IEC 61223-3-6

Edition 1.0 2020-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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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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- withdrawn,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.

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*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-2-45, IEC 61223-3-2 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/
- ISO Online browsing platform: available at http://www.iso.org/obp

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

[SOURCE: IEC TR 61223-1:1993, 3.2.4]

3.1.2
ARTEFACT
apparent structure, visible in the image, which does not represent a structure within the object

[SOURCE: IEC 61223-3-4:2000, 3.3.1]

3.1.3
AUTOMATIC EXPOSURE CONTROL
AEC
MODE OF OPERATION, in a radiological equipment, in which, in reaction to the properties of the object, one or more of the LOADING FACTORS or IRRADIATION conditions are controlled automatically in order to obtain a specified quantity of RADIATION of a desired quality

Note 1 to entry: Examples of such properties of the object are: thickness, composition, or X-ray TRANSMISSION. Examples for IRRADIATION conditions are anode materials of the X-RAY TUBE and ADDED FILTERS.

Note 2 to entry: This note applies to the French language only.

3.1.4
AVERAGE GLANDULAR DOSE
AGD
X-ray mammography average ABSORBED DOSE in the glandular tissue (excluding skin) in a uniformly compressed breast of known tissue composition, using a specified calculation method

[SOURCE: IEC 61223-3-2:2007, 3.7]

3.1.5
BASELINE VALUE
reference value of functional parameter, which is either:

– the value obtained for this parameter in the initial CONSTANCY TEST immediately following a STATUS TEST, or

– where described in a corresponding particular standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following a STATUS TEST

3.1.6
CONSTANCY TEST
CONSTANCY TESTING
each of a series of tests, carried out:

– to ensure that the functional performance of the equipment meets ESTABLISHED CRITERIA; or

– to enable the early recognition of changes in the properties of components of the equipment

Note 1 to entry: May use a subset of the ACCEPTANCE TEST.

[SOURCE: IEC TR 61223-1:1993, 3.2.6, modified – Note 1 to entry has been added.]

3.1.7
DIAGNOSTIC DOSIMETER
DOSIMETER
equipment which uses IONIZATION CHAMBERS and/or semiconductor detectors for the measurement of AIR KERMA, AIR KERMA length and/or AIR KERMA RATE in the beam of an X-ray machine used for diagnostic medical radiological examinations

Note 1 to entry: A DIAGNOSTIC DOSIMETER contains the following components:

– one or more detector assemblies which may or may not be an integral part of the measuring assembly;

– a measuring assembly; and/or

– one or more stability check devices.

[SOURCE: IEC 61674:2012, 3.1, modified – Note 1 to entry has been rephrased.]

3.1.8
ESTABLISHED CRITERIA
acceptable variations, in a QUALITY ASSURANCE PROGRAMME, in results of a CONSTANCY TEST which signal satisfactory functional performance of the equipment tested

3.1.9
FOCAL SPOT
perpendicular PROJECTION of the actual FOCAL SPOT on the reference plane

Note 1 to entry: The shortened term "FOCAL SPOT" refers to the effective FOCAL SPOT (IEC 60806 [1][1]).

3.1.10
LINEARIZED DATA
ORIGINAL DATA to which the inverse CONVERSION FUNCTION has been applied

Note 1 to entry: The LINEARIZED DATA are directly proportional to the AIR KERMA.

Note 2 to entry: For practical reasons, AIR KERMA proportional data can be generated by applying the inverse response function (see 10.1.3).

[SOURCE: IEC 62220-1-2:2007, 3.7, modified – Note 2 to entry has been added.]

3.1.11
MAMMOGRAPHIC TOMOSYNTHESIS
DBT
technique using MAMMOGRAPHIC X-RAY EQUIPMENT to produce multiple tomographic images reconstructed from multiple PROJECTIONS acquired over a total angular range of less than 180°

Note 1 to entry: This note applies to the French language only.

[SOURCE: IEC 60601-2-45:2011 and IEC 60601-2-45:2011/AMD1:2015, 201.3.210, modified – The abbreviated term "DBT" has been added, as well as Note 1 to entry.]

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1 Numbers in square brackets refer to the Bibliography.

3.1.12
MEASUREMENT UNCERTAINTY
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified – The notes to entry have been deleted.]

3.1.13
ORIGINAL DATA
RAW DATA to which the corrections as in normal clinical use have been applied

Note 1 to entry: Some detectors execute linear image processing due to their physical concept. As long as this image processing is linear and image-independent, these operations are allowed as an exception.

Note 2 to entry: See IEC 60601-2-45:2011, 201.3.208.

3.1.14
QUALITY ASSURANCE PROGRAMME
detailed instruction for carrying out actions of quality assurance for individual items of equipment, systems of equipment or facilities, including quality administrative elements and QUALITY CONTROL techniques

3.1.15
RAW DATA
PIXEL values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE or counts from photon counting systems without any corrections

[SOURCE: IEC 60601-2-45:2011, 201.3.209, modified – The word "software" has been deleted in "software corrections".]

3.1.16
REFERENCE ROI
REGION OF INTEREST (size 5 mm x 5 mm) in the PROJECTION

Note 1 to entry: The centre of the ROI is positioned 60 mm perpendicular to the chest edge of the PATIENT SUPPORT and centred laterally.

Note 2 to entry: This note applies to the French language only.

3.1.17
SIGNAL DIFFERENCE TO NOISE RATIO
SDNR
ratio, in a digital image, of the difference of mean PIXEL values of the contrast object and image background and the standard deviation of the image background PIXEL value

Note 1 to entry: This note applies to the French language only.

3.1.18
SIGNAL TO NOISE RATIO
SNR
measure of signal strength versus the background NOISE, defined as the ratio of mean PIXEL values of an area of interest in an image to the standard deviation of the PIXEL value of the area of interest

Note 1 to entry: This note applies to the French language only.

3.1.19
STATUS TEST
test carried out to establish the functional status of equipment at a given time

3.1.20
ZERO DEGREE ANGLE STATIONARY MODE
MODE OF OPERATION of the tomosynthesis equipment identical to a tomosynthesis mode, without the tomosynthesis movement of the X-RAY BEAM with the PATIENT SUPPORT surface positioned horizontally and the beam axis as close as possible perpendicular to it

3.2 Symbols and abbreviated terms

Symbol/abbreviated term	Physical quantity/Description	Unit
K_E	ENTRANCE SURFACE AIR KERMA	mGy
FWHM	full width at half maximum	mm
MTF	MODULATION TRANSFER FUNCTION	-
PMMA	polymethylmethacrylate	-
ROI	region of interest	-

4 General aspects of the ACCEPTANCE TEST

4.1 Levels of requirements

4.1.1 Local regulatory

Local regulatory requirements, including test procedures and acceptable values, shall take precedence over similar contractual requirements or corresponding items in this document.

4.1.2 Contractual

Individual contractual requirements, including test procedures and acceptable values, shall take precedence over similar corresponding items in this document.

Requirements for STATUS TESTS should be included in the contractual requirements.

4.1.3 General

In the absence of specific regulatory or contractual requirements, the test procedures in this document shall be applicable.

Values and acceptable tolerances shall be in accordance with the MANUFACTURER's specifications for the equipment.

The aim of the ACCEPTANCE TEST is to demonstrate that the specified characteristics of the equipment lie within specified tolerances. These tolerances are determined by regulatory or contractual requirements.

4.2 General conditions in test procedures

Prior to the ACCEPTANCE TEST procedures, an inventory of the equipment shall be established.

The X-RAY EQUIPMENT and its components shall be unambiguously identified, for example with respect to type and SERIAL NUMBER, and checked against the order contract. The check shall also encompass ascertaining that the ACCOMPANYING DOCUMENTS, records and acceptance criteria according to this document are complete, that delivery is complete, and that the documents relate to the equipment delivered.

Ensure that the configuration of the equipment under this test allows accessing the different PROJECTIONS as ORIGINAL DATA.