
Ovrednotenje in kosovno preskušanje v medicinskih oddelkih za slikanje - 3-6. del: Preskusi sprejemljivosti in konstantnosti - Slikovni učinek mamografske rentgenske opreme, ki se uporablja v mamografskem načinu delovanja tomosinteze (IEC 61223-3-6:2020)

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 (IEC 61223-3-6:2020)

iTeh STANDARD PREVIEW

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)

<https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-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)

Ta slovenski standard je istoveten z: EN IEC 61223-3-6:2020

ICS:

11.040.50 Radiografska oprema Radiographic equipment

SIST EN IEC 61223-3-6:2020 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN IEC 61223-3-6:2020](https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020)

<https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020>

EUROPEAN STANDARD

EN IEC 61223-3-6

NORME EUROPÉENNE

EUROPÄISCHE NORM

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)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This European Standard was approved by CENELEC on 2020-03-13. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

<https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-03140c311002/iec-61223-3-6-2020>

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

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.

<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 mammographic stereotactic devices	EN 60601-2-45	2011
+ A1	2015	SIST EN IEC 61223-3-6:2020	+ 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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN IEC 61223-3-6:2020](https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020)

<https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020>



IEC 61223-3-6

Edition 1.0 2020-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**

[SIST EN IEC 61223-3-6:2020](https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-df7096464a7c/iec-61223-3-6-2020)

[https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-](https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-df7096464a7c/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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-7812-3

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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 IEC 61223-3-6:2020.....	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

- 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All USERS should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 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) 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 61223-3-6 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

<https://standards.iteh.ai/catalog/standards/sist/1895090d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020>

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.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

[SIST EN IEC 61223-3-6:2020](https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020)

<https://standards.iteh.ai/catalog/standards/sist/1893b50d-285c-4092-98a0-d8ce86e444a0/sist-en-iec-61223-3-6-2020>

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

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