INTERNATIONAL STANDARD

IEC 61223-2-10

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

Part 2-10: Constancy tests – X-ray equipment for mammography

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

Partie 2-10: Essais de constance – Equipements de mammographie

Reference number
IEC 61223-2-10:1999(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

INTERNATIONAL STANDARD

IEC 61223-2-10

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

Part 2-10: Constancy tests – X-ray equipment for mammography

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

Partie 2-10: Essais de constance – Equipements de mammographie

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE V

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-10: Constancy tests – X-ray equipment for mammography

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-2-10 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/372/FDIS	62B/384/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 3.

Annexes A and F form an integral part of this standard.

Annexes B, C, D and E are for information only.

This standard forms part 2-10 of IEC 61223, which will include the following parts:

Part 1: General aspects

Part 2-1: Constancy tests – Film processors

Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly

Part 2-3: Constancy tests – Darkroom safelight conditions

Part 2-4: Constancy tests – Hard copy cameras

Part 2-5: Constancy tests – Image display devices

Part 2-6: Constancy tests – X-ray equipment for computed tomography

Part 2-7: Constancy tests – Equipment for intra-oral dental radiography excluding dental panoramic equipment

Part 2-9: Constancy tests – Equipment for indirect radioscopy and indirect radiography

Part 2-10: Constancy tests – X-ray equipment for mammography

Part 2-11: Constancy tests – Equipment for general direct radiography

The committee has decided that this publication remains valid until 2003. At this date, in accordance with the committee's decision, the publication will be

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

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

Some provisions or statements in the body of this part of IEC 61223 require additional information. Such information is presented in annex D, Rationale. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-10: Constancy tests – X-ray equipment for mammography

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which

– generate, influence the propagation of and detect X-RADIATION;

– process, record and present radiographic information in RADIOLOGICAL INSTALLATIONS with mammographic X-RAY EQUIPMENT using INTENSIFYING SCREENS with RADIOGRAPHIC FILM.

Special accessories of mammographic X-RAY EQUIPMENT such as biopsy plates and stereotactic devices are not within the scope of this standard.

This standard is a part of a series of Particular Publications (international standards and technical reports) which define methods of testing the constancy of operation of various subsystems of diagnostic X-RAY EQUIPMENT.

This standard gives methods of tests for the constancy of properties of diagnostic X-RAY EQUIPMENT as described in IEC 61223-1 (see clause 2).

This part of IEC 61223 is designed to be applicable to X-ray equipment for mammography without digital imaging devices.

1.2 Object

This standard defines

– the essential parameters which describe or affect the performance of the above components of X-RAY EQUIPMENT;

– methods of checking that variations in measured quantities related to those parameters are within acceptable limits, in order to maintain adequate standards of imaging whilst reducing unnecessary IRRADIATION of the PATIENT.

The methods are based upon assessments of RADIOGRAMS of appropriate TEST DEVICES.

The purpose of the methods is

– to establish a reference level of performance when equipment is accepted;

– to detect and verify any significant variation in performance which may require corrective action.

Because RADIOLOGICAL INSTALLATIONS differ widely from each other, it is not possible in this standard to specify target values and tolerances for the parameters which would be generally applicable as criteria of acceptable performance. Guidance is given, however, as to the degree of variation in single measurements which might require appropriate action.

This standard does not deal with

– aspects of mechanical and electrical safety;

– checks of the effectiveness of the direct means of protection against X-RADIATION;

– optimization of imaging performance.

With regard to the measurements, reference is made to methods described in related publications which, for practical reasons, should be carried out prior to the application of the methods described in this standard (see clause 2).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61223. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 61223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61223-2-1:1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 61223-2-2:1993, *Evaluation and routine testing in medical imaging departments – Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly*

IEC 61223-2-3:1993, *Evaluation and routine testing in medical imaging departments – Part 2-3: Constancy tests – Darkroom safelight conditions*

IEC 61223-2-5:1994, *Evaluation and routine testing in medical imaging departments – Part 2-5: Constancy tests – Image display devices*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms (which are not printed in SMALL CAPITALS) have particular meanings, as follows:

– "shall" indicates a requirement that is mandatory for compliance;

– "should" indicates a strong recommendation that is not mandatory for compliance;

– "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;

– "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;

– "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the equipment under consideration, usually concerning its intended purpose, or the parameters or conditions associated with its use or with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788 or other IEC publications or in 3.3 of this standard; see annex A. Where a defined term is used as a qualifier in 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 definition”. Test specifications are in italics.

NOTE – Attention is drawn to the fact, that in cases 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.

3.3 Definitions

3.3.1
FILM BASE PLUS FOG DENSITY
for CONSTANCY TESTS in X-RAY EQUIPMENT, the optical density in an area of the RADIOGRAM, on the processed control film, that has not been exposed to light from a sensitometer. (This definition has been taken from IEC 61223-2-1.)

3.3.2
NET OPTICAL DENSITY
density above FILM BASE PLUS FOG DENSITY

4 General aspects of CONSTANCY TESTS

For the results of the CONSTANCY TESTS described in this standard to be valid, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test.

In particular, attention shall be paid to darkroom safelight conditions, according to IEC 61223-2-3, and proper film processing, according to IEC 61223-2-1 (see clause 2). When using FILM ILLUMINATORS special attention should also be paid to lighting conditions.

Careful consideration shall be given to the operating and test conditions, under which the equipment is checked, including the influences of environmental changes.

All equipment under test and the test equipment shall be identified at the initial CONSTANCY TEST in order to ensure that the same items are used in subsequent CONSTANCY TESTS.

NOTE – If the MANUFACTURER provides proposals for the method and frequency of CONSTANCY TESTS in the ACCOMPANYING DOCUMENTS, they should preferably be followed.

4.1 General conditions affecting test procedures

The CONSTANCY TESTS described in this standard have been designed to be easily reproducible, i.e., their results should be affected only by changes in the parameters under investigation. The number of test tools and test equipment has been kept to a minimum and restricted where possible to devices that are passive, inherently simple or reasonably stable. However, it is important

– to perform CONSTANCY TESTS with LOADING FACTORS which are the same as those used most frequently in clinical practice;
– to reproduce and record all significant settings of the X-RAY EQUIPMENT and ACCESSORIES each time a test is undertaken, and to check that the same equipment, components and ACCESSORIES are being used;

– to consider the influence of environmental changes on the results. Variations in mains voltage and, if evaluating images from IMAGE DISPLAY DEVICE, room lighting conditions are of special importance;
– to use RADIOGRAPHIC FILM which is handled, processed and viewed in accordance with the standards and technical reports referenced in clause 2;
– to check the performance of the test instrumentation regularly, particularly when any significant variation in the X-RAY EQUIPMENT is suspected.

NOTE – Where appropriate national standards exist, measuring equipment should be referable to them.

Before the CONSTANCY TESTS are started, the constancy of the radiographic film, the film processing and the film viewing conditions have to be checked.

4.2 Establishment of BASELINE VALUES

When new X-RAY EQUIPMENT is brought into use, or any component of the X-RAY EQUIPMENT, ACCESSORIES or test equipment is changed, which may cause a variation in the test result, an initial CONSTANCY TEST shall be carried out immediately after an ACCEPTANCE TEST has indicated that the performance is satisfactory. The purpose of the initial CONSTANCY TEST is to establish new BASELINE VALUES for the parameters tested.

4.3 Frequency of CONSTANCY TESTS

The CONSTANCY TESTS shall be repeated as directed in the appropriate subclauses of this standard. In addition, the CONSTANCY TESTS shall be repeated

– whenever malfunction is suspected;
– immediately after the equipment has undergone maintenance that could affect the performance parameter under test;
– to confirm the test results, whenever the results are outside the criteria.

Records of the BASELINE VALUES shall be kept until a new initial CONSTANCY TEST is performed. The results of the CONSTANCY TESTS shall be kept at least two years.

4.4 Identification of equipment, instrumentation and test conditions

All X-RAY EQUIPMENT under test or used for testing shall be unequivocally identified.

Interchangeable components of X-RAY EQUIPMENT such as

– ADDED FILTERS;
– ANODE material;
– BEAM LIMITING DEVICES;
– compression plates, PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;
– ANTI-SCATTER GRID;
– RADIOGRAPHIC FILM type and emulsion number;
– FILM PROCESSOR;

together with items of test instrumentation such as:

– combination of a RADIOGRAPHIC CASSETTE and INTENSIFYING SCREENS;
– TEST DEVICES;
– sensitometer;
– densitometer;
– force balance;

and settings of variables such as

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;

– AUTOMATIC CONTROL SYSTEM density control and sensor position;

– LOADING FACTORS;

– magnification position;

– nominal FOCAL SPOT size, if applicable;

shall be marked and/or recorded so that the items and settings used in the initial CONSTANCY TEST can be used with the mammographic X-RAY EQUIPMENT under test.

NOTE 1 – Most of the tests should be performed with the particular RADIOGRAPHIC CASSETTE used for the initial CONSTANCY TEST. This cassette, hereafter referred to as the "test cassette", may be kept exclusively for test procedures or identified among those used regularly in clinical work. Whereas the first is more likely to provide a stable tool for revealing changes in the equipment, the second approach will be more representative of changes of the whole system, including those due to the ageing of the cassette itself.

NOTE 2 – It is essential that any RADIOGRAPHIC FILM used in the test is of the same type as the film used in clinical practice for mammography.

RADIOGRAMS of a TEST DEVICE shall be taken with the test cassette, with the same INTENSIFYING SCREENS and film type. The RADIOGRAPHIC FILM shall be processed under known comparable conditions, and appropriate allowance shall be made for any changes in film batch according to the method specified in IEC 61223-2-1. If the film type and/or associated processing conditions are changed, a new initial CONSTANCY TEST shall be carried out.

TEST DEVICES are described for each of the performance tests described in clause 5 of this standard. In practice, some tests, for example those described in 5.1 through 5.4, may be performed simultaneously by using a composite TEST DEVICE which combines the properties of a number of individual TEST DEVICES. TEST DEVICES are discussed in detail in annex F.

5 Performance tests

5.1 X-RAY EQUIPMENT – Imaging performance

*5.1.1 Image density

5.1.1.1 Summary

A standard TEST DEVICE is exposed under standard conditions and the NET OPTICAL DENSITY of the image is measured at a specific position in the RADIOGRAM. RADIOGRAMS are made under both manual and AUTOMATIC EXPOSURE CONTROL. Evaluation may reveal changes in the performance under AUTOMATIC EXPOSURE CONTROL as well as changes in the RADIATION output, RADIATION QUALITY, ATTENUATION in the RADIATION BEAM and sensitivity of the imaging system.

5.1.1.2 Test equipment

The test cassette shall be used for this test.

An optical densitometer shall be used which reads consistently within ±0,02 over the range from 0 to 3,5.

The reference thickness of the ATTENUATION PHANTOM (40 mm) is used to simulate a PATIENT during the test under manual control. Three different thicknesses (preferably 20 mm, 40 mm, 60 mm) of the ATTENUATION PHANTOM shall be used for the test under AUTOMATIC EXPOSURE CONTROL.

5.1.1.3 Test procedure

Ensure that all interchangeable parts and the geometric arrangement of the X-RAY EQUIPMENT are as in the initial CONSTANCY TEST. Place the loaded test cassette in the RADIOGRAPHIC CASSETTE HOLDER, and the ATTENUATION PHANTOM in the same position as in the initial CONSTANCY TEST, centred from side to side and aligned with the proximal (chest wall) edge of the breast support table.

a) *Testing under manual control*

Make an IRRADIATION with the manual settings of the LOADING FACTORS of the X-RAY EQUIPMENT as used in the initial CONSTANCY TEST. In the case of an initial CONSTANCY TEST, adjust the LOADING FACTORS and repeat if necessary to obtain a NET OPTICAL DENSITY between 1,0 and 1,6; record the LOADING FACTORS for subsequent use.

b) *Testing under AUTOMATIC EXPOSURE CONTROL*

Ensure that the AUTOMATIC EXPOSURE CONTROL sensor is in the position used for the initial CONSTANCY TEST and completely covered by the TEST DEVICE, with X-RAY TUBE VOLTAGE, density control and other relevant settings identical to those used in the initial CONSTANCY TEST. Make RADIOGRAMS of at least three different thicknesses of the ATTENUATION PHANTOM, in steps of not more than 20 mm and including the 40 mm "reference" thickness. Record, if possible, the IRRADIATION TIME or the CURRENT TIME PRODUCT, the ANODE material and the ADDED FILTER after each IRRADIATION.

Process the exposed films in accordance with the procedure referred to in 4.4. Measure on each RADIOGRAM the NET OPTICAL DENSITY at the point defined in the initial CONSTANCY TEST, which was preferably in the mid-line of the film and between 20 mm and 30 mm from the chest wall. This area may be marked by fixing a fibre washer to the ATTENUATION PHANTOM.

5.1.1.4 Data evaluation

Compare the measured values of NET OPTICAL DENSITY in the RADIOGRAMS with the established BASELINE VALUES, after correcting for changes in the film batch or the processing conditions. Compare the corrected optical densities of the RADIOGRAMS obtained for the different thicknesses of the ATTENUATION PHANTOM (with AUTOMATIC EXPOSURE CONTROL) with the respective values obtained during the initial CONSTANCY TEST.

NOTE – If IRRADIATION TIME or CURRENT TIME PRODUCT data are available, compare the IRRADIATION TIME or CURRENT TIME PRODUCT recorded during the test under AUTOMATIC EXPOSURE CONTROL with the values obtained during the initial CONSTANCY TEST.

5.1.1.5 Criteria to be applied

The NET OPTICAL DENSITY should be within ±0,20 of the BASELINE VALUES.

NOTE – A deviation of ±0,20 with regard to the BASELINE VALUES is acceptable if variations in NET OPTICAL DENSITY due to speed variations in film emulsions and film processing are not included. It is nevertheless well recognized that ±0,10 is a common tolerance limit for breast screening services.

Under AUTOMATIC EXPOSURE CONTROL, any variation in NET OPTICAL DENSITY between tests should be in the same direction and closely correlated for all thicknesses of the ATTENUATION PHANTOM. The range of individual BASELINE VALUES for different thicknesses may be greater than ±0,20 of the value for the reference thickness. If the measured optical densities fall within ±0,20 of their BASELINE VALUES but some have increased and others decreased, further investigation is recommended.

NOTE – If a CONSTANCY TEST on IRRADIATION TIME or CURRENT TIME PRODUCT is performed using the 40 mm thickness of the ATTENUATION PHANTOM, these parameters should normally be within ±20 % of the BASELINE VALUE.

5.1.1.6 Action to be taken

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.1.1.7 Frequency of constancy tests

The CONSTANCY TEST shall be performed at least quarterly. A higher frequency is recommended if there are doubts concerning the reliability of the X-RAY SOURCE ASSEMBLY, the HIGH-VOLTAGE GENERATOR or the AUTOMATIC EXPOSURE CONTROL.

NOTE – If the X-RAY EQUIPMENT is heavily used, particularly for breast screening, a simplified test, using only the standard thickness of the ATTENUATION PHANTOM and the mode (manual or AUTOMATIC EXPOSURE CONTROL) clinically used, should be repeated at least once a week, or, in the case of remote film processing, daily.

5.1.2 Artefacts

5.1.2.1 Summary

This test is intended to reveal artefacts in the imaging system that might reduce the diagnostic quality of the image. Probable sources of artefacts are ANTI-SCATTER GRID failures such as misalignment, decentring, mechanical damage or incorrect movement and uneven ATTENUATION of the RADIATION BEAM by the breast support, compression paddle or ADDED FILTERS.

5.1.2.2 Test equipment

– FILM ILLUMINATOR;

– Magnifying lens with a magnification factor between 5 and 10.

5.1.2.3 Test procedure

Examine the RADIOGRAMS obtained from the test in 5.1.1, together with the corresponding ones obtained in the initial CONSTANCY TEST. Use a FILM ILLUMINATOR and view the RADIOGRAMS

a) *from the distance normally used in clinical practice; and*

b) *with a magnifying lens.*

5.1.2.4 Data evaluation

a) Compare the gross density variation in the RADIOGRAMS with the corresponding RADIOGRAMS from the initial CONSTANCY TEST. Examine the RADIOGRAMS with respect to the occurrence of patterns, stains, dots and other phenomena that are not present in the initial CONSTANCY TEST.

b) If a MOVING GRID is used, inspect the RADIOGRAM and record any appearance of grid lines.

5.1.2.5 Criteria to be applied

Any visible deterioration in the homogeneity of the film density across the RADIOGRAM, the occurrence of any pattern not present before or the more pronounced appearance of grid lines, should lead to further action.

NOTE – Grid lines should not be visible in normal clinical use, and should not be visible if the ATTENUATION PHANTOM has a thickness of 20 mm or greater as in the present test.

5.1.2.6 Action to be taken

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.1.2.7 Frequency of constancy tests

This test shall be performed with the same frequency as specified in 5.1.1.7.

5.1.3 High-contrast resolution

5.1.3.1 Summary

This test checks the constancy of the spatial resolution of the X-RAY EQUIPMENT by producing a radiographic image of a high-contrast TEST DEVICE associated with an homogeneous SCATTERING PHANTOM.

NOTE 1 – The purpose of this test is to investigate the constancy of the spatial resolution in a simulated clinical configuration. Where there is a choice of FOCAL SPOTS, the large FOCAL SPOT should be used with the TEST DEVICES resting on the breast support table (contact RADIOGRAPHY) and the small FOCAL SPOT should be used with the TEST DEVICES resting on the magnification stand.

NOTE 2 – The high-contrast TEST DEVICE (see figure 2 and annex F) may be modified by replacing the periodic pattern of radio-opaque material with an arrangement of mesh wires according to the alternative high-contrast TEST DEVICE (see figure 3 and annex F). Data evaluation and criteria to be applied should focus on the detection of any visible deterioration in the image of the mesh wires.

5.1.3.2 Test equipment

The following test equipment is required:

– the test cassette;
– a magnifying lens with a magnification factor between 5 and 10;
– the ATTENUATION PHANTOM of reference thickness (40 mm);
– a high-contrast TEST DEVICE containing periodic patterns of radio-opaque materials. (A detailed description of a high-contrast TEST DEVICE is provided in annex F.)

5.1.3.3 Test procedure

If this technique is commonly used in clinical practice, the CONSTANCY TEST shall be carried out with the MOVING GRID in the RADIATION BEAM.

If the test results do not satisfy the criterion in 5.1.3.5 when using a STATIONARY GRID repeat the CONSTANCY TEST with the STATIONARY GRID removed.

NOTE 1 – *If the test suggests the ANTI-SCATTER GRID may be causing the problem, it is advisable to undertake a separate radiograph to demonstrate the condition of the ANTI-SCATTER GRID.*

NOTE 2 – *To avoid damage, do not remove the MOVING GRID when tools are required to do so.*

Place the loaded test cassette in the RADIOGRAPHIC CASSETTE HOLDER. Use the same type of film and the same FOCAL SPOT TO IMAGE RECEPTOR DISTANCE as in the initial CONSTANCY TEST.

Place the ATTENUATION PHANTOM on the breast support, within ±1 mm of its position used in the initial CONSTANCY TEST. Place the high-contrast TEST DEVICE on top of the ATTENUATION PHANTOM in the same orientation and within ±1 mm of its position used in the initial CONSTANCY TEST. The distance between the high-contrast TEST DEVICE and the film shall be within ±2 mm of that used in the initial CONSTANCY TEST.

Make an IRRADIATION with the LOADING FACTORS used for the initial CONSTANCY TEST. Process the exposed film in accordance with the procedure referred to in 4.4.

NOTE 1 – *Because film density affects the evaluation of high-contrast resolution, it is advisable to work at a film density between 1,2 and 1,6 above FILM BASE PLUS FOG DENSITY.*

NOTE 2 – *Perform this test according to current clinical practice:*

– *The time between loading and IRRADIATION should be the same as in clinical practice. If poor resolution is detected, repeat the test with a delay of 10 min to 20 min between loading and IRRADIATION to allow any entrapped air to escape, and compare the results.*
– *Procedures for loading, exposing and unloading the cassette should be the same as in clinical practice.*

Repeat this procedure for all sizes of FOCAL SPOT and ANODE materials.

5.1.3.4 Data evaluation

Examine the radiographic image with the aid of the magnifying lens and record the maximum spatial frequencies visible in directions parallel with, and perpendicular to, the tube axis. These are the cut-off frequencies under the test conditions. Compare the films with the corresponding RADIOGRAMS from the initial CONSTANCY TEST each time this test is performed, to ensure a consistent criterion of visibility. Note that spurious resolution ("aliasing") may occur: modulation of the image first decreases with increasing object frequency then details reappear in the images of higher frequency objects. The cut-off frequency is that of the *first* disappearance of detail.

5.1.3.5 Criteria to be applied

The measured cut-off frequency shall not be reduced by more than one line pair group compared with the cut-off frequency in the initial CONSTANCY TEST.

5.1.3.6 Action to be taken

If the system fails to meet the criterion, the guidance given in annex C should be followed.

5.1.3.7 Frequency of constancy tests

This test shall be performed according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at intervals of not more than six months.

5.2 RADIATION BEAM – Geometric characteristics

NOTE – Mammographic X-RAY EQUIPMENT is constructed in such a way that the beam geometry is unlikely to change unless the equipment is visibly damaged or deliberately altered. Reconstruction, replacement of components or service activities that might change the geometric characteristics should be verified by an ACCEPTANCE TEST. Whenever malfunction is suspected, or immediately after the equipment has undergone maintenance that could affect geometric characteristics, the following points shall be checked:

– all interchangeable diaphragms are permanently marked with their field size and intended FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;

– the diaphragms fit firmly in a definite position;

– the LIGHT FIELD provides satisfactory illumination of the breast;

– the LIGHT FIELD and the IMAGE RECEPTION AREA are congruent;

– for units with variable FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, the distance is clearly indicated and the adjustment lock is secure.

5.2.1 Summary

This test is intended to reveal changes in the geometry of the part of the field at the chest wall.

5.2.2 Test equipment

A TEST DEVICE bearing test steel balls on its chest wall side is used to test the constancy of the geometry; see the alternative high-contrast TEST DEVICE in annex F.

5.2.3 Test procedure

The test procedure is the same as in 5.1.3 on high-contrast resolution. The RADIOGRAM of this test may be used.

5.2.4 Data evaluation

Count the number of steel balls totally visible in the RADIOGRAM.

5.2.5 Criteria to be applied

At least two of the five balls at each side of the high-contrast TEST DEVICE shall be totally visible in the RADIOGRAM.

5.2.6 Action to be taken

If the system fails to meet the criterion, the guidance given in annex C should be followed.

5.3 COMPRESSION DEVICE

5.3.1 Summary

The condition of the compression paddle is examined visually. The compression force is measured with a force balance.

NOTE – Due to the nature of mammographic examinations, i.e. the application of final compression manually under supervision of the PATIENT's reactions, only the constancy of automatic motorized pre-compression can be tested. The compression force to be investigated during CONSTANCY TESTS should be chosen according to clinical practice. Though a typical value is in the range between 50 N and 200 N, no value will be proposed here. As it is used only for the pre-compression, a fairly low tolerance for the compression of the motorized compression is acceptable.

5.3.2 Test equipment

The following test equipment shall be provided:

– A force balance with overall reproducibility (including stability and display resolution) better than ±5 N over the range between 50 N and 300 N.

– An air- or water-filled bag, 20 mm to 50 mm thick and 100 mm to 150 mm long and wide, or a soft rubber block of similar dimensions.

5.3.3 Test procedure

Inspect the compression plates for cracks, deformation, local weakening, etc.

Place the force balance on the breast support with the bag on its sensitive area. Operate the COMPRESSION DEVICE and record the reading of the balance. If the maximum force is variable and selective, measure both the highest selectable value and the value normally used clinically. If these values are displayed on the X-RAY EQUIPMENT, record them. Check that compression is applied smoothly and symmetrically and that the compression paddle releases correctly.

Warning – Use a compliant device such as a water-filled bag to spread the force over the compression paddle. Small contact areas will damage the paddle. Ensure that the force balance does not damage the breast support table; use a load-spreading plate if necessary.

5.3.4 Data evaluation

Compare the measured compression force with the established BASELINE VALUES, and, if available, with the reading on the built-in measuring device of the X-RAY EQUIPMENT.

NOTE – Compression forces between 50 N and 200 N are usual in normal clinical use. Local or national clinical service standards may suggest an upper limit.

5.3.5 Criteria to be applied

The manually measured compression force should be within ±10 N of the BASELINE VALUES, and, if applicable, within ±10 N of the reading of the built-in device.

For motorized pre-compression (see note in 5.3.1), the measured compression force should be within ±20 % of the BASELINE VALUES.

5.3.6 Action to be taken

Cracked, deformed or weakened compression paddles should be replaced. Jerky movement, asymmetric compression or failure to release smoothly may require attention to the mechanism or control system.

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.3.7 Frequency of CONSTANCY TESTS

This test shall be repeated according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at intervals of not more than six months.

For mammographic equipment with a high WORKLOAD weekly tests are recommended.

5.4 Mammographic cassettes and INTENSIFYING SCREENS

5.4.1 Preparatory measures

When examining the devices, instructions given in the ACCOMPANYING DOCUMENTS shall be followed.

Each single INTENSIFYING SCREEN or pair of INTENSIFYING SCREENS shall be given an individual identification such as a number. This identification shall be marked in an unobtrusive position on one INTENSIFYING SCREEN so that it will be recorded on the film.

The identification shall be repeated on the outside of the mammographic cassette.

Each mammographic cassette shall be labelled with

- type of the RADIOGRAPHIC CASSETTE;
- name of the MANUFACTURER of the INTENSIFYING SCREENS contained;
- types of the INTENSIFYING SCREENS contained;
- date of acquisition of the INTENSIFYING SCREENS;
- date of the most recent cleaning of the INTENSIFYING SCREENS.

The general condition of all mammographic cassettes and the INTENSIFYING SCREENS shall be checked at least every six months as follows:

1) Examine the interior and exterior of each cassette for:
   – correct labelling;
   – signs of warping and fatigue of the material provided to ensure the contact between RADIOGRAPHIC FILM and INTENSIFYING SCREEN.
2) Examine the hinge assembly and closure mechanism of the cassettes for wear and damage.
3) Examine each INTENSIFYING SCREEN and each cassette for dust, dirt, abrasions, worn or stained areas at least monthly. Clean or replace if necessary.

*5.4.2 Contact between INTENSIFYING SCREENS and film

5.4.2.1 Summary

The uniformity and homogeneity of the contact between the INTENSIFYING SCREENS and the film is verified by studying the RADIOGRAM of a wire mesh.

5.4.2.2 Test equipment

Film-screen contact TEST DEVICE

A wire mesh of linear dimensions not less than the IMAGE RECEPTION AREA of the mammographic cassette to be tested.

A detailed description of a film-screen contact TEST DEVICE is given in annex F.

5.4.2.3 Test procedure

Place the mammographic cassette to be tested in the RADIATION BEAM on top of the breast support at the largest FOCAL SPOT TO IMAGE RECEPTOR DISTANCE achievable with the X-RAY EQUIPMENT. Place the wire mesh flat on top of the incident face of the mammographic cassette. If necessary, use a "dummy" cassette in the RADIOGRAPHIC CASSETTE HOLDER to allow an IRRADIATION to be made.

Irradiate the mammographic cassette under test using the smallest FOCAL SPOT available and LOADING FACTORS that will produce an optical density on the processed RADIOGRAM of about 2,5 above FILM BASE PLUS FOG DENSITY in the absence of the wire mesh. If necessary, attenuate the X-RAY BEAM sufficiently to achieve the required optical density by supporting an appropriate thickness of the ATTENUATION PHANTOM so that it completely intercepts the X-RAY BEAM.

IRRADIATION in manual mode is preferable, because it assures the desired density value on the film more easily.

NOTE – Perform this test as according to current clinical practice.

– The time between loading and IRRADIATION should be the same as in clinical practice. If poor contact is detected, repeat the test with a delay of 10 min to 20 min between loading and IRRADIATION to allow any entrapped air to escape, and compare the results.

– Procedures for loading, exposing and unloading the cassette should be the same as in clinical practice.

5.4.2.4 Data evaluation

View the RADIOGRAMS on the FILM ILLUMINATOR under the same conditions as used in clinical practice.

Compare the RADIOGRAM with the RADIOGRAM made during initial CONSTANCY TEST.

5.4.2.5 Criteria to be applied

NOTE – If regions of the image of the wire mesh on the RADIOGRAM appear dark or non-uniform, the film-screen contact may be poor and will impair the quality of the recorded diagnostic information.

Visible impairment of the film-screen contact requires corrective action.

For actions to be taken, the following criterion shall be applied:

– the presence of any areas of poor contact.

NOTE – Good film-screen contact is most important near the chest wall edge of the cassette in mammography, whereas in general RADIOGRAPHY the centre of the cassette is considered the most critical area for film-screen contact.

5.4.2.6 Action to be taken

Large patches of poor film-screen contact may be caused by air trapped between screen and film during loading. This should be suspected where cassettes are machine-loaded and used immediately afterwards (as in many breast screening units). To eliminate this cause, make two test IRRADIATIONS. Establish the test configuration, then make one IRRADIATION immediately after loading the cassette in the normal way. Process the film, reload the cassette, and repeat the test IRRADIATION not less than 12 h later. If the same artefacts are visible, suspect wear or damage to the screen-cassette assembly. If they have disappeared, the fault is almost certainly due to air entrapment.

Further guidance is given in annex C.

5.4.2.7 Frequency of constancy tests

The ACCEPTANCE TEST for new, repaired or re-screened cassettes can form the BASELINE VALUES for the constancy series of tests. Subsequent tests should be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such instructions are provided, the CONSTANCY TESTS shall be performed at least annually.

5.4.3 Relative sensitivity of INTENSIFYING SCREEN-cassette imaging systems

5.4.3.1 Summary

The constancy of the relative sensitivities of INTENSIFYING SCREENS-cassette assemblies is determined by comparing the optical densities produced by equally irradiated mammographic cassettes.

INTENSIFYING SCREENS-cassette assemblies showing deviation from the determined mean optical density of more than ±0,2 are regarded as inappropriate for further mammographic work.

The same batch of RADIOGRAPHIC FILM and the same processing conditions shall be used for all mammographic cassettes tested.

5.4.3.2 Test equipment

The following test equipment shall be provided:

– An ATTENUATION PHANTOM of the standard thickness (40 mm) is used to provide a realistic RADIATION QUALITY and dose rate. A detailed description of the ATTENUATION PHANTOM is provided in annex F.
– An optical densitometer which reads consistently within ±0,02 over the range between 0 and 3,5.

5.4.3.3 Test procedure

Place the ATTENUATION PHANTOM on the breast support.

All RADIOGRAPHIC CASSETTES to be tested are loaded with RADIOGRAPHIC FILMS of the same package.

The loaded RADIOGRAPHIC CASSETTE is placed into the cassette holder and irradiated using the AEC mode with LOADING FACTORS so as to produce an optical density between 0,80 and 1,50 in the processed RADIOGRAM. The test is repeated for all cassettes.

All films shall be processed in the same FILM PROCESSOR and fed into the processor in the same position and orientation, to minimize differences due to inhomogeneous conditions within the FILM PROCESSOR.

5.4.3.4 Data evaluation

The optical density is measured for each RADIOGRAM in the mid-line of the film at a specific distance from the chest wall, for example 30 mm.

5.4.3.5 Criteria to be applied

The deviation of optical density from the mean value should be within ±0,20.

5.4.3.6 Action to be taken

Screen-cassette assemblies not complying with the above criterion shall be rejected for further mammographic work.

Further guidance is given in annex C.

5.4.3.7 Frequency of constancy tests

The ACCEPTANCE TEST for new, repaired or re-screened cassettes can form the BASELINE VALUES for the constancy series of tests. Subsequent tests should be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such instructions are provided, the CONSTANCY TESTS shall be performed at least annually.

5.5 Mammographic film

The recommended test for constancy of the performance of the FILM PROCESSOR incorporates those procedures documented in IEC 61223-2-1. FILM BASE PLUS FOG DENSITY, SPEED INDEX and CONTRAST INDEX are monitored to check constancy. Trends in these parameters can be used to diagnose the particular cause of change and initiate corrective action.

The particular demands of mammography and the distinctive features of mammographic film require that some of the test procedures be carried out with special care, and some additional tests are helpful. These complementary aspects are summarized below.

The control film for the sensitometric test shall be of the same type and of the same emulsion number as the film used for mammography in clinical practice.

The step wedge of the sensitometer should provide two levels of exposure and also enable evaluation of the contrast in the toe of the sensitometric curve. It should therefore provide at least two optical densities on the processed control films within the ranges of 0,20 to 0,30 and 0,40 to 0,60 above FILM BASE PLUS FOG DENSITY. The difference between the measured optical densities of these two steps should be within ±0,03 of the BASELINE VALUE if the diagnostic performance of the film is to remain constant.

New film batches shall be tested together with the old ones before they are used for clinical work. If the results indicate that the new batch does not meet the established criteria, reference should first be made to the MANUFACTURER'S specified tolerances for the parameters measured, or to those agreed in the supply contract for the film. Large deviations in speed, contrast and toe sensitivity may be caused by changes in storage conditions or the use of films of widely differing ages. If clinically significant changes or variations outside the MANUFACTURER'S specification cannot be traced to causes under the USER'S control, the film supplier should be involved to ascertain their origin.

6 Statement of compliance

The test report shall be headed:

Test report

on constancy test of X-ray equipment for mammography

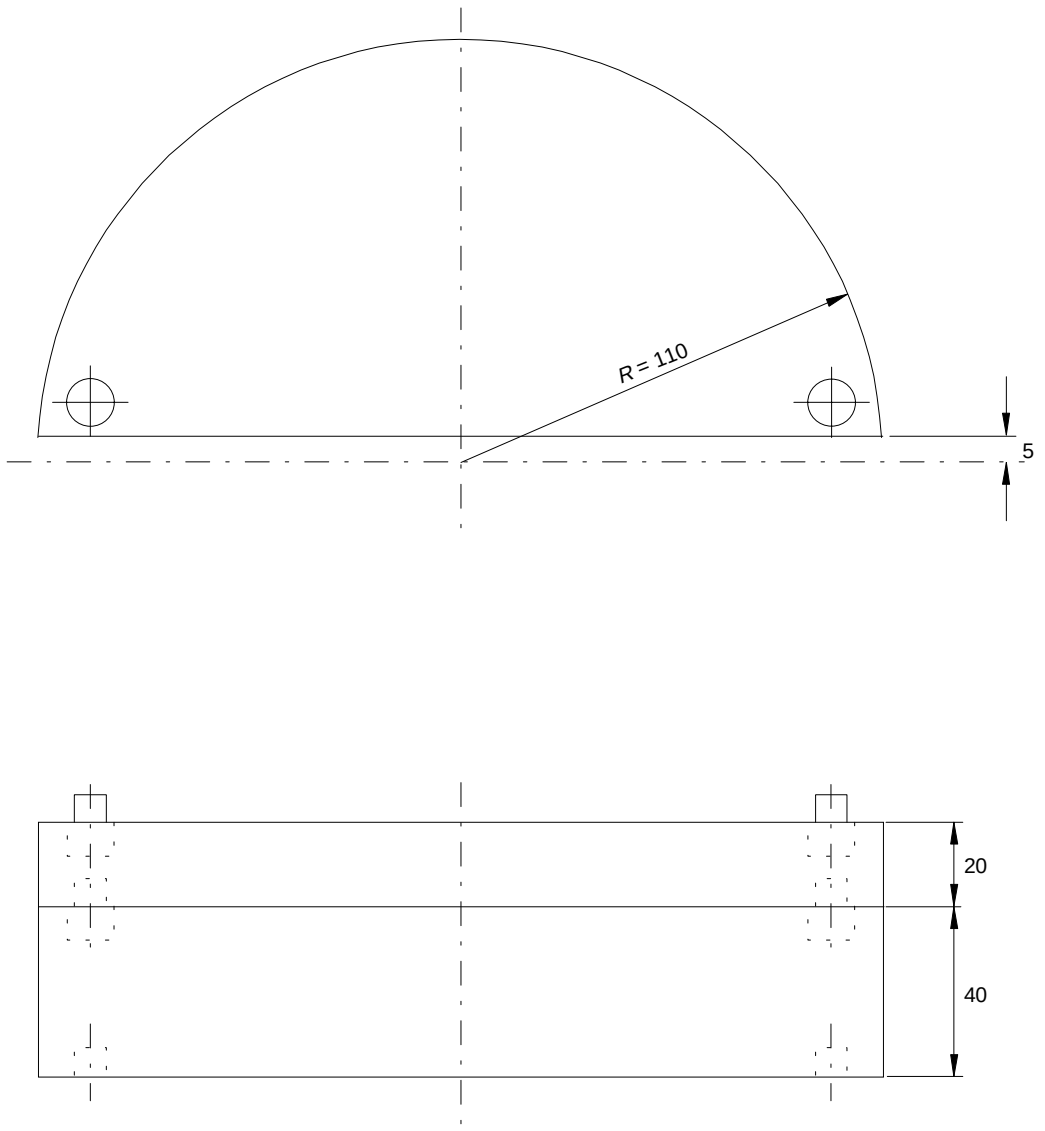
according to IEC 61223-2-10:1999

Compliance with this standard shall be stated as follows:

The X-ray equipment for mammography,....*), complies with IEC 61223-2-10:1999.

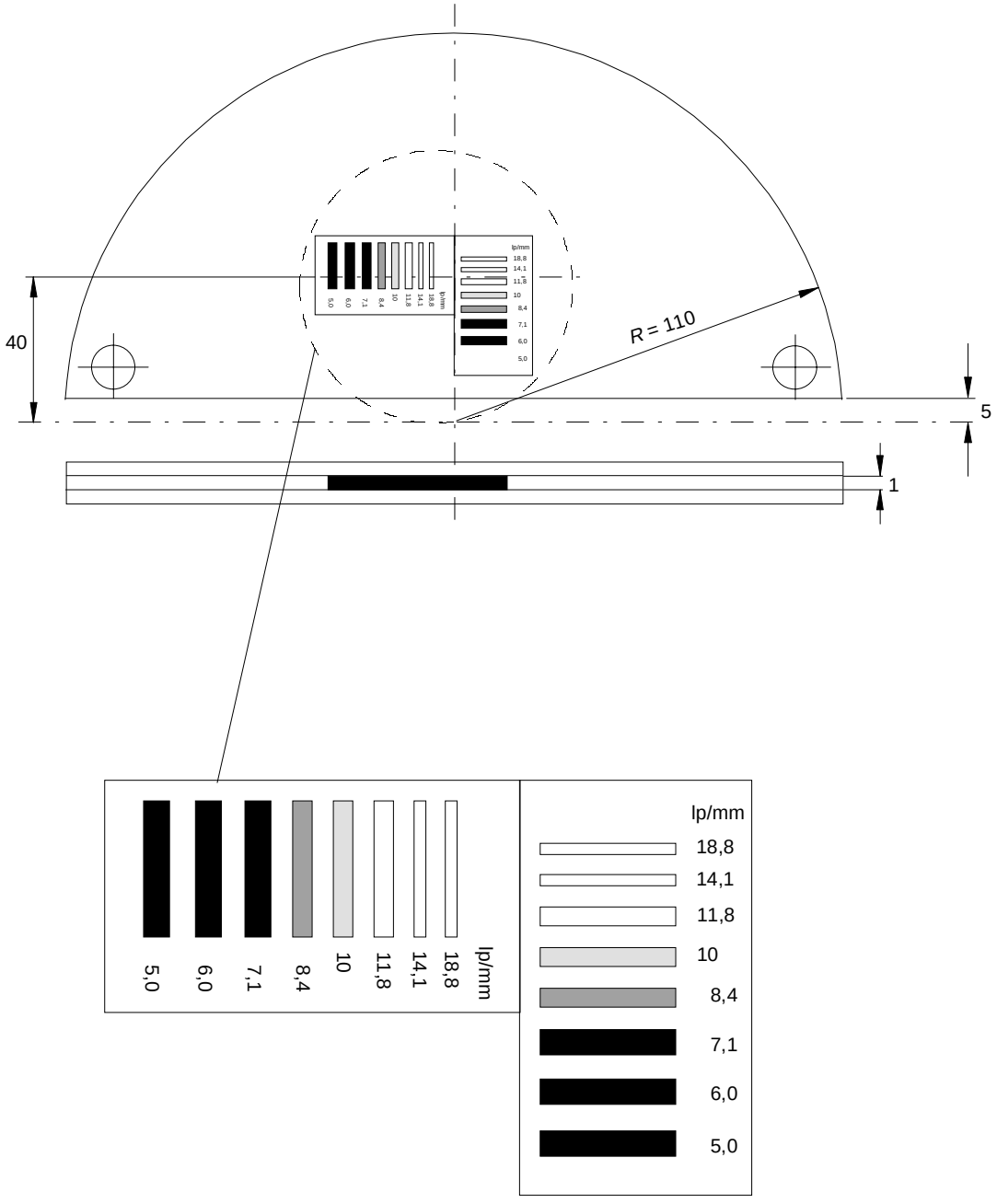
———————

* Identification (for example name of equipment, model or type reference).



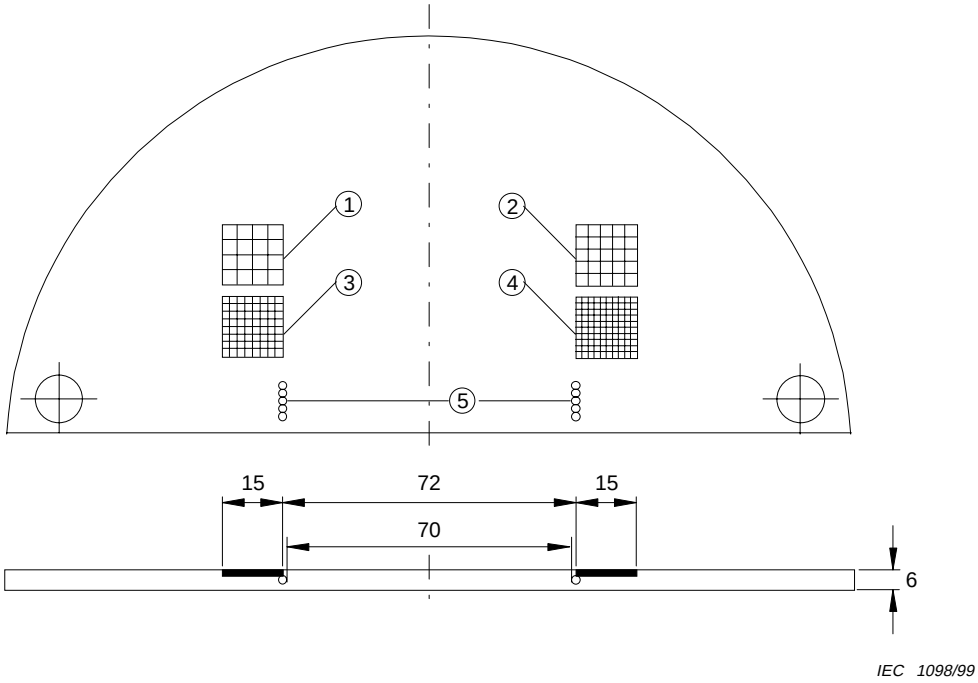
Dimensions in millimetres

Figure 1 – ATTENUATION PHANTOM



Dimensions in millimetres

Figure 2 – High-contrast TEST DEVICE



Key

(1) – (4) Stainless steel gauze

(1)	100 micron	mesh	width	60 micron	wire	diameter
(2)	80 micron	"	"	50 micron	"	"
(3)	63 micron	"	"	40 micron	"	"
(4)	40 micron	"	"	32 micron	"	"

(5) String of balls, of a diameter of 2 mm, to check the position of the radiation beam

Dimensions in millimetres, unless stated otherwise

Figure 3 – Alternative high-contrast TEST DEVICE

Annex A
(normative)

Terminology – Index of defined terms

Annex B
(informative)

Example of a form for the standardized test report

Test report
on constancy tests of X-ray equipment for mammography according to IEC 61223-2-10:1999

Identifications

Person performing test Identification:

a) X-RAY EQUIPMENT

Mammographic X-RAY EQUIPMENT Identification:

– X-RAY SOURCE ASSEMBLY
– X-RAY TUBE ASSEMBLY
– HIGH-VOLTAGE GENERATOR
– BEAM LIMITING DEVICES

Components and ACCESSORIES Identification:

– ADDED FILTERS
– BEAM LIMITING DEVICES
– PATIENT SUPPORT/RADIOGRAPHIC CASSETTE HOLDER
– compression plates
– ANTI-SCATTER GRID
– RADIOGRAPHIC FILM, Type
– RADIOGRAPHIC FILM, Emulsion number
– RADIOGRAPHIC FILM, Date of first use (batch)
– RADIOGRAPHIC CASSETTE, dedicated for test
– RADIOGRAPHIC CASSETTE, to be tested
– INTENSIFYING SCREENS

Darkrooms Identification:

– FILM PROCESSOR Identification:

NOTE – It may be advisable to record data from the processing of the sensitometric wedge such as temperature of developer, FILM BASE PLUS FOG DENSITY, contrast and speed.

Test equipment Identification:

– ATTENUATION PHANTOM, high-contrast TEST DEVICE, alternative high-contrast TEST DEVICE, film-screen contact TEST DEVICE
– densitometer
– sensitometer
– force balance/scales

Test arrangement Values:

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
– reception area
– position and orientation of the TEST DEVICES

Standard test conditions (including environmental influences)

– FOCAL SPOT selected
– ANODE material
– ADDED FILTERS
– X-RAY TUBE VOLTAGE
– X-RAY TUBE CURRENT
– CURRENT TIME PRODUCT
– X-RAY TUBE LOADING TIME
– position of AUTOMATIC EXPOSURE CONTROL device
– programme step of the AUTOMATIC CONTROL SYSTEM
– compression force selected

NOTE 1 – Variables should be set on the same scale range. The actual LOADING of the ANODE resulting from choosing for instance 100 mA for 0,20 s will usually differ from that obtained by setting 200 mA for 0,1 s.

NOTE 2 – Mechanical variables and those electrical variables set by continuous controls should be approached from the same direction, to eliminate backlash effects. It is a good practice to set all controls to zero and reset to desired values to eliminate backlash effects.

History of tests

– most recent test on darkroom conditions Date:
– most recent test on film processing equipment Date:
– most recent initial CONSTANCY TEST Date:
– previous CONSTANCY TEST Date:

b) Mammographic cassettes

See IEC 61223-2-2, annex B.

c) Film processing

See IEC 61223-2-1, annex B.

Test results

Initial CONSTANCY TEST

– image density:

• manual exposure control optical density
• AUTOMATIC EXPOSURE CONTROL optical density

optical densities measured at position: (for example in x-y coordinates)

– CURRENT TIME PRODUCT of the X-RAY TUBE
– LOADING TIME of the X-RAY TUBE
– grid lines or other artefacts on RADIOGRAMS absent ☐ present ☐
– maximum spatial frequency visible parallel to axis of X-RAY TUBE
– maximum spatial frequency visible perpendicular to axis of X-RAY TUBE
– compression force measured with scales
– compression force indicated at X-RAY EQUIPMENT

CONSTANCY TEST

(similar tests as for initial CONSTANCY TEST)

Annex C
(informative)

Guidance on action to be taken

C.1 If the test result indicates that the equipment does not perform according to specified requirements or to ESTABLISHED CRITERIA, the performance of the test equipment should be verified, and the result confirmed by repeating the test, before any further action is initiated.

C.2 If the result of the repeated test confirms that the equipment fails to perform according to the specified requirements or to ESTABLISHED CRITERIA, one or more of the following actions may be taken:

a) as specified in the QUALITY ASSURANCE PROGRAMME for the equipment tested;

b) information of the person responsible for the management of the QUALITY ASSURANCE PROGRAMME;

c) information of the person responsible for the daily management of the equipment tested.

C.3 If the result of a test indicates, that the equipment fails marginally to perform according to specified requirements or to ESTABLISHED CRITERIA, i.e. the equipment can still safely be used in clinical practice for the investigations made with this equipment

a) the result of the next CONSTANCY TEST should be awaited but meanwhile, the quality of the clinical images produced should be closely monitored;

b) the frequency of the CONSTANCY TEST should be increased;

c) the failure of the CONSTANCY TEST should be recorded as an item requiring attention when the next routine servicing is carried out.

C.4 If equipment has a history of failing to perform according to ESTABLISHED CRITERIA of a CONSTANCY TEST, the personnel described in items b) and c) of C.2 should consider

a) carrying out a STATUS TEST; together with

b) a relaxation in the criteria to be applied; together with

c) a restriction on the use of the equipment tested with respect to the category of radiological application; together with

d) thorough non-routine service and overhaul of equipment by authorized service personnel; together with

e) placing the equipment on the list of equipment requiring replacement.

C.5 If the result of a test substantially fails to perform according to specified requirements or to ESTABLISHED CRITERIA:

a) a STATUS TEST is carried out and its result is referred to the personnel described in items b) and c) of C.2;

b) an examination is made to determine whether servicing of the equipment
   - is appropriate; and
   - should be immediate; and

c) a decision is made whether
   - further clinical use of the equipment is suspended; or
   - action according to C.4 is taken.

C.6 Other action to be decided upon by the USER.

Annex D
(informative)

Rationale

Concerning 5.1.1 **Image density**

The procedures for image density CONSTANCY TESTS reflect the particular characteristics of mammographic imaging equipment. Tube ageing and AUTOMATIC EXPOSURE CONTROL non-linearity are particularly important in mammography, so the tests described in 5.1.1 are more detailed and more frequent than would be required in general RADIOGRAPHY.

a) Molybdenum and rhodium ANODES are less "rugged" than conventional tungsten-coated devices, since both materials have a lower melting point. We may therefore expect a significant variation in output characteristics as the number of IRRADIATIONS increases. Occasional checks of image density under *manual* control will help determine the replacement schedule for a tube, even if it is only used under AUTOMATIC EXPOSURE CONTROL. If it is occasionally used in manual mode, perhaps for symptomatic investigations or localization, it is important to be able to assess the appropriate LOADING FACTORS if required. These are likely to have changed when several IRRADIATIONS have been made since the last manual operation. Significant changes in output characteristics, as shown by film density variation in manual mode, may be associated with ANODE crazing. This test offers a simple alternative to imaging the FOCAL SPOT to determine the cause of decreased resolution; see 5.1.3.

b) The AUTOMATIC EXPOSURE CONTROL in a mammographic installation is a "constant density" device, not a "constant IRRADIATION" system. It is difficult to interpret the results of a dosimetric test in terms of film density. While a high-quality DOSEMETER may be used to check an AUTOMATIC EXPOSURE CONTROL in general RADIOLOGY, it is not a useful test tool in mammography.

X-RAY BEAM hardening is significant in mammography. The exit spectrum from a large breast is significantly different from that of a small breast, so the intensifying screen response will be different, even for a constant AIR KERMA RATE at the IMAGE RECEPTION AREA of the cassette.

The X-ray PHOTON yield per unit ANODE charge is low at low X-RAY TUBE VOLTAGES so that mammographic X-ray film is usually working in the "reciprocity failure" region. That is, the image density depends on dose rate as well as integrated dose in the image plane.

Tube output flux will vary with age, as stated above. In the case of tubes with molybdenum ANODES, it is more dependent on X-RAY TUBE VOLTAGE than is the object contrast. (Object contrast is relatively unaffected because much of the image-forming spectrum is in the molybdenum K_{α} lines, so that small variations in X-RAY TUBE VOLTAGE, and increasing age, will alter the entrance dose required to produce a given image density.)

Sophisticated AUTOMATIC EXPOSURE CONTROL devices may compensate for these effects by measuring the output spectrum, output dose rate, object thickness, or by interrogating the LOADING FACTORS, and calculating the required cut-off dose in the image plane that will produce a constant image density. The parameters of that calculation depend on the particular film and screen in use and should be set by the service engineer. For this reason the only valid demonstration of AUTOMATIC EXPOSURE CONTROL constancy is that the PHANTOM image density remains constant when the IRRADIATION conditions are reproduced from time to time.

AUTOMATIC EXPOSURE CONTROL compensation is rarely perfect and usually cannot compensate for very large or very small breasts. There will be some variation therefore in image density between the various PHANTOM thicknesses, but the density for a given PHANTOM thickness should be reproducible and the difference in density for any two PHANTOM thicknesses should be reasonably constant if the LOADING FACTORS are kept constant.

c) A breast screening service places particular importance on medium-term stability of the imaging performance of the X-RAY EQUIPMENT. It is important to maintain a high patient throughput with optimum image quality, and it is sometimes necessary to bring the screening service to the PATIENT. It is therefore quite common to install an X-ray system in a vehicle with no facility for processing the films immediately.

In the case of remote film processing the constancy test for the automatic exposure control by a measurement of the entrance dose at three phantom thicknesses is a reliable check that the mammographic X-ray system is suitable for use.

Where films are processed immediately, the value of a CONSTANCY TEST for AUTOMATIC EXPOSURE CONTROL is mainly in eliminating the AUTOMATIC EXPOSURE CONTROL from any subsequent investigation of poor image quality. Weekly tests are then usually adequate. In the case of remote film processing, the CONSTANCY TEST for AUTOMATIC EXPOSURE CONTROL (see item b)), where IRRADIATION TIME or CURRENT TIME PRODUCT is recorded, is the only feasible check that the X-ray system is suitable for use.

When the X-RAY EQUIPMENT is located in a vehicle or a building without continuous temperature control, moisture condensation often affects the performance of the AUTOMATIC EXPOSURE CONTROL. In this case, the CONSTANCY TEST is a valuable "start-of-day" procedure. If immediate processing is available, the image density check may suggest a variation in LOADING FACTORS or AUTOMATIC EXPOSURE CONTROL setting, to compensate for small variations in AUTOMATIC EXPOSURE CONTROL performance and maintain image quality. If such a variation is made at the beginning of a session, the CONSTANCY TEST should be repeated as the equipment approaches equilibrium.

Concerning 5.4.2 **Contact between INTENSIFYING SCREEN and film**

The use of a wire mesh to detect loss of film-screen contact is common in general RADIOGRAPHY. Fine-grain screens, single-emulsion film, and special processing are used in mammography to obtain the most effective combination of spatial resolution and contrast resolution consistent with PATIENT dose considerations. Defects that would not be revealed by a general screen contact test would degrade the resolution of a mammographic image and reduce its diagnostic effectiveness. A finer mesh is therefore employed in this procedure.

If the mesh were too fine, defects in the mesh itself, or artefacts caused by occasional dust particles, would appear on the test film and be indistinguishable from the permanent effects of cassette warping or loss of contact force.

It is important to limit the test IRRADIATION so that the boundaries of the dark areas on the film are not blurred by SCATTERED RADIATION. This would give the appearance of defective or non-uniform contact when the cause of variation across the film was actually the non-uniformity of the incident RADIATION. As mammographic film usually has a single emulsion only, the ideal test film will therefore have a lower optical density in the dark areas than that applied in testing a general radiographic cassette.

Annex E
(informative)

Bibliography

1 Stanton L., Day J. L., Villafana T., Miller C. H. and Lightfoot D. A., "Dosage Evaluation in Mammography", *Radiology*, 1984, 150: 577-584

2 Prado K. L., Rakowski J. T., Barragan F. and Vanek K. N., "Breast Radiation Dose in Film/Screen Mammography", *Health Physics*, 1988, 55: 81-83

3 Frederick E. E., Squillante M. R., Cirignano L. J., Hahn R. W. and Entine G., "Accurate Automatic Exposure Controller for Mammography: Design and Performance", *Radiology*, 1991, 178: 393-396

4 Wu X, Barnes G.T. and Tucker D.M. “Spectral Dependence of Glandular Tissue Dose in Screen-Film Mammography”, *Radiology,* 1991, 179: 143-148

5 Wu X, Barnes G.T. and Tucker D.M. “Normalized Average Glandular Dose in Molybdenum Target-Rhodium Filter and Rhodium Target-Rhodium Filter Mammography”, *Radiology,* 1994, 193: 83-89

Annex F
(normative)

PHANTOMS and TEST DEVICES

General

In order to check the constancy of the performance of the X-RAY EQUIPMENT, several PHANTOMS and TEST DEVICES are necessary. These are designed to fulfil two objectives:

– to simulate the PATIENT with respect to the ATTENUATION and the hardening of the RADIATION BEAM;

– to provide information related to the imaging geometry and imaging quality by containing specific detailed test components.

For the performance tests described in clause 5, one PHANTOM and three TEST DEVICES are needed. Their main characteristics are described in detail below.

All PHANTOMS and TEST DEVICES should be made with polymethyl-methacrylate, (PMMA). At the low RADIATION energies used in mammography, materials normally regarded as tissue equivalent differ widely from each other and from breast tissues in their ATTENUATION properties. PMMA gives consistent results, is easy to handle, and its relation to breast tissue has been widely studied. For example, 40 mm PMMA has similar characteristics to 45 mm of average breast tissue, and is used as the reference thickness in some of the tests in this standard.

NOTE – For reasons of reproducibility, a support for the PHANTOMS and TEST DEVICES should be used, so that they are aligned with the proximal edge of the breast support table.

ATTENUATION PHANTOM

The ATTENUATION PHANTOM is used to simulate the ATTENUATION, SCATTERING and hardening of the X-RAY BEAM by breast tissue. The cross-section of the ATTENUATION PHANTOM may be rectangular or semi-circular, provided the length is at least 150 mm and the width at least 80 mm. The ATTENUATION PHANTOM shall be composed of separate layers of the same material, so that thicknesses between 20 mm and 60 mm can be assembled, in steps of not more than 20 mm.

Small markers inserted near the edge of the sheets of material are useful for identifying the particular combination of sheets used to produce a particular RADIOGRAM.

An example of an ATTENUATION PHANTOM is shown in figure 1.

High-contrast TEST DEVICE

The high-contrast TEST DEVICE is designed to test the constancy of the high-contrast resolution of X-RAY EQUIPMENT. The device should contain periodic patterns of bars cut from thin foils of high atomic number material (for example, 20 μm lead or gold). The periodic pattern shall give a square wave response and provide a range of spatial frequencies from at least five to 15 line pairs per mm, either continuously or in groups of at least three line pairs with increments in spatial frequency not exceeding 20 % between adjacent groups.

The bar pattern should be fixed on a supporting plate made with PMMA which is 2 mm thick or less. The bars should be orientated in at least two directions at right angles. The whole pattern should be contained within an area not exceeding 40 mm × 40 mm. The device shall include markings on the external surface which permit its reproducible positioning within the RADIATION BEAM.

An example of a high-contrast TEST DEVICE is shown in figure 2.

Alternative high-contrast TEST DEVICE

The alternative high-contrast TEST DEVICE is equivalent to the high-contrast TEST DEVICE in its overall concept. It provides an alternative arrangement to test the constancy of the high-contrast resolution. Instead of applying a pattern of bars as in the high-contrast TEST DEVICE, a structure of mesh wires is provided. The two rows of steel balls for testing the constancy of the geometrical characteristics (see 5.2) may, of course, be combined with the periodic pattern of bars as described in the high-contrast TEST DEVICE.

An example of an alternative high-contrast TEST DEVICE is shown in figure 3.

Film-screen contact TEST DEVICE

The film-screen contact TEST DEVICE is designed to test the efficacy of the contact between the RADIOGRAPHIC FILM and the INTENSIFYING SCREENS used in mammographic cassettes. The device consists of a metal wire mesh not smaller than the IMAGE RECEPTION AREA of the mammographic cassette to be tested. The wire mesh should be vigorously compressed and permanently mounted between rigid PMMA sheets in order to protect the mesh and keep it flat.

The wire mesh should have a square pattern of such a quality that its structure appears uniform when viewed through a magnifying lens on a FILM ILLUMINATOR.

The diameter of the wires should be approximately 0,3 mm to 0,4 mm and the separation between the centres of adjacent wires should be approximately three diameters; see the description of a similar TEST DEVICE in 5.2.2 of IEC 61223-2-2.

Standards Survey

The IEC would like to offer you the best quality standards possible. To make sure that we continue to meet your needs, your feedback is essential. Would you please take a minute to answer the questions overleaf and fax them to us at +41 22 919 03 00 or mail them to the address below. Thank you!

Customer Service Centre (CSC)

International Electrotechnical Commission
3, rue de Varembé
1211 Genève 20
Switzerland

or

Fax to: **IEC**/CSC at +41 22 919 03 00

Thank you for your contribution to the standards-making process.

Nicht frankieren
Ne pas affranchir

Non affrancare
No stamp required

A Prioritaire

RÉPONSE PAYÉE

SUISSE

Customer Service Centre (CSC)
International Electrotechnical Commission
3, rue de Varembé
1211 GENEVA 20
Switzerland

Q1 Please report on **ONE STANDARD** and **ONE STANDARD ONLY**. Enter the exact number of the standard: *(e.g. 60601-1-1)*

.....

Q2 Please tell us in what capacity(ies) you bought the standard *(tick all that apply).* I am the/a:

purchasing agent ❑
librarian ❑
researcher ❑
design engineer ❑
safety engineer ❑
testing engineer ❑
marketing specialist ❑
other.....

Q3 I work for/in/as a: *(tick all that apply)*

manufacturing ❑
consultant ❑
government ❑
test/certification facility ❑
public utility ❑
education ❑
military ❑
other.....

Q4 This standard will be used for: *(tick all that apply)*

general reference ❑
product research ❑
product design/development ❑
specifications ❑
tenders ❑
quality assessment ❑
certification ❑
technical documentation ❑
thesis ❑
manufacturing ❑
other.....

Q5 This standard meets my needs: *(tick one)*

not at all ❑
nearly ❑
fairly well ❑
exactly ❑

Q6 If you ticked NOT AT ALL in Question 5 the reason is: *(tick all that apply)*

standard is out of date ❑
standard is incomplete ❑
standard is too academic ❑
standard is too superficial ❑
title is misleading ❑
I made the wrong choice ❑
other .....

Q7 Please assess the standard in the following categories, using the numbers:
(1) unacceptable,
(2) below average,
(3) average,
(4) above average,
(5) exceptional,
(6) not applicable

timeliness.....
quality of writing.....
technical contents.....
logic of arrangement of contents .....
tables, charts, graphs, figures.....
other .....

Q8 I read/use the: *(tick one)*

French text only ❑
English text only ❑
both English and French texts ❑

Q9 Please share any comment on any aspect of the IEC that you would like us to know:

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

ISBN 2-8318-4904-7

ICS 11.040.50

Typeset and printed by the IEC Central Office
GENEVA, SWITZERLAND