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**IEC
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61223-3-2

Second edition
Deuxième édition
2007-07

**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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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	8
3 Terms and definitions	9
4 General aspects of the ACCEPTANCE TEST.....	12
4.1 Levels of compliance	12
4.2 General conditions in test procedures	12
4.3 Documents and data for the tests	13
4.4 Test conditions	14
4.5 Scope of tests	14
4.6 Test EQUIPMENT	15
4.7 Evaluating the test results	16
5 Test methods for mammographic X-RAY EQUIPMENT	17
5.1 Initial test and inventory	17
5.2 X-RAY TUBE VOLTAGE	17
5.3 HALF VALUE LAYER (HVL)	18
5.4 NOMINAL FOCAL SPOT VALUE	19
5.5 X-RAY FIELD limitation and beam alignment	19
5.6 Radiation output	20
5.7 AUTOMATIC EXPOSURE CONTROL (AEC).....	20
5.8 Reproducibility of the AIR KERMA	26
5.9 ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE.....	26
5.10 Breast COMPRESSION DEVICE	27
5.11 Uniformity.....	28
5.12 Dynamic range of mammographic X-RAY EQUIPMENT using digital X-ray image receptors, including storage phosphor systems	30
5.13 Spatial resolution	31
5.14 LOW CONTRAST DETECTABILITY	34
5.15 Entrance surface AIR KERMA.....	35
5.16 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES	36
6 Baseline values for CONSTANCY TESTS	37
7 Test report and statement of compliance	37
Annex A (informative) TEST DEVICES and arrangements for testing the automatic exposure control system with a digital X-RAY IMAGE RECEPTOR.....	39
Annex B (informative) TEST DEVICE for testing the dynamic range of systems with a digital X-RAY IMAGE RECEPTOR.....	43
Annex C (informative) Test methods for screen-film X-ray image receptor	44
Annex D (informative) Test methods for storage phosphor system	46

Annex E (informative) Example of a method for the determination of the AVERAGE GLANDULAR DOSE	49
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.....	51
Annex G (informative) LOW CONTRAST DETECTABILITY test for mammographic X-RAY EQUIPMENT using an integrated digital X-RAY IMAGE RECEPTOR or storage phosphor plates	52
Annex H (informative) Example of a mammographic stereotactic TEST DEVICE	54
Annex I (normative) Set-up for HALF-VALUE LAYER measurements	55
Annex J (informative) Definition of the ROIs for testing lag effects	56
Annex K (informative) ARTIFACTS and other non-uniformities	57
Annex L (informative) Cross reference and history	59
 Bibliography.....	 60
 Terminology – Index of defined terms	 62
 Figure A.1 – Basic ATTENUATION Plates.....	 39
Figure A.2 – Alternative design for the top attenuating plate	40
Figure A.3 – Alternative design for the two additional attenuating plates (two pieces required).....	41
Figure A.4 – Measurement of CNR: 2-step methods.....	42
Figure B.1 – Test object for the dynamic range (to be used together with a 20 mm PMMA plate placed on top)	43
Figure F.1 – Example of 45° test pattern for the evaluation of the system contrast transfer function.....	51
Figure H.1 – Example of a mammographic stereotactic TEST DEVICE.....	54
Figure I.1 – Set-up for HALF-VALUE LAYER measurements.....	55
Figure J.1 – Definition of the ROIs for testing lag effects.....	56
 Table 1 – Symbols, physical quantities, abbreviations and units used in this standard	 11
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	18
Table E.1 – <i>g</i> for breasts simulated with PMMA	50
Table E.2 – <i>c</i> for breasts simulated with PMMA	50
Table E.3 – Typical HVL measurements for different tube voltage and TARGET FILTER combinations	50
Table E.4 – <i>s</i> for clinically used spectra [Dance et al. 2000].....	50
Table L.1 – Cross reference list for Editions 1 and 2 of this standard	59

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 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 μ Gy to 500 μ Gy 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 $\pm 0,1$ 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 $\times$ 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.

NOTE 2 The tolerances of the film position in the cassette should be taken into account in the evaluation of the results, for example by positioning the film within the cassette manually as close to the chest wall edge as possible and centring it in the transverse direction.

5.6 Radiation output

5.6.1 Requirements

The reproducibility of the radiation output with the CURRENT TIME PRODUCT shall comply with the MANUFACTURER's specification. The AIR KERMA RATE (in mGy/s) and the radiation output (in $\mu\text{Gy/mAs}$) shall comply with the MANUFACTURER's specifications.

5.6.2 Test method

The AIR KERMA shall be measured at a point located 40 mm over the PATIENT SUPPORT, centred laterally, and 6 cm off its chest wall edge.

a) Radiation output reproducibility

At least 5 measurements of the AIR KERMA shall be performed at a specific combination of CURRENT TIME PRODUCT and X-RAY TUBE VOLTAGE.

b) Radiation output

For all combinations of TARGET and FILTER stated in the ACCOMPANYING DOCUMENTS, the AIR KERMA RATE (in mGy/s) and the specific radiation output (in $\mu\text{Gy/mAs}$) shall be determined at an X-RAY TUBE VOLTAGE of 28 kV, for all FOCAL SPOTS, without a breast compression plate in the RADIATION BEAM.

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.

5.6.3 Evaluation of the measurements

a) Radiation output reproducibility

The measurements shall be evaluated by calculating the coefficient of variation and comparing it with the specified tolerance. The coefficient of variation shall be calculated as the quotient of the standard deviation of the AIR KERMA values divided by the mean of the AIR KERMA values.

b) Radiation output

The measured AIR KERMA RATES (in mGy/s) shall be compared with the specified values.

Values of specific radiation output (in $\mu\text{Gy/mAs}$) shall be calculated from the MEASURED VALUES by referencing them to a distance of 100 cm from the FOCAL SPOT. The specific radiation output values shall be compared with the specified values.

NOTE For measuring in the unattenuated RADIATION BEAM and for different TARGET FILTER combinations, MANUFACTURERS of DOSIMETERS usually give calibration factors according to the DOSIMETER's energy dependency.

5.7 AUTOMATIC EXPOSURE CONTROL (AEC)

5.7.1 AEC for film-screen systems

5.7.1.1 General

The performance of the AEC shall be evaluated by measuring the optical density of the film.

In addition, the reproducibility of AIR KERMA shall be tested with constant IRRADIATION conditions. In parallel to all tests, the CURRENT TIME PRODUCT shall be recorded for evaluation of consistency. All settings shall be kept constant during the tests.

5.7.1.2 Requirements

- a) Using AEC at a specified X-RAY TUBE VOLTAGE with specified IRRADIATIONS and specified test devices shall give optical densities in the specified range for a specified screen-film system.
- b) The variation of optical densities with TEST DEVICE thickness, X-RAY TUBE VOLTAGE and ANTI-SCATTER GRID/no ANTI-SCATTER GRID techniques shall be within the specified tolerances.
- c) Adjacent correction steps shall lead to a change in optical density or in LOADING FACTORS within the specified tolerances.

5.7.1.3 Test methods

5.7.1.3.1 Multiple AEC sensors

In case of multiple OPERATOR selectable AEC sensor configurations, only one reference configuration shall be selected and tested according to 5.7.1.3.2. The other selectable sensor configurations shall be compared to this reference configuration using the same settings as for the reference RADIOGRAM. The optical density of the obtained RADIOGRAMS shall be within the specified limits. If there is no provision for manual selection of the AEC sensor configurations, the test shall be performed using the configuration selected by the EQUIPMENT.

5.7.1.3.2 Test method and setting for optical density

The TEST DEVICE shall be of material PMMA. The active area of the AEC sensor shall remain in the same position throughout the tests, and it shall be fully covered by the TEST DEVICE. A breast compression plate shall be in the RADIATION BEAM. The active area of the AEC sensor shall not be too close to the chest wall edge of the PATIENT SUPPORT or to any edge of the TEST DEVICE to avoid effects, such as interfering scatter effects caused by the edge of the TEST DEVICE.

Use the RADIOGRAPHIC FILM, INTENSIFYING SCREEN and RADIOGRAPHIC CASSETTE types which are intended to be used with PATIENTS. Use the same RADIOGRAPHIC CASSETTE for all these tests and process the films under normal, stable conditions. Measure the optical densities or the optical densities differences in the same specified areas of the film and compare with the MANUFACTURER's specifications.

NOTE The risk of unstable film processing conditions taking influence on the measurement results can be reduced by performing the test without interruptions. For reducing the influence of latent image fading, it is important to keep a constant time interval between the IRRADIATION and the film processing.

5.7.1.3.3 Reference RADIOGRAM

With the technique preferred as default technique by the USER, a reference RADIOGRAM shall be made, using an X-RAY TUBE VOLTAGE of 28 kV. The TARGET, the FILTER and the FOCAL SPOT shall be chosen according to the INSTRUCTIONS FOR USE.

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.

This reference RADIOGRAM shall be made using a TEST DEVICE of 40 mm thickness and the optical density D of the RADIOGRAM shall be in the range of 1,4 to 2,0.

The optical density measured in this RADIOGRAM shall serve as reference value for the test in 5.7.1.3.4.

5.7.1.3.4 Test method for the influence of layer thickness variation and X-RAY TUBE VOLTAGE variation for ANTI-SCATTER GRID/no ANTI-SCATTER GRID techniques

With all settings of the AEC as used in 5.7.1.3.3, including the correction step, RADIOGRAMS are to be made for at least three different TEST DEVICE thicknesses (e.g. 20 mm, 40 mm, 60 mm), using different combinations of X-RAY TUBE VOLTAGE, TARGET, and FILTER, with or without ANTI-SCATTER GRID according to the INSTRUCTIONS FOR USE. At least three different values of X-RAY TUBE VOLTAGE shall be used. For each RADIOGRAM the deviation of the optical density from the reference value determined before shall be evaluated.

5.7.1.3.5 Step size and adjustable range of optical density

For the evaluation of the optical density control, the correction step settings are to be varied within an optical density of $\pm 0,5$ around the density of the reference RADIOGRAM, with the other conditions as defined under 5.7.1.3.3. The difference in optical density of the films shall be evaluated for adjacent steps.

5.7.2 AEC for mammographic X-RAY EQUIPMENT using storage phosphor plates and for systems with an integrated digital X-RAY IMAGE RECEPTOR

5.7.2.1 General

Using the definition for AEC within this document, the AEC test for mammographic X-RAY EQUIPMENT with storage phosphor plates and for systems with an integrated digital X-RAY IMAGE RECEPTOR should include the test of following three items:

- AEC setting confirmation test;
check that the storage phosphor plate sensitivity lies between the upper and lower limit for each AEC setting which will be used in clinical practice;
- reproducibility and accuracy test, as described in 5.8;
- LOW CONTRAST DETECTABILITY test, as described in 5.14.2.

Accordingly, the AEC test for mammographic X-RAY EQUIPMENT using storage phosphor plates and for systems with an integrated digital X-RAY IMAGE RECEPTOR, the AEC test procedure includes the AEC setting confirmation test and the reproducibility and accuracy test above.

NOTE Contrary to film/screen imaging, where the imaging performance of the image receptor is nominal only on a very narrow range of exposure (film latitude), the selection of IRRADIATION parameters is not necessarily meant to maintain constant doses or levels. Its primary goal is to ensure that a consistent image quality and dose level is reached for the various possible properties of the breasts to be imaged. However, it should be noticed that a constantly high image quality level cannot be reached for all the breast thicknesses with acceptable patient dose levels. Image quality will generally be inferior, as well as dose will generally be higher for larger/denser breasts. As a consequence, no attempt will be made to check a strict constancy of image parameters or dose for various breast properties or operating conditions.

The performance of the AEC shall be evaluated by jointly assessing image quality as measured by the CONTRAST TO NOISE RATIO in specified conditions, and the dose to the patient as characterized by the AVERAGE GLANDULAR DOSE, and comparing them to the specifications provided by the MANUFACTURER.

In addition, the reproducibility of AIR KERMA shall be tested with constant IRRADIATION conditions.

5.7.2.2 Requirements

Using AEC operation to produce RADIOGRAMS of each of a set of specified TEST DEVICES,

- the values of contrast to noise ratio (CNR) in the radiograms shall be higher than the minimum values specified by the manufacturer and shall conform with the system image quality test defined in 5.14.2. Alternatively, the dose value corresponding and converted from the image quality specified by the values of the CNR specific to the X-ray generator and receptor system combination in the radiograms shall be higher than the minimum values specified by the manufacturer and shall be conformed with the system image quality test in accordance with 5.14.2.

Alternatively, the values of signal to noise ratio (SNR) in the radiograms shall be higher than the minimum values specified by the manufacturer and shall conform with the system image quality test defined in 5.14.2;

- the average glandular dose deduced in the same conditions shall be lower than the maximum values specified by the manufacturer;
- reproducibility and accuracy in each test condition shall be within the limit values specified by the manufacturer.

The requirements shall be met for the various usable operating conditions present in the EQUIPMENT (e.g. pre-selected IRRADIATION programs or dose mode, magnification mode)

5.7.2.3 Determination of operating conditions

5.7.2.3.1 TEST DEVICES

The test shall be performed using a TEST DEVICE according to the MANUFACTURER's specifications and in compliance with 4.6.6.1.

NOTE 1 It should be noted that the European guidelines require tests from 20 mm to 70 mm with 10 mm steps, plus 45 mm.

NOTE 2 More and more EQUIPMENT are using flexible or articulated breast compression plates, that behave differently in their reaction to breast area. Since the compressed breast thickness can be used as an input parameter to the AEC, care should be taken that this measurement is not altered too much compared to a real breast. For the same reason, the PHANTOM shape could be improved by a chamfer or rounded edge.

5.7.2.3.2 Operating conditions

If it is possible to select the active area of the AEC sensor manually, it shall remain in the same position throughout the tests. The active area of the AEC sensor shall be sufficiently distant to the chest wall edge of the PATIENT SUPPORT to avoid effects caused by the edge of the TEST DEVICE, such as interfering scatter effects caused by the edge of the TEST DEVICE. The AEC sensor shall be fully covered by the TEST DEVICE.

NOTE 1 The AEC sensor can be either a distinct device as with film/screen radiography or, more probably, a specific function of the EQUIPMENT generating a signal from the image receptor to the AEC.

A breast compression plate shall be in the RADIATION BEAM, and a typical compression force applied, according to the MANUFACTURER's specification.

NOTE 2 The prescribed compression force may differ from a clinically relevant force, due to the difference in behaviour of breast compression plate between a rigid PHANTOM and the breast.

When an AEC mode requires the preliminary manual setting of some of the parameters of the exposure (X-RAY TUBE VOLTAGE, TARGET, and FILTER, presence or not of an ANTI-SCATTER GRID), they shall be selected according to the INSTRUCTIONS FOR USE.

For each RADIOGRAM to be acquired, only the attenuating plates shall be present in the field of view.

NOTE 3 The rationale is to avoid any interference between the automatic exposure sensor and structures present in the contrast detail plate or DOSIMETER sensor.

If the manual setting of some of the parameters requires the knowledge of the object thickness, it shall be determined from the EQUIPMENT display instead of the actual thickness of the test plates.

5.7.2.3.3 Test method

The exposure shall be performed

- for the different TEST DEVICE thickness (20 mm, 40 mm, 60 mm, 70 mm),
- using the various degrees of automatic operation available in the EQUIPMENT, and
- at different modes of operations available on the EQUIPMENT as specified. Examples of such modes of operation are different levels of sensitivity, or image quality, or resolution,
- for reproducibility and accuracy in each test condition.

For each exposure, the set of parameters including both the manual settings and those resulting from the AEC operation shall be used for the test in 5.7.2.5.2.

5.7.2.4 Determination of the CONTRAST TO NOISE RATIO (CNR)

5.7.2.4.1 TEST DEVICE

Test objects according to 5.7.2.3.1 shall be used, supplemented with a piece of aluminium foil positioned on top (see Figure A.4 for an example). The aluminium foil shall have a thickness of $(0,20 \pm 0,01)$ mm, and the purity of the aluminium shall be 99,9 %.

NOTE 1 The measurement of the CONTRAST TO NOISE RATIO is used only to evaluate the MANUFACTURER'S specification on the system. This measurement does not imply that the value measured can be directly related to clinical image quality.

NOTE 2 Information on the chemical composition of aluminium can be found in EN 573-3.

5.7.2.4.2 Acquisition of the RADIOGRAMS without the aluminium foil

For each of the conditions where an exposure has been made as described in 5.7.2.3.3, select the manual operation, adjust all x-ray parameters to the values previously recorded and acquire a RADIOGRAM in conditions allowing to perform measurements on a raw image. If the value of CURRENT TIME PRODUCT cannot be adjusted within 5 % of the previous value, make two images using the two closest selectable positions respectively lower and higher than the value obtained in automatic mode.

5.7.2.4.3 Acquisition of the RADIOGRAMS with the aluminium foil

Position, on top of the attenuating plates, the aluminium foil described in 5.7.2.4.1, laterally centred, and repeat the operations described in 5.7.2.4.2.

5.7.2.4.4 Determination of the CNR on the RADIOGRAMS

For each of the conditions where a pair of RADIOGRAMS has been acquired (respectively without and with the aluminium foil), measure the average pixel value m and pixel standard deviation σ in the regions of interests described in Figure A.4, respectively placed inside the image of the aluminium foil (m_{Al} , σ_{Al}) and inside image of the background (m_{BG} , σ_{BG}).

$$\text{Compute CNR} = \frac{m_{BG} - m_{Al}}{\sqrt{\frac{(\sigma_{BG}^2 + \sigma_{Al}^2)}{2}}}$$

If $\sigma_{BG} - \sigma_{Al}$ is small, the formula may be simplified by using σ_{BG} as the denominator.

If it has been necessary to acquire two images at CURRENT TIME PRODUCT values lower and higher than the values obtained in automatic mode, determine the CNR values for each of the CURRENT TIME PRODUCT values and determine the CNR value at the desired level by linear interpolating CNR² versus X-RAY TUBE CURRENT TIME PRODUCT.

5.7.2.5 Determination of the AVERAGE GLANDULAR DOSE (AGD)

5.7.2.5.1 Test conditions

Remove the TEST DEVICE; for each of the measuring conditions where an exposure was performed, position the breast compression plate in the same position, and a DOSIMETER sensor as close as possible to the underside of the breast compression plate (i.e. the side contacting the patient breast). If necessary, the sensor can be positioned using a block of low density (< 100 kg/m³) polymer foam placed on the PATIENT SUPPORT.

5.7.2.5.2 Determination of the entrance surface AIR KERMA

For each of the conditions where an automatic exposure has been made as described in 5.7.2.3.3, select the manual operation, adjust all x-ray parameters to the values previously recorded, and perform an exposure using the same value of CURRENT TIME PRODUCT as during the aforementioned automatic exposure. If it is not possible to use the same value, use the closest value possible. The entrance surface AIR KERMA shall be determined by applying to the measurement a correction factor proportional to the ratio in CURRENT TIME PRODUCT (assuming a good linearity of AIR KERMA versus CURRENT TIME PRODUCT).

If the distance between the reference plane of the dose sensor and the breast compression plate is larger than 1 % of the distance between the FOCAL SPOT and the surface of the breast compression plate facing the detector, a correction shall be applied using the inverse square law.

5.7.2.5.3 Determination of the AGD

The AVERAGE GLANDULAR DOSE shall be determined using the method specified by the MANUFACTURER. An example of such a method is in Annex E.

5.7.2.5.4 Evaluation of the results

For each of the RADIOGRAMS, compare the results with the values specified by the MANUFACTURER.

- The MEASURED VALUE of the CNR shall be higher or equal to the specified minimum. Alternatively, for a specific X-ray generator and receptor system combination, the dose value corresponding to the values of the CNR shall be higher than the minimum values specified by the MANUFACTURER.
- The MEASURED VALUE of the reproducibility and accuracy in each test condition shall be within the limit values.

5.8 Reproducibility of the AIR KERMA

5.8.1 Requirement

Under constant test conditions the AIR KERMA shall remain within the specified tolerances.

5.8.2 Test procedure

Use test objects according to 4.6.6.1 in a configuration of 40 mm total thickness and place them on the PATIENT SUPPORT. Place the detector for AIR KERMA measurement on top, and take care that the detector does not cover the chamber nor the active area of the AEC sensor nor interferes otherwise with the AEC function. The AIR KERMA shall be measured at five subsequent LOADINGS applied at a constant X-RAY TUBE VOLTAGE. The reproducibility shall be evaluated using the coefficient of variation which is calculated as the quotient of the standard deviation and the mean of the AIR KERMA values measured.

5.9 ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE

5.9.1 Requirements

The ATTENUATION of the RADIATION BEAM for material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE shall not exceed the specified values.

5.9.2 Test methods

The evidence of compliance with the specification shall be provided by the MANUFACTURER.

5.10 Breast COMPRESSION DEVICE

5.10.1 General

The following parameters shall be tested:

- a) indication of force,
- b) maximum compression force, and
- c) sustainability of the compression force applied.

5.10.2 Requirements

- a) Indication of force

The value of the applied force displayed shall be within MANUFACTURER's specification.

- b) Maximum compression force

For a motorized breast COMPRESSION DEVICE, the maximum possible compression force shall be within MANUFACTURER's specification.

- c) Sustainability of the compression force applied

The applied compression force shall be maintained according to the specified values.

5.10.3 Test method

5.10.3.1 Test EQUIPMENT

The following test EQUIPMENT is required:

- a force scale, and
- a soft rubber block, 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide.

5.10.3.2 Test procedure

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Place the scale on the PATIENT SUPPORT and fix it so that it will not fall down in any orientation. Place the soft rubber block on the sensitive area of the scale. Operate the breast COMPRESSION DEVICE, thus clamping the soft rubber block, and record the reading of the scale and the displayed value.

The compression should also be tested at 90° and 180° of the X-RAY TUBE – image receptor assembly rotation, if the test instrument can be used at these angles.

Perform at least five measurements of compression force in a sequence of 1 min over the range stated in the ACCOMPANYING DOCUMENTS, equally distributed from zero compression to the maximum possible compression force.

5.10.4 Determination of compliance

- a) Indication of force

Compare the MEASURED VALUES with the displayed values, applying the above requirements of accuracy.

b) Maximum compression force

Compare the maximum MEASURED VALUE with the value stated in the ACCOMPANYING DOCUMENTS.

c) Sustainability of the compression force applied

Check that the compression force is maintained (tolerance –10 N) over a period of 1 min.

5.11 Uniformity

5.11.1 General

Except where explicitly mentioned, this subclause is not applicable to non-uniformities caused by RADIOGRAPHIC FILM and film processing, INTENSIFYING SCREENS, storage phosphor plates and RADIOGRAPHIC CASSETTES. In addition, except where explicitly mentioned, this subclause is not applicable to storage phosphor plate readers, HARD COPY CAMERAS, viewing boxes and IMAGE DISPLAY DEVICES. A discussion of ARTIFACTS and other non-uniformities is presented in Annex K.

5.11.2 Requirements

Mammographic images shall be free of such non-uniformities which could impact medical effectiveness.

Grid lines shall be completely blurred in the specified range of ATTENUATION layer thickness or LOADING TIME.

The extent of lag effects shall comply with the specified tolerances.

The intercepting layers in the RADIATION BEAM shall not generate ARTIFACTS in the radiographic image which could be detrimental to medical diagnostics.

5.11.3 Test methods

5.11.3.1 Basic test

- a) Insert a homogeneous ATTENUATION layer of 20 mm PMMA in the RADIATION BEAM, large enough so that no RADIATION can pass directly to the X-RAY IMAGE RECEPTOR. For X-RAY EQUIPMENT comprising an ANTI-SCATTER GRID take care that the FOCAL SPOT to grid distance is close to the ANTI-SCATTER GRID's focusing distance.
- b) Release an exposure in AEC mode using an X-RAY TUBE VOLTAGE of 25 kV or the nearest setting. If no AEC mode is available use a CURRENT TIME PRODUCT derived from clinical values. Perform the usual steps to produce a visible image. If RADIOGRAPHIC FILM is used the resulting optical density D should be about 1,6.
- c) View the RADIOGRAMS using the same room illumination level and the same means which are used in medical practice (viewing box or IMAGE DISPLAY DEVICE). For digital systems use values of contrast and brightness that correspond to those used in medical practice. Examine the RADIOGRAMS visually for the presence of any non-uniformity that could be detrimental to medical diagnostics. If images of scratches are detected on the RADIOGRAM, inspect the PMMA ATTENUATION layer to determine whether the PMMA or the X-ray image receptor is the cause. Retake the exposure with the ATTENUATION layer moved to confirm the origin or the scratches.

- d) Repeat the test for all PATIENT SUPPORTS and breast compression plates that are part of the X-RAY EQUIPMENT.

NOTE Applying digital post processing algorithms to essentially uniform images can produce excessive contrast enhancement that will not be present in clinical images.

5.11.3.2 Moving ANTI-SCATTER GRID blurring

Perform this test if the X-RAY EQUIPMENT comprises one or more moving ANTI-SCATTER GRIDS.

- a) Replace the ATTENUATION layer of 20 mm PMMA with ATTENUATION layers of specified thickness and repeat the procedure in 5.11.3.1. Alternatively, if the range to be tested has been specified in terms of LOADING TIME then use ATTENUATION layers of appropriate thickness so that the specified range of LOADING TIME is covered.
- b) Display, view and examine the RADIOGRAMS as described in 5.11.3.1.
- c) Repeat the test for all ANTI-SCATTER GRIDS that are part of the X-RAY EQUIPMENT.

5.11.3.3 Image distortion

Perform this test if the X-RAY IMAGE RECEPTOR is not a screen-film system.

- a) Modify the set-up specified for the basic test (ATTENUATION layer of 20 mm PMMA) by positioning a wire grid close to the X-RAY IMAGE RECEPTOR, large enough to cover the entire IMAGE RECEPTION AREA. The wire grid may be placed between two thin plates of PMMA to ensure that it is sufficiently flat.
- b) Make an image in the same way as described for the basic test.
- c) Examine the RADIOGRAM for any image distortion that could be detrimental to medical diagnostics.
- d) If clinically relevant limiting values for displacement of lines have been specified then perform the necessary measurements.

5.11.3.4 Lag effects

5.11.3.4.1 Additive lag effects

Perform this test if the X-RAY EQUIPMENT comprises a digital X-ray imaging device. Operate the digital X-ray imaging device according to the specifications of the MANUFACTURER.

- a) Place an ATTENUATION plate on the PATIENT SUPPORT. The ATTENUATION plate shall have dimensions of at least 60 mm by 60 mm. The ATTENUATION plate shall be tungsten (at least 0,1 mm thickness), stainless steel (at least 0,2 mm thickness), aluminum (at least 4,0 mm thickness), or other equivalent X-ray ATTENUATION material.
- b) Follow the method proposed by the MANUFACTURER and create an image. The MANUFACTURER shall specify the X-ray exposure IRRADIATION values for this first image.
- c) Follow the method(s) proposed by the MANUFACTURER for the treatment of the DIGITAL X-RAY IMAGING DEVICE between IRRADIATIONS.
- d) Follow the method proposed by the MANUFACTURER and create a second image without further IRRADIATION of the X-RAY IMAGE RECEPTOR. The MANUFACTURER shall specify the time interval between the first image and this second image.
- e) Using the first image, measure the average pixel value of a rectangular region enclosing at least 1 000 pixels adjacent to, but not overlapping, the area of the image of the ATTENUATION plate (ROI 2, see Figure J.1 of Annex J).

- f) Using the second image, measure the average pixel value of a rectangular region enclosing at least 1 000 pixels adjacent to, but not overlapping, the area of the image of the ATTENUATION plate (ROI 2, see Figure J.1 of Annex J).
- g) Using the second image, measure the average pixel value of a rectangular region enclosing at least 1 000 pixels within the area of the image covered by the ATTENUATION plate (ROI 1, see Figure J.1 of Annex J).
- h) Divide the difference of the measurements from steps f) and g) by the measurement from step e) and compare the result to assess acceptable additive lag effect performance within the tolerance specified by the MANUFACTURER.

5.11.3.4.2 Multiplicative lag effects (“Ghosting”)

Perform this test if the X-RAY EQUIPMENT comprises a DIGITAL X-RAY IMAGING DEVICE. Operate the DIGITAL X-RAY IMAGING DEVICE according to the specifications of the MANUFACTURER.

- a) Follow the method proposed by the MANUFACTURER and create an image without an ATTENUATION plate. The MANUFACTURER shall specify the X-ray exposure IRRADIATION values for this first image (Image1).
- b) Follow the method(s) proposed by the MANUFACTURER for the treatment of the DIGITAL X-RAY IMAGING DEVICE between IRRADIATIONS.
- c) Place the ATTENUATION plate specified in 5.11.3.4.1 on the PATIENT SUPPORT. Follow the method proposed by the MANUFACTURER and create an image. The MANUFACTURER shall specify the X-ray exposure IRRADIATION values for this second image (Image2).
- d) Follow the method(s) proposed by the MANUFACTURER for the treatment of the DIGITAL X-RAY IMAGING DEVICE between IRRADIATIONS.
- e) Remove the ATTENUATION plate from the PATIENT SUPPORT. Follow the method proposed by the MANUFACTURER and create an image. The MANUFACTURER shall specify the X-ray exposure IRRADIATION values for this third image (Image3) and the time interval between the second and third image acquisitions.
- f) Using the first and third images (Image1 and Image3), measure the average pixel value of a rectangular region enclosing at least 1 000 pixels within the area covered by the image of the high-contrast ATTENUATION plate (ROI 1, see Figure J.1 of Annex J).
- g) Using the first and third images (Image1 and Image3), measure the average pixel value of a rectangular region enclosing at least 1 000 pixels which is adjacent to, but not overlapping, the image of the high-contrast ATTENUATION plate (ROI 2, see Figure J.1 of Annex J).
- h) Calculate

$$\frac{(\text{Image1}_{\text{ROI1}} - \text{Image1}_{\text{ROI2}}) - (\text{Image3}_{\text{ROI1}} - \text{Image3}_{\text{ROI2}})}{(\text{Image1}_{\text{ROI2}} + \text{Image3}_{\text{ROI2}})/2}$$

and compare the result with the tolerance specified by the MANUFACTURER.

5.12 Dynamic range of mammographic X-RAY EQUIPMENT using digital X-ray image receptors, including storage phosphor systems

5.12.1 General

The dynamic range of the mammographic X-RAY EQUIPMENT is a measure of the maximum difference in breast thickness that can be imaged simultaneously, without any loss in information due to saturation of detector elements. This might occur during the imaging of a large breast where the breast thickness is high but the thickness of the skin line area is low.

5.12.2 Requirements

The number of steps visible shall be superior or equal to the number specified by the MANUFACTURER.

5.12.3 TEST DEVICE

A special PMMA plate of 40 mm thickness shall be used, terminated with a step wedge. The thinnest part of the step wedge shall be 3 mm thick, and the wedge shall procure 12 steps by increments of 3 mm every 3 mm (see figure B-1 for an example).

5.12.4 Test method

The dynamic range shall be measured as the smallest thickness of PMMA rendered without saturation when acquired in the conditions determined by the AEC for a 60 mm thickness TEST DEVICE.

Place on the PATIENT SUPPORT the special plate described in 5.12.3, with a 20 mm attenuating plate on top of it; set the breast COMPRESSION DEVICE and all other operating conditions as used for testing the AEC at 60 mm thickness of PMMA.

Acquire a RADIOGRAM in conditions allowing the determination of the dynamic range, in particular concerning the processing of the images.

5.12.5 Measurement of the RADIOGRAM

Using the instructions of the MANUFACTURER concerning the display or measurement conditions (e.g. comparison to the maximum reachable level, or standard deviation at 0), determine the number of steps non-saturated, from which the thickness of the smallest non-saturated step may be deduced.

5.12.6 Evaluation of the results

Compare the results with the values specified by the MANUFACTURER.

5.13 Spatial resolution

5.13.1 Mammographic X-RAY EQUIPMENT using RADIOGRAPHIC FILM

5.13.1.1 Requirements

The specified line groups shall be resolved when imaged in two orientations, parallel to the PATIENT SUPPORT chest wall edge and perpendicular to the chest wall edge. A line group in a bar pattern is considered to be resolved if its film image is a regular group of separated dark lines, provided that the number of lines in the image is the same as the number of slits in that line group. The lines on the film shall not appear interrupted.

NOTE This requirement excludes first order pseudo patterns. Such patterns are characterised by showing one dark line less than a correct image of the bar pattern. Higher order pseudo patterns have no relevance for acceptance testing.

5.13.1.2 Test procedure

One or more PMMA blocks of 40 mm overall thickness shall be placed on the PATIENT SUPPORT. An additional line test pattern of high ATTENUATION material and specified thickness shall be placed on top of the PMMA blocks. The test shall be performed with the line groups in both orientations required in 5.13.1.1. This test pattern should have a range of spatial frequencies from 8 to 16 lp/mm, preferably in 1 lp/mm increments. The line group corresponding to the limiting resolution shall be 6 cm from the chest wall edge and within 5 cm of the centreline.

RADIOGRAMS shall be made

- with all FOCAL SPOTS and TARGETS of the X-RAY TUBE in all combinations specified for NORMAL USE, and
- with X-RAY TUBE VOLTAGES and imaging techniques (grid/non grid/magnification) as specified.

The screen-film system and the optical density shall be chosen as for the reference RADIOGRAM taken in 5.7.1.3.3 when testing the performance of the AUTOMATIC EXPOSURE CONTROL. The line group images shall be evaluated with a magnifying glass in each RADIOGRAM

NOTE The distance of the bar patterns to the PATIENT SUPPORT and to its chest wall edge strongly influence the test results.

5.13.1.3 Evaluation of the results

Evaluate the results for:

- each of the geometric configurations (contact, geometric magnification),
- each of the relevant TARGET track/spectral FILTRATION combinations.

Compare the results with the values specified by the MANUFACTURER.

5.13.2 Mammographic X-RAY EQUIPMENT using digital X-ray image receptors and storage phosphor systems

5.13.2.1 General

A test for spatial resolution shall be provided by the manufacturer.

Unless specified by the manufacturer, measurements of MODULATION TRANSFER FUNCTION (MTF) can be used to check conformity to contractual specifications, and, even more, to check for possible degradation with time, i.e. for constancy testing. However it should be noted that MTF is not sufficient to state absolute performance; detective quantum efficiency (DQE) should be used instead.

NOTE Currently a set of IEC standards to describe DQE measurements is under development.

In addition, care should be taken to differentiate the detector MTF, as described in IEC 62220-1-2, which requires performing measurements in very precise conditions, different from the set up inside the system, from the overall system MTF, including the contributions of the FOCAL SPOT, the geometry, etc. In the context of acceptance testing of a system, these effects will be deliberately looked for, and the term “system contrast transfer function (SCTF)” is therefore preferred.

The result of the test proposed will deviate from the MTF for detectors with high MTF below Nyquist frequency.

NOTE The method chosen, derived from the work by Droege *et al.*, may give results somehow different from those given by other methods (such as those derived from edge response); to avoid confusion, the term “system contrast transfer function” will be retained instead of MTF.

5.13.2.2 Requirements

The system contrast transfer shall be determined for a finite number of spatial frequencies and compared to the minimum values specified by the MANUFACTURER.

5.13.2.3 Test procedure

Unless specified by the MANUFACTURER, The System Contrast Transfer Function shall be measured in relevant conditions, derived from the RMS value of a periodic square pattern placed on top of attenuating plates 40 mm thick, respectively in contact and magnification conditions.

The test shall be performed for at least one combination of TARGET tracks and spectral FILTRATIONS available, as specified by the MANUFACTURER.

In order to limit the number of measurements, and to avoid the presence of moiré patterns, the measurements shall be made with the periodic resolution pattern oriented at 45° or in the directions recommended by the MANUFACTURER.

Reproduce the configuration used to test the AEC with 40 mm object thickness, except the compression plate of the breast COMPRESSION DEVICE.

On top of the attenuating plates, position a periodic resolution bar pattern, made of thin highly attenuating material such as lead or gold. The thickness of the material shall be 50 µm or smaller.

The required spatial frequencies of the pattern are respectively 2 lp/mm and 4 lp/mm for the “contact” configuration, and 4 lp/mm and 8 lp/mm for the “magnification” configuration, within 5 %. Each frequency pattern shall contain a minimum of 5 periods, a number of 8 or more being preferred. The length of the bars constituting the pattern shall be larger than 10 periods. The bars shall be oriented at $45^\circ \pm 2^\circ$ relative to the edge of the image receptor corresponding to the chest wall side or in the directions and locations recommended by the MANUFACTURER.

The centres of the periodic bar patterns shall be placed at 60 mm from the edge of the PATIENT SUPPORT intended to be placed at the chest wall side, as close as possible to the axis, perpendicular to the chest wall side and no more than 20 mm from that axis.

Zones with the same material and thickness as the attenuating and transparent parts of the periodic resolution patterns shall be placed immediately adjacent to the periodic pattern. These zones shall be the same size or larger than the largest periodic pattern, and positioned in a location ensuring that the average and standard deviation of pixel values measured in these zones are representative of the average and standard deviation in the location of the resolution bar patterns.

NOTE 1 An example of TEST DEVICE configuration is given in Annex F; however, any other configuration respecting the same requirements may be used. If a dedicated TEST DEVICE is not available, standard patterns may be used instead; then, the complete measuring process may require a multiple step operation to acquire all required data.

NOTE 2 For certain EQUIPMENT it may be necessary to perform the test with the test pattern parallel and perpendicular to the centreline instead of the 45° angle.

5.13.2.4 Test method

a) Acquisition of the RADIOGRAMS

For each configuration, acquire a RADIOGRAM using the same technique factors as used for the determination of the CNR and AGD at 40 mm thickness.

When different TARGET material/spectral FILTRATIONS are used, select the X-RAY TUBE VOLTAGE according to the specifications of the MANUFACTURER, and the tube loading (mAs) in order to reach a detector element value in the images within $\pm 25\%$ of the value reached using the TARGET material/spectral FILTRATION determined by the AEC.

The TEST DEVICE shall be positioned on top of the PATIENT SUPPORTS used for each of the geometric configurations (“contact”, and “magnification”); the FOCAL SPOTS shall be selected accordingly. The region of interest must be large enough to show the bar pattern.

b) Measurements

For each of the resolution bar patterns, measure the average and standard deviation in the images of

- the bar patterns at frequency f : m_f and σ_f ,
- the attenuating reference zone: m_a and σ_a , and
- the transparent reference zones: m_t and σ_t .

c) Computations

For each of the spatial frequencies f in each of the operating conditions, compute the system contrast transfer function $M(f)$:

$$M_0 = \frac{\sqrt{2}}{\pi} |m_a - m_t| \quad \sigma^2 = \frac{\sigma_a^2 + \sigma_t^2}{2} \quad M(f) = \frac{\sqrt{\sigma_f^2 - \sigma^2}}{M_0}$$

5.13.2.5 Evaluation of the results

Evaluate the results for

- each of the geometric configurations (contact, geometric magnification),
- each required spatial frequency, and
- each of the relevant TARGET track/spectral FILTRATION combinations.

Compare the results with the values specified by the MANUFACTURER.

5.14 LOW CONTRAST DETECTABILITY

5.14.1 Mammographic X-RAY EQUIPMENT using RADIOGRAPHIC FILM

5.14.1.1 Requirements

LOW CONTRAST DETECTABILITY requirements should be specified by the MANUFACTURER.

5.14.1.2 Test procedures

Unless specified by the MANUFACTURER, a TEST DEVICE with low contrast structures (holes drilled in a layer of 40 mm thickness of PMMA) shall be used. Each hole shall have a diameter between 5 mm and 6 mm. The series of holes should have a depth of 0,1 mm, 0,15 mm, 0,2 mm, 0,25 mm, 0,3 mm, 0,35 mm, 0,4 mm with a tolerance of $\pm 0,02$ mm.

The TEST DEVICE shall be placed on the PATIENT SUPPORT. RADIOGRAMS shall be made

- with all TARGETS and FILTERS of the X-RAY TUBE, in all combinations specified for NORMAL USE; and
- with X-RAY TUBE VOLTAGES and imaging techniques (grid/non grid/magnification) as specified.

The screen-film system and the optical density shall be chosen as for the reference RADIOGRAM when testing the performance of the AUTOMATIC EXPOSURE CONTROL.

The number of visible low contrast objects shall be determined for each RADIOGRAM.

NOTE The results of this test depend strongly on the screen-film system used. The FOCAL SPOT has virtually no influence because the low contrast objects have a size of several millimetres.

5.14.2 Mammographic X-RAY EQUIPMENT using an integrated digital X-RAY IMAGE RECEPTOR or storage phosphor plates

5.14.2.1 Requirements

LOW CONTRAST DETECTABILITY requirements should be specified by the MANUFACTURER. An example is given in Annex G.

5.14.2.2 Test procedures

LOW CONTRAST DETECTABILITY tests should be performed as specified by the MANUFACTURER. An example is given in Annex G.

5.15 Entrance surface AIR KERMA

5.15.1 Mammographic X-RAY EQUIPMENT using RADIOGRAPHIC FILM

5.15.1.1 Requirements

The entrance surface AIR KERMA shall not exceed the specified value. For mammographic X-RAY EQUIPMENT using RADIOGRAPHIC FILM the entrance surface AIR KERMA shall be referred to an optical density of $D = 1,6$.

NOTE Depending on the design of the X-RAY TUBE, MANUFACTURERS usually specify the TARGET FILTER combination Mo/30 μ m Mo or the combination W/60 μ m Mo to be used for imaging medium breasts. It is recommended to apply the same upper limit of entrance surface AIR KERMA for both combinations.

5.15.1.2 Test procedure

Use the same IRRADIATION conditions as for the first reference RADIOGRAM when testing “performance of the AEC”. The AIR KERMA shall be determined at a height of 40 mm $\pm$ 1 mm over the PATIENT SUPPORT, and at a distance of 6 cm from the chest wall edge. No SCATTERED RADIATION from the TEST DEVICE shall contribute to the measurement. For mammography X-RAY EQUIPMENT using RADIOGRAPHIC FILM the entrance surface AIR KERMA K_E shall be determined by using the measured AIR KERMA K and referring to the optical density $D = 1,6$ by calculation.

NOTE 1 If the DOSIMETER does not allow a measurement free of backscattered radiation then the AIR KERMA K may be determined by an IRRADIATION in manual mode, without using the TEST DEVICE. Then the AIR KERMA for the same CURRENT TIME PRODUCT as used for the first reference RADIOGRAM when testing “performance of the AEC” can be calculated.

NOTE 2 The approximation $K_E \approx K \times 1,6/D$ leads to a sufficiently accurate result for K_E , provided the measured optical density is close to $D = 1,6$. For measured optical densities in the range $D = 1,4$ to $D = 1,8$ the error in calculation does not exceed $\pm 5 \%$.

5.15.2 Mammographic X-RAY EQUIPMENT using an integrated digital X-RAY IMAGE RECEPTOR or storage phosphor plates

5.15.2.1 Requirement

The entrance surface AIR KERMA shall not exceed the specified value of dose or signal level by the MANUFACTURER. For mammographic X-RAY EQUIPMENT using integrated digital X-RAY IMAGE RECEPTOR, the entrance surface AIR KERMA shall be referred to a signal level specified by the MANUFACTURER.

5.15.2.2 Test procedure

Use IRRADIATION conditions specified by the MANUFACTURER for this test. The AIR KERMA shall be determined at a height of $40 \text{ mm} \pm 1 \text{ mm}$ over the PATIENT SUPPORT, and at a distance of 6 cm from the chest wall edge. No SCATTERED RADIATION from the TEST DEVICE shall contribute to the measurement. For mammographic X-RAY EQUIPMENT using a digital detector, the entrance surface AIR KERMA K_E shall be determined by using the measured AIR KERMA K .

NOTE If the DOSIMETER does not allow a measurement free of backscattered radiation then the AIR KERMA K may be determined by an IRRADIATION in manual mode, without using the TEST DEVICE. Then, the AIR KERMA for the same CURRENT TIME PRODUCT, as used for the first reference RADIOGRAM when testing performance of the AEC, can be calculated.

5.16 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES

5.16.1 Requirement

The accuracy of biopsy needle tip position in x , y , and z directions shall be within the specified range in the specified stereotactic biopsy volume.

5.16.2 TEST DEVICE

A mammographic stereotactic TEST DEVICE of a design which allows testing for different biopsy needle directions is required for the test. It consists of a mounting plate which is perforated so that it can serve as a locator for the test needles. At least three steel needles of different lengths are to be fixed in the mounting plate, the outer parts perpendicular to its surface and pointing in the same direction. An example of the arrangement is shown in Annex H.

The steel needles are test needles, their tips serve as test objects. They shall be placed in a pattern so that the specified stereotactic biopsy volume can be covered. It shall be possible to locate one of them within $\pm 5 \text{ mm}$ of the centre of that volume, and two of the other test needle tips also inside the specified stereotactic biopsy volume and within 10 mm of the extreme x , y , z points that are intended to be reconstructed with the MAMMOGRAPHIC STEREOTACTIC DEVICE.

5.16.3 Test method

Measure the biopsy needle length and compare the result to the nominal biopsy needle length, or to the biopsy needle length value stored or programmed in the MAMMOGRAPHIC STEREOTACTIC DEVICE. The measured length shall agree with the nominal length to within $\pm 0,3$ mm. Place the TEST DEVICE on the PATIENT SUPPORT of the MAMMOGRAPHIC STEREOTACTIC DEVICE, so that one of the test needle tips is located to within ± 5 mm of the centre of the specified stereotactic biopsy volume, and two of the other test needle tips are also located inside the specified stereotactic biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed. An attenuating, homogeneous material, for example 2 mm Al, may be attached close to the X-RAY SOURCE ASSEMBLY.

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Acquire a pair of stereo views. On each image select all projections of the test needle tips within the specified stereotactic biopsy volume and reconstruct their x, y, z positions. For each test needle, position the biopsy needle tip according to the position calculated by the MAMMOGRAPHIC STEREOTACTIC DEVICE. Measure and record the differences in x, y, z positions between each test needle tip and the biopsy needle tip. Repeat the procedure with the X-RAY TUBE ASSEMBLY–image receptor assembly rotated to the extremities of the range specified by the MANUFACTURER for clinical use of angular deviation in each direction and also to any intermediate deviations of 90 degrees or multiples thereof. If the MAMMOGRAPHIC STEREOTACTIC DEVICE is designed for more than one biopsy needle direction relative to the X-RAY TUBE ASSEMBLY–image receptor assembly, then repeat the procedure at six different directions within the range specified by the MANUFACTURER for clinical use, including at least two directions at extremities of the specified range.

Compare the differences in the x, y, and z directions to the requirement above.

6 Baseline values for CONSTANCY TESTS

When the mammographic X-RAY EQUIPMENT has passed the ACCEPTANCE TEST, the baseline values for the subsequent CONSTANCY TESTS shall be defined. For determining the baseline values, the measuring procedures and EQUIPMENT for constancy testing shall be used.

7 Test report and statement of compliance

A test report shall be drawn up with the following items:

- description of the mammographic X-RAY EQUIPMENT tested, including individual identification data for all components;
- compilation of relevant performance and functioning specifications;
- description of the test EQUIPMENT, including film and processing data;
- test results;
- statement whether the tested mammographic X-RAY EQUIPMENT complies with the requirements of this standard and with the specified parameters; and
- the location, the date and the names of the persons performing the tests.

The test report shall be headed:

Test report on ACCEPTANCE TEST of mammographic X-RAY EQUIPMENT according to IEC 61223-3-2:2007.