

Evaluation and routine testing in medical imaging departments —

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

ICS 11.040.50

National foreword

This British Standard is the UK implementation of EN 61223-3-2:2008. It is identical to IEC 61223-3-2:2007. It supersedes BS EN 61223-3.2:1997 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2008

© BSI 2008

ISBN 978 0 580 55611 1

Amendments/corrigenda issued since publication

Date	Comments

**Evaluation and routine testing in medical imaging departments -
Part 3-2: Acceptance tests -
Imaging performance of mammographic X-ray equipment
(IEC 61223-3-2:2007)**

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
(CEI 61223-3-2:2007)

Bewertung und routinemäßige Prüfung
in Abteilungen
für medizinische Bildgebung -
Teil 3-2: Abnahmeprüfungen -
Leistungsmerkmale zur Bildgebung
von Röntgen-Einrichtungen
für die Mammographie
(IEC 61223-3-2:2007)

This European Standard was approved by CENELEC on 2008-06-01. 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 Central Secretariat or to any CENELEC member.

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 Central Secretariat has the same status as the official versions.

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

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62B/651/FDIS, future edition 2 of IEC 61223-3-2, 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 was approved by CENELEC as EN 61223-3-2 on 2008-06-01.

This European Standard supersedes EN 61223-3-2:1996.

EN 61223-3-2:2008 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 EN 61223-3-2:1996 and EN 61223-3-2:2008.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2009-03-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2011-06-01

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/TR 60788, EN 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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-3-2:2007 was approved by CENELEC as a European Standard without any modification.

CONTENTS

INTRODUCTION.....	5
1 Scope.....	6
2 Normative references	7
3 Terms and definitions	8
4 General aspects of the ACCEPTANCE TEST.....	11
4.1 Levels of compliance	11
4.2 General conditions in test procedures	11
4.3 Documents and data for the tests	12
4.4 Test conditions	13
4.5 Scope of tests	13
4.6 Test EQUIPMENT	14
4.7 Evaluating the test results	15
5 Test methods for mammographic X-RAY EQUIPMENT	16
5.1 Initial test and inventory	16
5.2 X-RAY TUBE VOLTAGE	16
5.3 HALF VALUE LAYER (HVL)	17
5.4 NOMINAL FOCAL SPOT VALUE	18
5.5 X-RAY FIELD limitation and beam alignment	18
5.6 Radiation output	19
5.7 AUTOMATIC EXPOSURE CONTROL (AEC)	19
5.8 Reproducibility of the AIR KERMA	25
5.9 ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE.....	25
5.10 Breast COMPRESSION DEVICE	26
5.11 Uniformity.....	27
5.12 Dynamic range of mammographic X-RAY EQUIPMENT using digital X-ray image receptors, including storage phosphor systems	29
5.13 Spatial resolution	30
5.14 LOW CONTRAST DETECTABILITY	33
5.15 Entrance surface AIR KERMA.....	34
5.16 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES	35
6 Baseline values for CONSTANCY TESTS	36
7 Test report and statement of compliance	36
Annex A (informative) TEST DEVICES and arrangements for testing the automatic exposure control system with a digital X-RAY IMAGE RECEPTOR.....	38
Annex B (informative) TEST DEVICE for testing the dynamic range of systems with a digital X-RAY IMAGE RECEPTOR.....	42
Annex C (informative) Test methods for screen-film X-ray image receptor	43
Annex D (informative) Test methods for storage phosphor system	45

Annex E (informative) Example of a method for the determination of the AVERAGE GLANDULAR DOSE	48
Annex F (informative) Example of TEST DEVICES and arrangements for testing the system contrast transfer function for systems with a digital X-RAY IMAGE RECEPTOR.....	50
Annex G (informative) LOW CONTRAST DETECTABILITY test for mammographic X-RAY EQUIPMENT using an integrated digital X-RAY IMAGE RECEPTOR or storage phosphor plates	51
Annex H (informative) Example of a mammographic stereotactic TEST DEVICE	53
Annex I (normative) Set-up for HALF-VALUE LAYER measurements	54
Annex J (informative) Definition of the ROIs for testing lag effects	55
Annex K (informative) ARTIFACTS and other non-uniformities	56
Annex L (informative) Cross reference and history	58
Annex ZA (normative) Normative references to international publications with their corresponding European publications.....	63
 Bibliography.....	 59
 Terminology – Index of defined terms	 61
 Figure A.1 – Basic ATTENUATION Plates.....	 38
Figure A.2 – Alternative design for the top attenuating plate	39
Figure A.3 – Alternative design for the two additional attenuating plates (two pieces required).....	40
Figure A.4 – Measurement of CNR: 2-step methods.....	41
Figure B.1 – Test object for the dynamic range (to be used together with a 20 mm PMMA plate placed on top).....	42
Figure F.1 – Example of 45° test pattern for the evaluation of the system contrast transfer function.....	50
Figure H.1 – Example of a mammographic stereotactic TEST DEVICE.....	53
Figure I.1 – Set-up for HALF-VALUE LAYER measurements.....	54
Figure J.1 – Definition of the ROIs for testing lag effects.....	55
 Table 1 – Symbols, physical quantities, abbreviations and units used in this standard	 10
Table 2 – Examples of typical HALF-VALUE LAYERS (HVL) in millimetres of aluminium (mm Al) for mammographic X-RAY EQUIPMENT with different TARGET FILTER combinations operated at different X-RAY TUBE VOLTAGES	17
Table E.1 – <i>g</i> for breasts simulated with PMMA	49
Table E.2 – <i>c</i> for breasts simulated with PMMA	49
Table E.3 – Typical HVL measurements for different tube voltage and TARGET FILTER combinations	49
Table E.4 – <i>s</i> for clinically used spectra [Dance et al. 2000].....	49
Table L.1 – Cross reference list for Editions 1 and 2 of this standard	58

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 semiconductor 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)	-
$\bar{G}$	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	μ Gy
K_N	Nominal AIR KERMA to generate a net density $D_n = 1,0$ (following the procedure of this standard)	μ Gy
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;

- test report on HARD COPY CAMERAS and IMAGE DISPLAY DEVICES; and
- test report on storage phosphor system.

4.4 Test conditions

Different categories of tests can be identified:

- visual inspection;
- functional tests; and
- system performance.

The tests shall yield information reasonably necessary for a demonstration of performance over the full range of OPERATOR accessible variables.

All relevant data, such as the identification of the mammographic X-RAY EQUIPMENT tested, identification of the test EQUIPMENT used, geometrical set-up, operating characteristics, correction factors and test results of the ASSOCIATED EQUIPMENT (film, screen, processing) shall be recorded with the test results. The record shall include the location, the date and the names of the persons performing the tests.

If not specified otherwise, in all tests where a TEST DEVICE is required, it shall be placed directly on the PATIENT SUPPORT. The TEST DEVICE shall be centred laterally on the PATIENT SUPPORT, and the chest wall edges of the TEST DEVICE and the PATIENT SUPPORT shall be in line.

4.5 Scope of tests

The following items are subject to acceptance testing within this standard:

- initial tests and inventory (5.1);
- X-RAY TUBE VOLTAGE (5.2);
- HALF VALUE LAYER (5.3);
- NOMINAL FOCAL SPOT VALUE (5.4);
- X-RAY FIELD limitation and beam alignment (5.5);
- radiation output (5.6);
- AUTOMATIC EXPOSURE CONTROL (AEC) (5.7);
- reproducibility of the AIR KERMA (5.8);
- ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE (5.9);
- breast COMPRESSION DEVICE (5.10);
- Uniformity (5.11);
- Dynamic range of mammographic X-RAY EQUIPMENT using digital X-ray image receptors, including storage phosphor systems (5.12);
- spatial resolution (5.13);
- LOW CONTRAST DETECTABILITY (5.14);
- entrance surface AIR KERMA (5.15); and
- Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES (5.16).

4.6 Test EQUIPMENT

4.6.1 General

The measurement EQUIPMENT used for the ACCEPTANCE TEST shall be certified as calibrated against a national or international standard where such a standard exists. Details on the test EQUIPMENT are specified in 4.6.2 to 4.6.8.

Test EQUIPMENT required but not specified in 4.6.2 to 4.6.8:

- thermometer (as required for film processor);
- block of foam rubber as specified in 5.10.3.1;
- magnifying glass (magnifying at least $\times 4$);
- TEST DEVICES;
- test cassette and radio-opaque markers as specified in 5.5.2;
- 20 mm PMMA as specified in 5.11.3.1;
- Wire grid as specified in 5.11.3.3;
- lag effects TEST DEVICE as specified in 5.11.3.4.1;
- spatial resolution bar pattern as specified in 5.13.1.2;
- TEST DEVICE with low contrast structures as specified in 5.14;
- step wedge in PMMA as described as an example in Annex B;
- stereotactic TEST DEVICE as described as an example in Annex H;
- measurement EQUIPMENT used for determining the baseline values for CONSTANCY TESTS according to Cause 6.

4.6.2 High-voltage measuring instrument

The high-voltage measuring instrument shall determine the X-RAY TUBE VOLTAGE within the specified range. Instruments based on either direct or indirect measurements following IEC 61676 (2002) may be used. The OVERALL UNCERTAINTY shall be less than $\pm 2\%$ or $\pm 0,7$ kV, whichever is the larger.

NOTE Special features of mammographic X-RAY EQUIPMENT such as molybdenum TARGETS and possible K-edge FILTERS will be taken into account when calibrating the devices used for indirect measurements. The quoted uncertainty with non-invasive test methods can often only be achieved with special calibration for the type of X-RAY EQUIPMENT under test.

4.6.3 CURRENT TIME PRODUCT measuring instrument

The range of this device shall cover the range of the CURRENT TIME PRODUCT selectable with the X-RAY EQUIPMENT, typically 0 mAs to 800 mAs. The OVERALL UNCERTAINTY shall not exceed $\pm 5\%$ or $\pm 0,5$ mAs, whichever is the larger. If the built-in CURRENT TIME PRODUCT measuring instrument is to be used in the ACCEPTANCE TEST, it shall be proven by calibration to comply with these specifications.

4.6.4 LOADING TIME measuring instrument

The LOADING TIME measuring instrument shall enable the LOADING TIME to be determined according to IEC 60601-2-45. The shortest and longest specified LOADING TIMES shall be measurable. The OVERALL UNCERTAINTY shall not exceed $\pm 2\%$ or ± 1 ms, whichever is the larger. If the built-in LOADING TIME measuring instrument is to be used in the ACCEPTANCE TEST, it shall be proved by calibration to comply with these specifications.

4.6.5 DOSIMETER

The range of the integrating DOSIMETER for the measurement of the AIR KERMA shall be at least 10 µGy to 500 µGy for the measurements behind a PHANTOM, and at least 0,1 mGy to 100 mGy for direct output measurements, with an OVERALL UNCERTAINTY less than ±10 %. This includes recombination losses at the AIR KERMA RATES involved (up to 100 mGy/s) and uncertainties with regard to the energy response of the DOSIMETER and the actual X-RAY SPECTRUM. The DOSIMETER used for measurement of AIR KERMA shall conform to IEC 61674.

4.6.6 ATTENUATION layers

4.6.6.1 TEST DEVICES for AUTOMATIC EXPOSURE CONTROL (AEC) system

The ATTENUATION layers shall be made of PMMA. The thickness of ATTENUATION layers shall be so that they can be stacked to form TEST DEVICES of 20 mm, 40 mm, 60 mm and 70 mm. The tolerances for the thickness shall be within ±1 mm, and the uniformity of the thickness shall be within ±0,1 mm. The other dimensions shall be either semi-circular with a radius of at least 100 mm, or rectangular with sides of at least 100 mm × 150 mm.

4.6.6.2 ATTENUATION layers for first HALF-VALUE LAYER measurements

There shall be at least two different layers of aluminium foils. The thickness of the layers shall be in the range from 0,2 mm to 0,6 mm, and should be chosen depending on the specified first HALF-VALUE LAYERS. The foils shall be of 99,9 % purity. The thickness of the foils shall be known within ±3 %.

NOTE Information on the chemical composition of aluminium can be found in EN 573-3.

4.6.7 Densitometer

The densitometer shall cover the optical density range 0 to 4,0 with an OVERALL UNCERTAINTY that meets the conditions:

$$|\Delta D| \leq 0,02 \text{ (for } D \leq 1)$$

and $|\Delta D| / D \leq 0,02 \text{ (for } D > 1)$

4.6.8 Compression force measuring device

A force scale with a range of at least 50 N to 300 N and an OVERALL UNCERTAINTY of less than ±5 N shall be used.

4.7 Evaluating the test results

Whenever specified limiting values or tolerances are exceeded, verify the results by making at least two additional measurements.

In the evaluation of results concerning limit values (upper or lower), the uncertainty in the measurement shall be taken into consideration.

5 Test methods for mammographic X-RAY EQUIPMENT

5.1 Initial test and inventory

5.1.1 Requirements

The operation and functioning of the X-RAY EQUIPMENT shall comply with what is specified.

The INSTRUCTIONS FOR USE shall describe comprehensively how the mammographic X-RAY EQUIPMENT under test is to be operated. The function of all control devices (such as knobs, switches, touch-panels), indicators and displays shall be described, and all symbols shall be illustrated with their significance. Reproductions in the INSTRUCTIONS FOR USE shall be in agreement with the actual X-RAY EQUIPMENT, with respect to position, labels and symbols. The INSTRUCTIONS FOR USE shall be present in the language that has been agreed on.

In the case of a non-integrated image receptor, the ACCEPTANCE TESTS should be performed against the specification provided by the system integrator.

5.1.2 Test method

5.1.2.1 Visual inspection and functional check

The DIRECT FOCAL DISTANCE shall be checked by inspection of the ACCOMPANYING DOCUMENTS.

The compatibility of the components in the system (e.g. HARD COPY CAMERA) which are not an integral part of the mammographic X-RAY EQUIPMENT shall be assured by checking the ACCOMPANYING DOCUMENTS and by functional tests as defined by the MANUFACTURER.

The test is performed by visual inspection and functional check. It comprises:

- presence of all documents according to 4.3;
- inventory of EQUIPMENT under test, including individual identification data for all components;
- visual inspection of the INSTRUCTIONS FOR USE (IEC 60601-1);
- functional check of the mechanical adjustment devices;
- functional check and identification of the control elements;
- visual inspection of the labelling of the control elements;
- visual inspection of the markings; and
- mechanical integrity of the EQUIPMENT.

5.1.2.2 Mechanical functionality

Check against acceptance criteria according to this standard as agreed upon between the USER and the supplier of the EQUIPMENT, e.g. movements, speeds, forces, interlocks.

5.2 X-RAY TUBE VOLTAGE

5.2.1 Requirements

The MEASURED VALUES for the X-RAY TUBE VOLTAGE shall agree with the INDICATED VALUES on the X-ray generator control within the specified tolerances.

5.2.2 Test methods

The test shall comprise of at least three values for the X-RAY TUBE VOLTAGE, covering the clinical range of applications, for all FOCAL SPOTS and, when applicable, for the different settings of the X-RAY TUBE CURRENT. It is sufficient to perform the test for only one TARGET FILTER combination.

NOTE Direct measurements for the reproducibility of the X-RAY TUBE VOLTAGE are not part of the ACCEPTANCE TEST because the evaluation of the radiation output reproducibility (see 5.6) implies a statement on the X-RAY TUBE VOLTAGE reproducibility.

5.3 HALF VALUE LAYER (HVL)

5.3.1 Requirements

The HVL shall comply with the MANUFACTURER's specification and IEC 60601-2-45.

5.3.2 Test methods

Remove the breast compression plate for this test. A narrow beam geometry with a large distance between absorber and detector is used according to Annex I. Set the X-RAY TUBE VOLTAGE to 28 kV and measure the HALF-VALUE LAYER for each TARGET FILTER combination.

If an X-RAY TUBE VOLTAGE of 28 kV is not applicable to the system the test shall be performed according to the MANUFACTURER's specification.

Perform the AIR KERMA measurements at a point centred laterally over the PATIENT SUPPORT, and 6 cm off its chest wall edge. Examples of typical values for the HALF-VALUE LAYER for various combinations of TARGET and FILTER materials are given in Table 2.

Compare the results of the HALF-VALUE LAYER measurements with the specified values. For automatically or manually interchangeable FILTERS, check by HALF-VALUE LAYER measurements that the correct FILTER is in the indicated position.

Table 2 – Examples of typical HALF-VALUE LAYERS (HVL) in millimetres of aluminium (mm Al) for mammographic X-RAY EQUIPMENT with different TARGET FILTER combinations operated at different X-RAY TUBE VOLTAGES

TARGET and FILTER materials	HVL at 25 kV mm Al	HVL at 28 kV mm Al
Mo + 30 µm Mo	0,28	0,32
Mo + 25 µm Rh	0,36	0,40
W + 60 µm Mo	0,35	0,37
W + 50 µm Rh	0,48	0,51
Rh + 25 µm Rh	0,34	0,39
W + 500 µm Al	0,40	0,46

NOTE In a good approximation, the HALF VALUE LAYER (HVL) can be calculated by using the following equation:

$$\text{HVL} = \frac{d_1 \cdot \ln(2 \cdot K_2/K_0) - d_2 \cdot \ln(2 \cdot K_1/K_0)}{\ln(K_2/K_1)}$$

if the thickness d_1 and d_2 of the aluminium foils used do not differ by more than 0,2 mm from the HALF VALUE LAYER to be determined. K_1 and K_2 are the related values of AIR KERMA, and K_0 is the AIR KERMA measured without any additional aluminium foil in the RADIATION BEAM. All AIR KERMA values refer to the same CURRENT TIME PRODUCT.

5.4 NOMINAL FOCAL SPOT VALUE

5.4.1 Requirements

The specification for the NOMINAL FOCAL SPOT VALUE stated in the ACCOMPANYING DOCUMENTS shall comply with IEC 60336.

5.4.2 Test method

Compliance of the FOCAL SPOT size to the specified NOMINAL FOCAL SPOT VALUE according to IEC 60336 shall be done by inspection of the ACCOMPANYING DOCUMENTS of the tube provided by the MANUFACTURER.

5.5 X-RAY FIELD limitation and beam alignment

5.5.1 Requirements

The extent of the RADIATION BEAM shall comply with the tolerances specified in IEC 60601-2-45. In addition all those parts of an object placed on the PATIENT SUPPORT that are specified to be imaged shall be visible in the RADIOGRAM.

5.5.2 Test methods

Check the alignment of the RADIATION BEAM with the IMAGE RECEPTION AREA for all specified DIRECT FOCAL DISTANCES, PATIENT SUPPORTS, TARGETS and FOCAL SPOTS, and for all available X-RAY IMAGE RECEPTOR formats.

Place on top of the PATIENT SUPPORT a test cassette in such a way that it overlaps all sides of the image receptor beneath, with sufficient margins. The test cassette which contains a film and screen, or storage phosphor material shall be large enough to cover the image receptor evaluated. The test cassette may be rotated so as to cover the image receptor. Place radio-opaque markers, for example graduated rulers, on top of the test cassette. Make an image and process the film of the test cassette or read out its storage phosphor plate, respectively. The displacement between the RADIATION BEAM and the image receptor can be measured from the two images. In case no film processing or CR capability is available on the site, alternate x-ray sensors, such as long persistence phosphors or instant processing films shall be used.

To test the visibility of those parts of the object placed at the edge of the PATIENT SUPPORT intended to be in contact with the chest wall, an image of a TEST DEVICE incorporating markers at a fixed distance from this edge should be used. For image receptors using reloadable cassettes such as screen film or CR this measurement should be repeated several times to check whether the insertion of the image receptor (film or plate) in the cassette is reproducible.

NOTE 1 In the case of film screen systems, it may be desirable to specify a slight over-framing of the IMAGE RECEPTION AREA because this permits the USER to avoid transparent margins on the film. This can be justified in the interests of reading diagnostic information from the mammograms, especially in circumstances where a masking of films for viewing is impracticable.