                                      | 19 |
| 7.3.2 Frequency of testing .....                                             | 19 |
| 7.4 Action to be taken .....                                                 | 19 |
| 8 Alignment and collimation checks .....                                     | 19 |
| 8.1 Requirements .....                                                       | 19 |
| 8.2 Test method.....                                                         | 19 |
| 8.3 CONSTANCY TESTING .....                                                  | 20 |
| 8.3.1 Test method .....                                                      | 20 |
| 8.3.2 Frequency of testing .....                                             | 20 |
| 8.4 Equipment .....                                                          | 20 |
| 8.5 Action to be taken.....                                                  | 20 |
| 9 AEC-system.....                                                            | 20 |
| 9.1 General.....                                                             | 20 |
| 9.2 Short term reproducibility .....                                         | 21 |
| 9.2.1 Requirements .....                                                     | 21 |
| 9.2.2 Test method .....                                                      | 21 |
| 9.2.3 CONSTANCY TESTING .....                                                | 21 |

|        |                                                |    |
|--------|------------------------------------------------|----|
| 9.2.4  | Equipment .....                                | 21 |
| 9.2.5  | Action to be taken.....                        | 21 |
| 9.3    | Long term reproducibility.....                 | 21 |
| 9.3.1  | Requirements .....                             | 21 |
| 9.3.2  | Test method .....                              | 22 |
| 9.3.3  | CONSTANCY TESTING .....                        | 22 |
| 9.3.4  | Action to be taken.....                        | 22 |
| 9.4    | AEC performance .....                          | 22 |
| 9.4.1  | Requirements .....                             | 22 |
| 9.4.2  | Test method .....                              | 22 |
| 9.4.3  | CONSTANCY TESTING .....                        | 25 |
| 9.4.4  | Equipment .....                                | 25 |
| 9.4.5  | Action to be taken.....                        | 25 |
| 10     | Image receptor .....                           | 25 |
| 10.1   | Response function .....                        | 25 |
| 10.1.1 | General .....                                  | 25 |
| 10.1.2 | Requirements .....                             | 26 |
| 10.1.3 | Test method .....                              | 26 |
| 10.1.4 | CONSTANCY TESTING .....                        | 26 |
| 10.1.5 | Action to be taken.....                        | 26 |
| 10.2   | Detector element failure.....                  | 27 |
| 10.2.1 | Requirements .....                             | 27 |
| 10.2.2 | Test method .....                              | 27 |
| 10.2.3 | CONSTANCY TESTING .....                        | 27 |
| 10.2.4 | Equipment .....                                | 27 |
| 10.2.5 | Action to be taken.....                        | 27 |
| 10.3   | Uncorrected DEFECTIVE DETECTOR ELEMENTS.....   | 27 |
| 10.3.1 | General .....                                  | 27 |
| 10.3.2 | Requirements .....                             | 27 |
| 10.3.3 | Test method .....                              | 27 |
| 10.3.4 | CONSTANCY TESTING .....                        | 28 |
| 10.3.5 | Equipment .....                                | 28 |
| 10.3.6 | Action to be taken.....                        | 28 |
| 10.4   | System PROJECTION MTF.....                     | 28 |
| 10.4.1 | General .....                                  | 28 |
| 10.4.2 | Requirements .....                             | 28 |
| 10.4.3 | Test method .....                              | 29 |
| 10.4.4 | CONSTANCY TESTING .....                        | 29 |
| 10.4.5 | Equipment .....                                | 29 |
| 10.4.6 | Action to be taken.....                        | 29 |
| 11     | Image quality of the reconstructed image ..... | 29 |
| 11.1   | PHANTOM testing .....                          | 29 |
| 11.1.1 | General .....                                  | 29 |
| 11.1.2 | Requirements .....                             | 29 |
| 11.1.3 | Test method .....                              | 30 |
| 11.1.4 | CONSTANCY TESTING .....                        | 30 |
| 11.1.5 | Action to be taken.....                        | 30 |
| 11.2   | z-resolution (ARTEFACT spread function).....   | 30 |
| 11.2.1 | Requirements .....                             | 30 |

|                       |                                                                                    |    |
|-----------------------|------------------------------------------------------------------------------------|----|
| 11.2.2                | Test method .....                                                                  | 30 |
| 11.2.3                | CONSTANCY TESTING .....                                                            | 32 |
| 11.2.4                | Equipment .....                                                                    | 32 |
| 11.2.5                | Action to be taken.....                                                            | 32 |
| 12                    | Missed tissue .....                                                                | 32 |
| 12.1                  | General.....                                                                       | 32 |
| 12.2                  | Missed tissue at chest wall side in the reconstructed tomosynthesis volume .....   | 33 |
| 12.2.1                | Requirements .....                                                                 | 33 |
| 12.2.2                | Test method .....                                                                  | 33 |
| 12.2.3                | CONSTANCY TESTING .....                                                            | 33 |
| 12.2.4                | Equipment .....                                                                    | 33 |
| 12.2.5                | Action to be taken.....                                                            | 33 |
| 12.3                  | Missed tissue at the top and bottom of the reconstructed tomosynthesis volume..... | 33 |
| 12.3.1                | Requirements .....                                                                 | 33 |
| 12.3.2                | Test method .....                                                                  | 33 |
| 12.3.3                | CONSTANCY TESTING .....                                                            | 34 |
| 12.3.4                | Equipment .....                                                                    | 35 |
| 12.3.5                | Action to be taken.....                                                            | 35 |
| 13                    | ARTEFACTS in the tomosynthesis data sets.....                                      | 35 |
| 13.1                  | General.....                                                                       | 35 |
| 13.2                  | ARTEFACT evaluation.....                                                           | 35 |
| 13.2.1                | Requirements .....                                                                 | 35 |
| 13.2.2                | Test method .....                                                                  | 35 |
| 13.2.3                | CONSTANCY TESTING .....                                                            | 35 |
| 13.2.4                | Equipment .....                                                                    | 35 |
| 13.2.5                | Action to be taken.....                                                            | 35 |
| 13.3                  | GEOMETRIC DISTORTION.....                                                          | 35 |
| 13.3.1                | Requirements .....                                                                 | 35 |
| 13.3.2                | Test method .....                                                                  | 36 |
| 13.3.3                | Equipment .....                                                                    | 37 |
| 13.3.4                | Action to be taken.....                                                            | 37 |
| 14                    | Dosimetry for digital breast tomosynthesis.....                                    | 37 |
| 14.1                  | Requirements .....                                                                 | 37 |
| 14.2                  | Test method.....                                                                   | 38 |
| 14.3                  | CONSTANCY TESTING .....                                                            | 39 |
| 14.3.1                | Test method .....                                                                  | 39 |
| 14.3.2                | Frequency of testing .....                                                         | 39 |
| 14.4                  | Equipment .....                                                                    | 39 |
| 14.5                  | Action to be taken.....                                                            | 39 |
| Annex A (informative) | Tables for dosimetry calculation in digital breast tomosynthesis .....             | 40 |
| Annex B (normative)   | Guidance on action to be taken .....                                               | 44 |
| B.1                   | Failing the ESTABLISHED CRITERIA at first measurement .....                        | 44 |
| B.2                   | Failing the ESTABLISHED CRITERIA at multiple measurements .....                    | 44 |
| B.3                   | Marginally failing the ESTABLISHED CRITERIA .....                                  | 44 |
| B.4                   | History of repeatedly failing the ESTABLISHED CRITERIA.....                        | 44 |
| B.5                   | Substantially failing the ESTABLISHED CRITERIA .....                               | 45 |
| B.6                   | Cases not covered by Clauses B.1 to B.5 .....                                      | 45 |



|                                                      |    |
|------------------------------------------------------|----|
| Annex C (informative) Image quality evaluation ..... | 46 |
| Annex D (informative) ARTEFACTS .....                | 47 |
| Bibliography .....                                   | 48 |
| Index of defined terms .....                         | 52 |

|                                                                                                                                                       |    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Figure 1 – Set-up for measuring the alignment between the reconstructed and the irradiated volume at the chest wall edge of the PATIENT SUPPORT ..... | 20 |
| Figure 2 – Top and 3D view of setup for the AEC performance measurements .....                                                                        | 23 |
| Figure 3 – Placement of ROI for the AEC performance measurement .....                                                                                 | 24 |
| Figure 4 – Top and 3D view of setup for the evaluation of z-resolution .....                                                                          | 31 |
| Figure 5 – Front and side view of setup for the evaluation of z-resolution .....                                                                      | 32 |
| Figure 6 – Configuration for the determination of missed tissue for curved paddles .....                                                              | 34 |
| Figure 7 – Top and 3D view of setup for the evaluation of GEOMETRIC DISTORTION .....                                                                  | 36 |
| Figure 8 – Front and side view of setup for the evaluation of GEOMETRIC DISTORTION .....                                                              | 37 |
| Figure 9 – Top and 3D view of position of DOSIMETER to determine the incident AIR KERMA for dose estimation .....                                     | 39 |
| Table 1 – Tests, test frequencies, and test objects used in this document .....                                                                       | 17 |
| Table 2 – Height of the compression paddle when using different PMMA thicknesses .....                                                                | 24 |
| Table 3 – Limits for AGD versus the thickness of the PMMA and the height of the compression paddle .....                                              | 38 |
| Table A.1 – <i>g</i> factors for breasts simulated with PMMA .....                                                                                    | 40 |
| Table A.2 – <i>c</i> factors for breasts simulated with PMMA .....                                                                                    | 40 |
| Table A.3 – Typical HVL measurements for different tube voltage and TARGET FILTER combinations .....                                                  | 41 |
| Table A.4 – <i>s</i> factors for clinically used spectra .....                                                                                        | 41 |
| Table A.5 – <i>s</i> factors for clinically used spectra with W TARGET material .....                                                                 | 41 |
| Table A.6 – <i>s</i> factors for a tungsten TARGET filtered by 0,5 mm aluminium .....                                                                 | 42 |
| Table A.7 – <i>s</i> factors for a tungsten TARGET filtered by 0,7 mm aluminium .....                                                                 | 42 |
| Table A.8 – <i>T</i> factors vs. PMMA thickness for a variety of scan angles .....                                                                    | 43 |

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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

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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.

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## 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*