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Evaluation and routine testing in medical imaging departments –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

Essais d'évaluation et de routine dans les services d'imagerie médicale –

Partie 3-2: Essais d'acceptation – Performance d'imagerie des appareils de mammographie à rayonnement X

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

FOREWORD

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International Standard IEC 61223-3-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition, published in 1996. It constitutes a technical revision. This second edition has been expanded by including tests of equipment properties depending on X-RAY IMAGE RECEPTORS, by putting emphasis on the aspect of image quality and dose and through harmonization, where possible, with other recognized standards. Annex L compares the specific content of the first and second editions.

The text of this standard is based on the following documents:

FDIS	RVD
62B/651/FDIS	62B/659/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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.

In this standard, the following print types are used:

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

– explanations, advice, notes, general statements, exceptions and references: smaller type;

– TERMS DEFINED IN IEC 60788, IEC 60601-1 OR IN CLAUSE 3 OF THIS STANDARD: SMALL CAPITALS (see Index of defined terms).

NOTE 1 Where a defined term is used as a qualifier with another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a derived term without a definition..

NOTE 2 Where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for diagnostic X-RAY EQUIPMENT.

This second edition of the particular standard for the ACCEPTANCE TEST of mammographic X-RAY EQUIPMENT describes test methods for EQUIPMENT using RADIOGRAPHIC FILMS, EQUIPMENT using storage phosphor plates, EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS, and MAMMOGRAPHIC STEREOTACTIC DEVICES.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

1 Scope

This part of IEC 61223 applies to the effectiveness of mammographic X-RAY EQUIPMENT, with respect to image quality and dose, in combination with aspects of EQUIPMENT safety.

This standard applies to mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

The tests described in this standard require the quality and performance of the X-RAY IMAGE RECEPTORS to be assured prior to the acceptance testing when they are not an integral part of the mammographic X-RAY EQUIPMENT. This includes RADIOGRAPHIC FILMS, INTENSIFYING SCREENS, RADIOGRAPHIC CASSETTES, storage phosphor plates and ASSOCIATED EQUIPMENT such as film processors or storage phosphor plate readers, IMAGE DISPLAY DEVICES and HARD COPY CAMERAS.

For testing RADIOGRAPHIC CASSETTES and INTENSIFYING SCREENS, this standard makes reference to ISO 4090. Sensitivity and contrast for the screen-film image receptors are considered to be stated according to ISO 9236-3.

NOTE Currently there exists no IEC standard for acceptance testing of HARD COPY CAMERAS or IMAGE DISPLAY DEVICES.

By the measurements described in this standard, data for AVERAGE GLANDULAR DOSE calculation can be determined.

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

This part of IEC 61223 defines

a) the essential parameters which describe the performance of the above-mentioned mammographic X-RAY EQUIPMENT with regard to image quality and dose; and

b) the methods of testing whether measured quantities related to those parameters comply with specified tolerances.

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. This concept is described in 4.1.

This standard does not in itself specify limiting values or tolerances for the parameters under investigation.

A difficulty may arise with regard to the responsibility for acceptance testing when the film/screen combination, film processing chemistry or computed radiography system is changed. This arises from a combination of causes. Firstly, the image receptor MANUFACTURER and the X-RAY EQUIPMENT MANUFACTURER may be different. Secondly a change in image receptor or film processing chemistry may alter the system performance. When system integration such as the above occurs, it is important that acceptance testing is performed. When a change occurs which could alter system performance, it is essential that the system integrator (i.e. whoever is responsible for this change) discusses the implication of their change with the X-RAY EQUIPMENT MANUFACTURER so that the latter can adjust the imaging system if necessary.

ACCEPTANCE TESTING of mammographic X-RAY EQUIPMENT requires average skill in medical physics. However, the decision concerning who performs the test is determined by local rules (e.g. contract, regulation, law).

2 Normative references

The following referenced documents are indispensable for the application 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 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601 (all parts), *Medical electrical equipment*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-45, *Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices*

IEC 61223-2-1, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

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

IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

ISO 4090, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

ISO 9236-3, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Symbols, physical quantities, abbreviations and units used in this standard are given at the end of this clause in Table 1.

3.1
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 MANUFACTURER's specifications or requirements

[IEC 61223-1, definition 3.2.4, modified]

3.2
ARTIFACT
apparent structure, visible in the image, which does not represent a structure within the object

[IEC 61223-3-4, definition 3.3.1]

3.3
CONSTANCY TEST
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

[IEC 61223-1, definition 3.2.6]

3.4
DIRECT FOCAL DISTANCE
shortest distance from the FOCAL SPOT to the axis of symmetry of the effective IMAGE RECEPTION AREA perpendicular to the chest wall edge of the X-RAY IMAGE RECEPTOR

[IEC 60601-2-45, definition, 2.101.4, modified]

3.5
(DIAGNOSTIC) DOSIMETER
EQUIPMENT which uses IONIZATION CHAMBERS and/or semi-conductor 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

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 (optional)

[IEC 61674, definition 3.1]

3.6
LOW CONTRAST DETECTABILITY
capability of an imaging system to differentiate a low contrast object from a uniform background

3.7
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

3.8
CONTRAST TO NOISE RATIO
CNR
physical quantity describing the ability to distinguish between various contrast objects of a digital image and the inherent noise within the image, defined as the difference of mean pixel values of the contrast objects and image background, and divided by the standard deviation of the image background pixel value

3.9
ORIGINAL DATA
RAW DATA to which the corrections described below have been applied

The following linear and image-independent corrections of the RAW DATA are allowed in advance of the processing of the data for the determination of the CONVERSION FUNCTION, the NOISE POWER SPECTRUM, and the MODULATION TRANSFER FUNCTION. All the following corrections if used shall be made as in normal clinical use:

– replacement of the RAW DATA of bad or defective pixels by appropriate data;
– a flat-field correction comprising
  • correction of the non-uniformity of the RADIATION FIELD;
  • correction for the offset of the individual pixels, and
  • gain correction for the individual pixels;
– a correction for geometrical distortion;
– a correction for time variation during a scan.

NOTE 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.

3.10
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 software corrections

3.11
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

3.12
AUTOMATIC EXPOSURE CONTROL
AEC
in a radiological EQUIPMENT, mode of operation 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 at a pre-selected location a desired quantity of radiation of a desired quality

NOTE Examples of such properties of the object are: thickness, composition, or x-ray transmission. Examples for IRRADIATION conditions are the focal track of the X-RAY TUBE and ADDED FILTERS.

3.13
OVERALL UNCERTAINTY
uncertainty associated with the MEASURED VALUE, i.e. representing the bounds within which the ERROR OF MEASUREMENT is estimated to lie

[IEC 61674, definition 3.5.2]

3.14
LINEARIZED DATA
ORIGINAL DATA to which the inverse CONVERSION FUNCTION has been applied.

NOTE The LINEARIZED DATA are directly proportional to the exposure.

3.15
CONVERSION FUNCTION
plot of the large area output level (ORIGINAL DATA) of a DIGITAL X-RAY IMAGING DEVICE versus the number of exposure quanta per unit area (Q) in the DETECTOR SURFACE plane.

Table 1 – Symbols, physical quantities, abbreviations and units used in this standard

Symbol	Physical quantity	Unit
D	Visual optical density (usually called optical density)	-
D_n	Net density (optical density of a film minus its minimum density)	-
D_{min}	Minimum density (sum of fog and optical density of film base)	-
$\overline{G}$	Average gradient of a screen-film system in a given range of optical density	-
K	AIR KERMA	Gy
K_E	Entrance surface AIR KERMA	mGy
K_B	AIR KERMA in the IMAGE RECEPTION PLANE	µGy
K_N	Nominal AIR KERMA to generate a net density D_n = 1,0 (following the procedure of this standard)	µGy
Q	CURRENT TIME PRODUCT	mAs
AEC	AUTOMATIC EXPOSURE CONTROL	-
AGD	AVERAGE GLANDULAR DOSE	mGy
CNR	CONTRAST TO NOISE RATIO	-
HVL	HALF VALUE LAYER	mmAl
MTF	MODULATION TRANSFER FUNCTION	-
PMMA	Polymethylmethacrylate	-
ROI	Region of interest	-
SNR	SIGNAL TO NOISE RATIO	-
NOTE The nominal AIR KERMA K_N is not the same as the AIR KERMA K_s stated by the MANUFACTURER, but gives an estimate. The AIR KERMA K_s for a mammographic screen-film system is the AIR KERMA generating a net density D_n = 1,0 according to ISO 9236-3 (laboratory measurement).		

4 General aspects of the ACCEPTANCE TEST

4.1 Levels of compliance

Tests required by a higher level of compliance take precedence over similar tests with a lower level of compliance.

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.

NOTE 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.

4.2 General conditions in test procedures

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. 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 standard are complete, that delivery is complete, and that the documents relate to the EQUIPMENT delivered.

Prior to the ACCEPTANCE TEST, the X-RAY EQUIPMENT shall be calibrated for the specific needs of the image receptor in use. In case of a non-integrated image receptor, the system integrator shall provide the specifications and the conditions of use for the resulting system.

NOTE It is important to recognize that the energy response of image receptors can differ significantly as they differ in design, materials and technology. Adjusting the AUTOMATIC EXPOSURE CONTROL means that exposure parameters are tuned to reach a specified response values for the image receptor for a variety of ATTENUATION combinations.

For mammographic X-RAY EQUIPMENT using RADIOGRAPHIC FILMS, the film processing shall be tested prior to the ACCEPTANCE TESTing of the mammographic X-RAY EQUIPMENT. It has to be assured that the RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS, the RADIOGRAPHIC FILMS and the film processing perform in the specified way, for example with respect to sensitivity, reproducibility, contrast and absence of ARTIFACTS. A test of the performance of these components shall precede any ACCEPTANCE TEST measurements involving RADIOGRAPHIC FILMS, for example by applying the methods described in ISO 4090, in Annex C of this standard, and the CONSTANCY TESTS according to IEC 61223-2-1.

When digital images are quantitatively assessed, LINEARIZED DATA shall be used, and acquired with a RADIATION BEAM quality specified by the MANUFACTURER.

No post-processing shall be applied on the ORIGINAL DATA used for purposes of quantitative image analysis.

For mammographic X-RAY EQUIPMENT using a storage phosphor system, the storage phosphor system shall be tested prior to the acceptance testing of the mammographic X-RAY EQUIPMENT to assure that the storage phosphor system performs as designed. Examples of the test methods for storage phosphor tests are described in Annex D.

The IMAGE DISPLAY DEVICES involved in the ACCEPTANCE TEST shall be tested prior to the ACCEPTANCE TEST of the mammographic X-RAY EQUIPMENT. It has to be assured that the IMAGE DISPLAY DEVICES perform in the specified way, for example with respect to contrast and absence of ARTIFACTS.

The HARD COPY CAMERAS involved in the ACCEPTANCE TEST shall be tested prior to the ACCEPTANCE TEST of the mammographic X-RAY EQUIPMENT as recommended by the camera MANUFACTURER. It has to be assured that the HARD COPY CAMERAS perform in the specified way, for example with respect to contrast and absence of ARTIFACTS detrimental to patient diagnoses.

Non-invasive measurements are preferred for the ACCEPTANCE TEST. Whenever invasive tests are part of the programme, it shall be shown that the EQUIPMENT has been restored to its original condition.

NOTE 1 In general, for mammography X-RAY EQUIPMENT with a non-integrated X-RAY IMAGE RECEPTOR, the X-RAY EQUIPMENT may be tested before testing the system with the image receptor for those functions of the X-RAY EQUIPMENT which does not involve the performance of the image receptor.

NOTE 2 The test procedures and methods are established to demonstrate proper system setup and function and not to reflect performance under optimized clinical operation. As such, these specifications should not be used to compare expected clinical performance between systems. Other measures are needed for such comparisons.

4.3 Documents and data for the tests

Together with the mammographic X-RAY EQUIPMENT, the following documentation is required:

– statements of compliance with applicable parts of IEC 60601;
– list of EQUIPMENT/parts of EQUIPMENT ordered and actual delivery list (IEC 60601-1);
– list of applicable tests and acceptance criteria according to this standard as agreed upon between the USER and the supplier of the EQUIPMENT;
– results from tests performed earlier by the MANUFACTURER on the EQUIPMENT delivered as contracted;
– INSTRUCTIONS FOR USE
– reports on previous quality assurance tests where applicable; and
– documentation of technical changes performed on the EQUIPMENT.

The following documentation shall be present if applicable:

– test report on the film processing;
– report on RADIOGRAPHIC CASSETTE testing;
– test report on the viewing boxes;