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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

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. 09/20

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**EN IEC 61223-3-6**

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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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**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.

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IEC 60806:1984	NOTE	Harmonized as EN 60806:2004 (not modified)
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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)
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IEC 60627	NOTE	Harmonized as EN 60627
IEC 60601-2-28	NOTE	Harmonized as EN IEC 60601-2-28
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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**

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<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



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# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Evaluation and routine testing in medical imaging departments –  
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**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**



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# INTERNATIONAL STANDARD

# NORME INTERNATIONALE



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tomosynthèse en mammographie**

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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**

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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.

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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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**