INTERNATIONAL STANDARD

IEC 61223-2-11

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

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

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

Partie 2-11: Essais de constance – Appareils de radiographie générale directe

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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.*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

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.
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3) The documents produced have the form of recommendations for international use and are published in the form of standards, 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.
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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 61223-2-11 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/373/FDIS	62B/385/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 D form an integral part of this standard.

Annexes B and C are for information only.

This standard forms part 2-11 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.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

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; and
– process, present and store radiographic information in RADIOLOGICAL INSTALLATIONS with diagnostic X-ray systems using RADIOGRAPHIC FILM in DIRECT RADIOGRAPHY.

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 does not apply to equipment for special applications such as mammographic X-RAY EQUIPMENT or dental X-RAY EQUIPMENT; see complete list of all parts 2 of IEC 61223 in the foreword.

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 equipment for general direct radiography 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 such 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 International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

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*

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; 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.

4 General aspects of CONSTANCY TESTS

The methods for testing the constancy described in this standard are intended to enable the OPERATOR to detect changes in image quality of images produced by X-RAY EQUIPMENT.

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 environmental influences.

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.

Appropriate individual TEST DEVICES are described in detail in annex D for each of the test measurements described in clause 5 of this standard. In practice, a composite TEST DEVICE may be used, which combines the properties of some of the individual TEST DEVICES. Furthermore, some of the test procedures described separately in clause 5 may be performed simultaneously.

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. It is important

– to perform CONSTANCY TESTS with LOADING FACTORS which are the same as those used most frequently in clinical practice;

– to record and reproduce 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 particularly variations in supply voltage, on the results;

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

Before the CONSTANCY TESTS are started, the constancy of the radiographic cassettes, the radiographic film, the film processing and the film viewing conditions shall 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 or STATUS 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 should 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;

– BEAM LIMITING DEVICE;

– PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;

– RADIATION DETECTOR of the AUTOMATIC CONTROL SYSTEM;

– ANTI-SCATTER GRID;

together with items of test instrumentation such as

– combination of RADIOGRAPHIC CASSETTE and INTENSIFYING SCREENS;
– TEST DEVICES;
– RADIOGRAPHIC FILM type and emulsion number;
– FILM PROCESSOR;
– sensitometer;
– densitometer;

and settings of variables such as

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
– AUTOMATIC CONTROL SYSTEM density control and sensor position;
– LOADING FACTORS;
– 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 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 for the CONSTANCY TEST for the FILM PROCESSOR.

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.

4.5 Measured functional parameters

The imaging performance of a direct radiographic system is considered to be constant if the variations of the following functional parameters are found to meet applicable criteria:

– RADIATION output from the X-RAY SOURCE ASSEMBLY; see 5.1;
– RADIATION input to the IMAGE RECEPTION AREA; see 5.2;
– geometric characteristics; see 5.3;
– resolution of high-contrast detail; see 5.4:
– variation in optical density throughout a RADIOGRAM; see 5.5.

The constancy of the imaging performance may be affected by variations in one or more of the following parameters:

– value and wave-form of the mains voltage;
– value and wave-form of the X-RAY TUBE VOLTAGE;
– X-RAY TUBE CURRENT;
– LOADING TIME;
– IRRADIATION TIME under AUTOMATIC EXPOSURE CONTROL;
– FILTRATION and ATTENUATION by layers in the RADIATION BEAM;
– roughening of the TARGET in the ANODE of the X-RAY TUBE;

– distances of planes of interest from the FOCAL SPOT;
– limitation of the RADIATION BEAM;
– direction of the RADIATION BEAM;
– alignment of the RADIATION BEAM with the IMAGE RECEPTION AREA;
– coincidence of the RADIATION FIELD with the field indicated by the LIGHT FIELD-INDICATOR;
– movement of the MOVING GRID;
– positioning of the ANTI-SCATTER GRID;
– imaging properties of the FOCAL SPOT;
– mechanical stability.

5 Performance tests

5.1 RADIATION output from the X-RAY SOURCE ASSEMBLY

5.1.1 Summary

The RADIATION output from the X-RAY SOURCE ASSEMBLY is measured by means of a RADIATION METER. The measurements are carried out under manual and/or AUTOMATIC EXPOSURE CONTROL, depending upon the type and use of the X-RAY EQUIPMENT.

5.1.2 Test equipment

Measurements are performed using an integrating RADIATION METER having an overall reproducibility of ±5 % (including long-term stability, instrument noise and read-out ability).

As a substitute for the PATIENT when testing under AUTOMATIC EXPOSURE CONTROL, the ATTENUATION PHANTOM shall be used. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. A detailed description including consideration for the correct choice of an ATTENUATION PHANTOM is provided in annex D.

5.1.3 Test procedure

Place the RADIATION DETECTOR of the RADIATION METER in the RADIATION BEAM emerging from the X-RAY SOURCE ASSEMBLY. Measurement geometry shall be such that

– *the distance of the RADIATION DETECTOR from the FOCAL SPOT;*
– *the position of the RADIATION DETECTOR within the RADIATION FIELD;*

are reproduced to within ±1 % of the FOCAL SPOT to RADIATION DETECTOR distance used in the initial CONSTANCY TEST. The same RADIATION FIELD size shall be used.

Whenever possible, carry out this test under both manual and AUTOMATIC EXPOSURE CONTROL. If a measurement according to 5.2.3.2 is performed, a measurement according to 5.1.3.2 may be regarded as redundant.

5.1.3.1 Testing under manual control

Operate the X-RAY EQUIPMENT using manual settings of the LOADING FACTORS identical to those used in the initial CONSTANCY TEST.

Record the reading of the RADIATION METER.

5.1.3.2 Testing under AUTOMATIC EXPOSURE CONTROL

Align the X-RAY SOURCE ASSEMBLY with the X-RAY IMAGE RECEPTOR as in normal clinical practice.

Place the ATTENUATION PHANTOM in the RADIATION BEAM between the RADIATION DETECTOR of the RADIATION METER and the RADIATION DETECTORS of the AUTOMATIC CONTROL SYSTEM.

Position the RADIATION DETECTOR of the RADIATION METER so as not to affect the operation of the AUTOMATIC CONTROL SYSTEM.

NOTE – For every RADIATION DETECTOR, a specific instruction has to be given as to where it has to be positioned in order to minimize the effect on the AUTOMATIC EXPOSURE CONTROL. If ATTENUATION PHANTOMS are used which are attached to the X-RAY SOURCE ASSEMBLY (A2 or A3), making the measurement behind the PHANTOM (if the sensitivity of the RADIATION DETECTOR allows it) has to be considered.

Place an unloaded RADIOGRAPHIC CASSETTE in the CASSETTE CHANGER and operate the X-RAY EQUIPMENT in conjunction with the AUTOMATIC CONTROL SYSTEM using settings of the X-RAY TUBE VOLTAGE identical to those used in the initial CONSTANCY TEST. Use the same RADIOGRAPHIC CASSETTE.

Record the reading of the RADIATION METER. In addition, record the IRRADIATION TIME, CURRENT TIME PRODUCT, etc. after each IRRADIATION has been made, if these are indicated.

5.1.4 Data evaluation

Compare the measured values of RADIATION output with the established BASELINE VALUES.

5.1.5 Criteria to be applied

5.1.5.1 Testing under manual control

The RADIATION output should be within ±20 % of the BASELINE VALUES.

5.1.5.2 Testing under AUTOMATIC EXPOSURE CONTROL

The criteria to be applied depend on material used in the ATTENUATION PHANTOM.

If materials with low atomic number (up to 14) are used (for example water, polymethyl-methacrylate (PMMA), aluminium) the RADIATION output should be within the range +25 % to –20 % of the BASELINE VALUES.

For high atomic number materials, for example copper or lead, the action levels for the RADIATION output should be within ±25 % of the BASELINE VALUES.

When lead is used with X-RAY TUBE VOLTAGES above 90 kV, the action levels appropriate to low atomic number materials shall be applied.

5.1.6 Action to be taken

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

NOTE – A gradual decrease in the RADIATION output is to be expected as a result of ageing of the X-RAY TUBE. In order to allow for this, it will be necessary from time to time to determine new BASELINE VALUES. This holds especially for testing under manual control, whereas for AUTOMATIC EXPOSURE CONTROL a decrease in the RADIATION output is compensated and cannot be detected.

5.1.7 Frequency of CONSTANCY TESTS

Initially, a series of CONSTANCY TESTS should be carried out daily for at least one week in order to establish the BASELINE VALUES by calculating the mean value of the output measurements.

Subsequently, the CONSTANCY TESTS should be repeated in a two-week cycle up to six months, in order to obtain data regarding the reliability of the X-RAY SOURCE ASSEMBLY, HIGH-VOLTAGE GENERATOR and AUTOMATIC CONTROL SYSTEM. Thereafter, the CONSTANCY TESTS 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 least quarterly.

5.2 RADIATION input to the IMAGE RECEPTION AREA

5.2.1 Summary

The RADIATION input to the IMAGE RECEPTION AREA is determined from measurements of the optical density, recorded at specific points of a RADIOGRAM. Alternatively, the RADIATION input may be directly measured by means of a RADIATION METER.

NOTE – However a RADIATION METER takes no account of the X-RAY BEAM quality. The film method should therefore be preferred.

The measurements are carried out under manual and/or AUTOMATIC EXPOSURE CONTROL, depending upon the type and use of the X-RAY EQUIPMENT.

5.2.2 Test equipment

This test shall be performed using the same ANTI-SCATTER GRID, the same dedicated RADIOGRAPHIC CASSETTE and associated screen-film combination of the type normally used with the X-RAY EQUIPMENT under test. The systematic error of the optical densitometer used shall not be higher than ±0,02.

If a RADIATION METER is used, the instrument shall be of the integrating type with an overall reproducibility of ±5 % (including long-term stability, instrument noise and read-out ability).

The ATTENUATION PHANTOM shall be used as a substitute for the PATIENT. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. In addition, the film marker TEST DEVICE shall also be used in order to enable specific points in the RADIOGRAM to be identified where measurements of the optical density are to be made.

Detailed descriptions including consideration for the correct choice of the ATTENUATION PHANTOM and the film marker TEST DEVICE are provided in annex D.

5.2.3 Test procedure

If the equipment is provided with AUTOMATIC EXPOSURE CONTROL, perform the CONSTANCY TEST in automatic mode. Whenever possible, repeat this CONSTANCY TEST under manual control.

Align the X-RAY SOURCE ASSEMBLY with the X-RAY IMAGE RECEPTOR as in normal clinical practice.

If a RADIOGRAPHIC CASSETTE is used, put it into its place. If a RADIATION METER is used, place its RADIATION DETECTOR in the IMAGE RECEPTION AREA. Place the ATTENUATION PHANTOM and the film marker TEST DEVICE in the X-RAY BEAM between the FOCAL SPOT and the X-RAY IMAGE RECEPTOR.

For any item of test equipment, the measurement geometry shall be such that the distance from the FOCAL SPOT and the position within the RADIATION FIELD are reproduced to within 1 % of the distance from the FOCAL SPOT used in the initial CONSTANCY TEST. The same size of RADIATION FIELD shall be used.

Select at least two X-RAY TUBE VOLTAGE settings that are identical to the settings used in the initial CONSTANCY TEST.

a) Testing under manual control

Operate the X-RAY EQUIPMENT by using the manual settings of the LOADING FACTORS identical to those in the initial CONSTANCY TEST.

Process the irradiated film in accordance with the procedure referred to in 4.4.

Measure the optical density at specific points of the RADIOGRAM or record the signal indicated by the RADIATION METER.

If necessary, adjust the measured values of density in accordance with the procedure referred to in 4.4 to allow for any changes in film batch or processing conditions.

b) Testing under AUTOMATIC EXPOSURE CONTROL

Operate the X-RAY EQUIPMENT in conjunction with the AUTOMATIC CONTROL SYSTEM and using the X-RAY TUBE VOLTAGE and all other appropriate settings identical to those used in the initial CONSTANCY TEST.

Follow the same procedure as indicated in a) above for testing under manual control.

5.2.4 Data evaluation

Compare measured values of optical density or RADIATION input with the established BASELINE VALUES.

5.2.5 Criteria to be applied

a) Testing under manual control

The optical density should be within ±0,3 of the BASELINE VALUE. If a RADIATION METER is used, the RADIATION input should be within ±30 % of the BASELINE VALUE.

b) Testing under AUTOMATIC EXPOSURE CONTROL

The optical density should be within ±0,15 of the BASELINE VALUE. If a RADIATION METER is used, the RADIATION input should be within ±15 % of the BASELINE VALUE.

The above tolerances apply to RADIOGRAPHIC FILMS with an average gradient between 2 and 3.

5.2.6 Action to be taken

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

5.2.7 Frequency of CONSTANCY TESTS

Initially, a series of CONSTANCY TESTS should be carried out daily for at least one week in order to establish the BASELINE VALUES by calculating the mean of the measurements of optical densities or RADIATION input.

Thereafter, the CONSTANCY TESTS 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 least quarterly.

5.3 Geometric characteristics

5.3.1 Summary

These tests shall be performed to check the constancy of the following geometric characteristics of the X-RAY EQUIPMENT:

– the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;

– the perpendicular position of the RADIATION BEAM AXIS to the IMAGE RECEPTOR PLANE;

NOTE – Generally, it is sufficient to test the REFERENCE DIRECTION of the X-RAY SOURCE ASSEMBLY with respect to the surface of the PATIENT SUPPORT or the ENTRANCE SURFACE of the X-RAY IMAGE RECEPTOR. A change in parallelism between these surfaces and the IMAGE RECEPTOR PLANE is in most cases unlikely.

– the coincidence of the RADIATION FIELD with the LIGHT FIELD; see figure 202 of IEC 60601-1-3;

– the coincidence of the RADIATION FIELD with the X-RAY IMAGE RECEPTOR; see figure 202 of IEC 60601-1-3;

– the read-out of the RADIATION FIELD size, where applicable.

5.3.2 Test equipment

The following test equipment is required:

– tape measure;

– two cassettes with screens, of different sizes, for example 24 cm × 30 cm and 35 cm × 43 cm;

– RADIOGRAPHIC FILM;

– ruler;

– spirit level;

– TEST DEVICE for perpendicular position;

– TEST DEVICE for alignment.

In order to test the perpendicular position of the RADIATION BEAM AXIS to the IMAGE RECEPTOR PLANE, the TEST DEVICE shall be used.

The alignment TEST DEVICE is used to enable the edges and centre of the LIGHT FIELD and the unambiguous orientation of this TEST DEVICE to be identified on the RADIOGRAM.

If IRRADIATIONS are made under AUTOMATIC EXPOSURE CONTROL, the ATTENUATION PHANTOM shall also be used as a substitute for the PATIENT in order to provide appropriate ATTENUATION and hardening of the X-RAY BEAM.

Detailed descriptions of the ATTENUATION PHANTOM and the TEST DEVICES for the perpendicular position and alignment are provided in annex D.

5.3.3 Test procedure

5.3.3.1 Indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE

Step 1: Using the indicator associated with the X-RAY EQUIPMENT, set the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE to the value used in the initial CONSTANCY TEST.

Step 2: Measure the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE using the tape measure. If the position of the FOCAL SPOT is not clearly indicated on the surface of the X-RAY SOURCE ASSEMBLY, make this measurement from the same point on the X-RAY SOURCE ASSEMBLY as that used in the initial CONSTANCY TEST, for example the nearest point on the X-RAY SOURCE ASSEMBLY to the X-RAY IMAGE RECEPTOR.

5.3.3.2 Other geometric characteristics of over-couch X-RAY TUBE ASSEMBLIES with manually adjusted, fixed or automatic BEAM LIMITING SYSTEMS

The following test procedure describes a method of checking simultaneously all the characteristics listed in 5.3.1.

Step 1: Check that the PATIENT SUPPORT is horizontal using a spirit level. If a built-in angulation-indicator is used, check it against the spirit level and adjust if necessary. If the built-in angulation-indicator cannot be adjusted, record the deviation.

If the PATIENT SUPPORT cannot be brought to the horizontal position, record the deviation.

Step 2: Align the X-RAY SOURCE ASSEMBLY with the centre of the PATIENT SUPPORT or IMAGE RECEPTION AREA and adjust the X-RAY TUBE ASSEMBLY axis to be parallel to the long axis of the PATIENT SUPPORT using the facilities and indicators available on the equipment. Select the same FOCAL SPOT TO IMAGE RECEPTOR DISTANCE as used in the initial CONSTANCY TEST.

Step 3: Place a loaded 24 cm × 30 cm RADIOGRAPHIC CASSETTE (cassette "P": see figures 5a, 5b and 5c) in the centre of the CASSETTE CHANGER as determined by the clamps. Align the centre of the CASSETTE CHANGER with the X-RAY TUBE ASSEMBLY by means of the facilities provided and lock into position. Insert the CASSETTE CHANGER into the correct position for the X-RAY IMAGE RECEPTOR.

Step 4: For a manually adjusted or fixed BEAM LIMITING SYSTEM proceed directly to step 5.

Support a loaded 24 cm × 30 cm RADIOGRAPHIC CASSETTE (cassette "Q": see figure 5b) in a plane parallel to the PATIENT SUPPORT or X-RAY IMAGE RECEPTOR, but at a distance of between 20 cm and 30 cm closer to the X-RAY TUBE ASSEMBLY than the PATIENT SUPPORT or X-RAY IMAGE RECEPTOR. Orient the cassette so that the normal ENTRANCE SURFACE is on the side opposite the X-RAY TUBE ASSEMBLY and ensure that the cassette intercepts the entire X-RAY BEAM.

Measure and record the distance from the FOCAL SPOT to cassette "Q" at the centre of the LIGHT FIELD by means of the LIGHT FIELD INDICATOR and align the edges of the cassette parallel with the edges of the LIGHT FIELD.

NOTE – The distances from the FOCAL SPOT to the two RADIOGRAPHIC CASSETTES are different and there are more absorbing materials in front of cassette "P", such as the PATIENT SUPPORT and the ANTI-SCATTER GRID and the cassette "Q". The AIR KERMA to the two cassettes may therefore differ considerably and, in an attempt to facilitate the choice of a single set of LOADING FACTORS to provide adequate IRRADIATION of the films in both cassettes, cassette "Q" is used in the reverse orientation to that normally employed.

If the test cannot satisfactorily be performed with a single IRRADIATION, it will be necessary to perform two IRRADIATIONS with different LOADING FACTORS.

Step 5: For a manually adjusted or fixed BEAM LIMITING SYSTEM, place the alignment TEST DEVICE on the PATIENT SUPPORT or ENTRANCE SURFACE of the X-RAY IMAGE RECEPTOR. If the PATIENT SUPPORT is curved, place a thin, flat rigid surface of low ATTENUATION material, for example wood, across the PATIENT SUPPORT to maintain the TEST DEVICE in a plane parallel to the X-RAY IMAGE RECEPTOR.

For automatically adjusted BEAM LIMITING SYSTEMS place the alignment TEST DEVICE on the surface of cassette "Q" which is closest to the X-RAY TUBE ASSEMBLY.

The alignment TEST DEVICE incorporates the radio-opaque markings required in the evaluation of the size of the RADIATION FIELD.

Step 6: *Place the alignment TEST DEVICE in the centre of the LIGHT FIELD according to the LIGHT FIELD INDICATOR and align the edges of the TEST DEVICE parallel to the edges of the LIGHT FIELD.*

- *For automatically adjusted BEAM LIMITING SYSTEMS record the size and position of the LIGHT FIELD in relation to the markings on the external surface of the TEST DEVICE.*
- *For manually adjusted or fixed BEAM LIMITING SYSTEMS adjust the LIGHT FIELD size to the small field size markings on the alignment TEST DEVICE, for example 15 cm × 20 cm. Note the settings of the field size indicators of the BEAM LIMITING DEVICE. Record the extent of any asymmetry in the LIGHT FIELD, whereby one or more edges of the LIGHT FIELD cannot be set to coincide with the edges of the field defined by the alignment TEST DEVICE.*

Step 7: *Place the TEST DEVICE for the perpendicular position on top of the alignment TEST DEVICE so that the centre of the rings on the lower base of the TEST DEVICE for the perpendicular position coincides with the centre of the LIGHT FIELD indicated on the surface of the alignment TEST DEVICE. The test arrangements are shown in figures 5a and 5b.*

Step 8: *Make a radiographic IRRADIATION using the same LOADING FACTORS as in the initial CONSTANCY TEST in order to provide an optical density in the range from 0,5 to 1,5 on the processed RADIOGRAPHIC FILM.*

NOTE – If the IRRADIATION can only be made under AUTOMATIC EXPOSURE CONTROL, it may also be necessary to use the ATTENUATION PHANTOM (see 5.1.2) as a substitute for the PATIENT, in order to provide appropriate ATTENUATION and hardening of the X-RAY BEAM interacting with the AUTOMATIC CONTROL SYSTEM. For the placement of the ATTENUATION PHANTOM, see figures 5a and 5b.

- *For automatically adjusted BEAM LIMITING SYSTEMS, process the films in both cassettes.*
- *For manually adjusted or fixed BEAM LIMITING SYSTEMS, re-adjust the LIGHT FIELD to the maximum cassette size. Process the film in the cassette.*

Step 9: *Remove the TEST DEVICE and repeat the above procedure (steps 1 to 8) but using loaded 35 cm × 43 cm RADIOGRAPHIC CASSETTES as cassettes "P" and "Q".*

NOTE – A smaller RADIOGRAPHIC CASSETTE may be adequate at location "Q".

In addition, for fixed/manually adjusted BEAM LIMITING SYSTEMS, in step 6 use the larger field settings indicated on the alignment TEST DEVICE (for example 30 cm × 40 cm).

5.3.3.3 X-RAY EQUIPMENT in which the RADIATION BEAM can only be directed horizontally

The procedures described in items 5.3.3.1 and 5.3.3.2 above are applicable to over-couch X-RAY TUBE ASSEMBLIES. The same procedure may be adopted for X-RAY EQUIPMENT in which the RADIATION BEAM is directed horizontally, except that the procedures will need to be modified as follows.

- *Check that the PATIENT SUPPORT or X-RAY IMAGE RECEPTOR is in the vertical position instead of the horizontal position, using the built-in angulation-indicator or a spirit level if no such built-in angulation-indicator is provided.*
- *Provide means of supporting the TEST DEVICES in position versus the vertical surface of the PATIENT SURFACE or X-RAY IMAGE RECEPTOR input surface.*

5.3.3.4 X-RAY EQUIPMENT with under-couch X-RAY TUBE ASSEMBLIES

Because there is no light field-indication available with under-couch X-RAY TUBE ASSEMBLIES, it is not possible to perform checks on all the geometric characteristics described in 5.3.1. The only characteristic which can be checked without using methods of considerable complexity is the coincidence of the RADIATION FIELD with the X-RAY IMAGE RECEPTOR.

Step 1: *Check the PATIENT SUPPORT to be horizontal using the built-in angulation-indicator or a spirit level if no built-in angulation-indicator is provided. If the PATIENT SUPPORT is not horizontal or cannot be brought to the horizontal position, record the deviation.*

Step 2: *The under-couch X-RAY SOURCE ASSEMBLY will normally be aligned automatically with the centre of the IMAGE RECEPTION AREA when the X-RAY IMAGE RECEPTOR is in the operational position. Select the same FOCAL SPOT TO IMAGE RECEPTOR DISTANCE as used in the initial CONSTANCY TEST.*

For convenience this may be the maximum height at which the X-RAY IMAGE RECEPTOR can be set above the PATIENT SUPPORT.

Remove any secondary BEAM LIMITING DEVICE between the PATIENT and image receptor.

Step 3: *Place a loaded 24 cm × 30 cm RADIOGRAPHIC CASSETTE (cassette "P") in the centre of the CASSETTE CHANGER as determined by the clamps. Insert the CASSETTE CHANGER into the correct position for the X-RAY IMAGE RECEPTOR. The test arrangement is shown in figure 5c.*

Step 4: *Proceed to carry out this test in accordance with the method described for automatically adjusted BEAM LIMITING SYSTEMS in steps 4, 5, 8, and 9 of 5.3.3.2.*

5.3.4 Data evaluation

5.3.4.1 Manually adjusted or fixed BEAM LIMITING SYSTEMS

Step 1: *Measure the distances between the edges of the RADIATION FIELD as defined by the darker irradiated area on each RADIOGRAM produced in cassette "P" and the edges of the LIGHT FIELD as indicated by the images of the radio-opaque markers. For each pair of opposite edges add these measurements to calculate the degree of misalignment; see figure 6a.*

Step 2: *Measure the lengths of the edges of the RADIATION FIELD as determined by the darker irradiated area on each of the RADIOGRAMS produced in cassette "P". Subtract the indicated dimensions of field size from the measured dimensions; see figure 6b.*

5.3.4.2 Automatic BEAM LIMITING SYSTEMS except those with under-couch X-RAY TUBE ASSEMBLIES

Step 1: *Measure the distances between the edges of the RADIATION FIELD as defined by the darker irradiated area on each RADIOGRAM produced in cassette "Q" and the edges of the LIGHT FIELD as indicated by the images of the radio-opaque markers which correspond to the size and position of the LIGHT FIELD noted during the test; see step 2 of 5.3.3.2. Add these measurements for each pair of opposite edges to calculate the degree of misalignment.*

Step 2: *Measure the distances d_P and d_Q between two radio-opaque markers visible in both RADIOGRAMS, produced in cassettes "P" and "Q". Determine the magnification "m" by calculating the ratio d_P/d_Q.*

Measure the distances between the edges of the RADIATION FIELD as defined by the darker irradiated area on the RADIOGRAM produced in cassette "Q". To determine the distances between the edges of the RADIATION FIELD at the position of cassette "P", multiply these measured distances by "m".

Determine the difference between the estimated distance between the opposite edges of the RADIATION FIELD *and the corresponding distance between the edges of the* IMAGE RECEPTION AREA*. Add these differences for each pair of opposite edges to calculate the degree of misalignment.*

5.3.4.3 Under-couch X-RAY TUBE ASSEMBLIES

Make the measurements described in step 2 of 5.3.4.2.

NOTE – This test cannot be performed if any edge of the RADIATION FIELD is outside the boundary of the X-RAY IMAGE RECEPTOR.

5.3.5 Criteria to be applied

5.3.5.1 Indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE

The FOCAL SPOT TO IMAGE RECEPTOR DISTANCE shall be within ±1 % of the indicated distance and within ±1 % of the distance measured in the initial CONSTANCY TEST.

5.3.5.2 Perpendicular position of RADIATION BEAM AXIS to X-RAY IMAGE RECEPTOR (see note in 5.3.1)

The RADIATION BEAM AXIS shall be within 1,5° of the perpendicular axis to the IMAGE RECEPTION AREA. To check this, the image of the centre of the cross shall fall within the image of the inner circle of the TEST DEVICE for the perpendicular position.

5.3.5.3 Coincidence of RADIATION FIELD with LIGHT FIELD

In figure 6a, the measured discrepancies are represented by a_1 and a_2 on one axis and by b_1 and b_2 on the other. If the distance from the FOCAL SPOT is S, then, for compliance, the following relationships are true:

$$|a_1| + |a_2| \leq 0{,}02 \times S$$

$$|b_1| + |b_2| \leq 0{,}02 \times S$$

5.3.5.4 Coincidence of RADIATION FIELD with X-RAY IMAGE RECEPTOR

In figure 6b, the measured discrepancies are represented by c_1 and c_2 on one axis and by d_1 and d_2 on the other. If the distance from the FOCAL SPOT is S, then, for compliance, the following relationships are true:

$$|c_1| + |c_2| \leq 0{,}03 \times S$$

$$|d_1| + |d_2| \leq 0{,}03 \times S$$

$$|c_1| + |c_2| + |d_1| + |d_2| \leq 0{,}04 \times S$$

If, in addition to automatic beam limitation, a secondary BEAM LIMITING DEVICE is normally located between the PATIENT and the X-RAY IMAGE RECEPTOR, the misalignment criteria shall apply to the projection of the RADIATION FIELD as though the secondary BEAM LIMITING DEVICE were not present.

5.3.5.5 Accuracy of the numerical indication of the RADIATION FIELD size

The difference between the indicated dimensions of the RADIATION FIELD size and the measured dimensions shall be within ±2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

5.3.6 Action to be taken

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

5.3.7 Frequency of CONSTANCY TESTS

The tests shall be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at least quarterly.

5.4 Resolution of high-contrast detail

5.4.1 Summary

If variation in FOCAL SPOT size with time cannot be excluded, the following tests shall be performed.

This test checks the constancy of resolution of the X-RAY EQUIPMENT by producing a radiographic image of a high-contrast TEST DEVICE.

5.4.2 Test equipment

The following test equipment is required:

– a magnifying glass. A 2,5 × magnification is usually suitable;

– a high-contrast TEST DEVICE containing periodic patterns of radio-opaque materials (a detailed description of the high-contrast TEST DEVICE is provided in annex D);

– a dedicated RADIOGRAPHIC CASSETTE and associated screen-film combination of the type normally used with the X-RAY EQUIPMENT in clinical practice.

5.4.3 Test procedure

Place the dedicated loaded cassette in the IMAGE RECEPTOR PLANE at the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE used in normal clinical practice.

Place the high-contrast TEST DEVICE on the PATIENT SUPPORT, or the ENTRANCE PLANE of the SPOT FILM DEVICE so that the bar pattern is kept at about 200 mm from the surface (see annex D). Centre the X-RAY TUBE ASSEMBLY to the X-RAY IMAGE RECEPTOR and centre the test pattern to the X-RAY TUBE ASSEMBLY.

Orientate the main directions of the bars of the test pattern by approximately 45° to the X-RAY TUBE axis. For any item of test equipment, choose the measurement geometry so that the distance from the FOCAL SPOT and the position within the RADIATION FIELD can be reproduced to within ±1 % of the distance and position used in the initial CONSTANCY TEST.

Set the X-RAY TUBE VOLTAGE at about 70 kV and choose the LOADING FACTORS so as to provide an optical density of between 0,7 and 1,3 above FILM BASE PLUS FOG DENSITY in the unattenuated region of the processed film. Use the same LOADING FACTORS as those used in the initial CONSTANCY TEST.

NOTE – If the IRRADIATION can only be made under AUTOMATIC EXPOSURE CONTROL, it may also be necessary to use an ATTENUATION PHANTOM (see 5.1.2) as a substitute for the PATIENT, in order to provide appropriate ATTENUATION and hardening of the X-RAY BEAM interacting with the AUTOMATIC CONTROL SYSTEM. Under these circumstances, the ATTENUATION PHANTOM should be placed in the X-RAY BEAM as close as possible to the FOCAL SPOT as the X-RAY SOURCE ASSEMBLY will permit.

Take a RADIOGRAM with an X-RAY BEAM size of 100 mm × 100 mm measured at the PATIENT SUPPORT plane. Repeat the procedure for each available FOCAL SPOT size which can be selected.

For each test, note the LOADING FACTORS.

Process the irradiated films in accordance with the procedure referred to in 4.4.

5.4.4 Data evaluation

Examine the RADIOGRAM with the aid of a magnifying glass and record the maximum spatial frequencies visible. These are the cut-off frequencies under the test conditions.

In order to provide a comparison, undertake the same procedure with the RADIOGRAMS from the initial CONSTANCY TEST each time that this test is performed.

5.4.5 Criteria to be applied

By comparison with the cut-off frequency from the initial CONSTANCY TEST, the measured cut-off frequency shall not decrease by more than:

– 20 % for continuously varying resolution test patterns; or

– one line pair group.

5.4.6 Action to be taken

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

5.4.7 Frequency of CONSTANCY TESTS

The tests shall be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at least quarterly.

5.5 Variation in optical density throughout a RADIOGRAM

5.5.1 Summary

This test checks the constancy of the relative variations in the optical density measured at specific points of a RADIOGRAM. This test may be performed simultaneously with the test described in 5.2, i.e. one single RADIOGRAM provides the information required for both tests.

5.5.2 Test equipment

Measurements are performed using the same dedicated RADIOGRAPHIC CASSETTE and associated screen-film combination of the type normally used with the X-RAY EQUIPMENT under test. Use a densitometer which reads consistently within ±0,02.

An ATTENUATION PHANTOM is used as a substitute for the PATIENT. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. In addition, a film marker TEST DEVICE shall be used in order to allow for the identification of specific points in the RADIOGRAM where the measurements of the optical density are to be made; see figure 1. Detailed descriptions of an ATTENUATION PHANTOM and a film marker TEST DEVICE are provided in annex D.

5.5.3 Test procedure

Align the X-RAY SOURCE ASSEMBLY with the X-RAY IMAGE RECEPTOR as in normal clinical practice.

Place the loaded RADIOGRAPHIC CASSETTE in the IMAGE RECEPTION AREA and the film marker TEST DEVICE in the X-RAY BEAM between the FOCAL SPOT and the X-RAY IMAGE RECEPTOR.

If IRRADIATIONS can only be made under AUTOMATIC EXPOSURE CONTROL, use an ATTENUATION PHANTOM as a substitute for the PATIENT in order to provide appropriate ATTENUATION and hardening of the X-RAY BEAM.

For any item of test equipment, the measurement geometry shall be the same within ±1 % as used in the initial CONSTANCY TEST. Use the same RADIATION FIELD size.

For the initial CONSTANCY TEST select at least two X-RAY TUBE VOLTAGE settings that are typical for the radiological procedures for which the X-RAY EQUIPMENT is used. For the following CONSTANCY TESTS select the same settings as those used in the initial CONSTANCY TEST.

5.5.3.1 Testing under manual control

Operate the X-RAY EQUIPMENT using manual settings for the LOADING FACTORS identical to those used in the initial CONSTANCY TEST.

Process the irradiated film in accordance with the procedure referred to in 4.4.

Measure the optical density at the specific points on the RADIOGRAM indicated by the images of the radio-opaque markers; see figure 1.

If necessary, adjust the measured values of density in accordance with the procedure referred to in 4.4 to allow for any changes in film batch or processing conditions.

5.5.3.2 Testing under AUTOMATIC EXPOSURE CONTROL

Operate the X-RAY EQUIPMENT in conjunction with the AUTOMATIC CONTROL SYSTEM and use the X-RAY TUBE VOLTAGE settings and all other appropriate settings, for example density control, identical to those used in the initial CONSTANCY TEST.

Process the irradiated film in accordance with the procedure referred to in 4.4.

Measure the optical density at the specific points on the RADIOGRAM indicated by the images of the radio-opaque markers; see figure 1.

If necessary, adjust the measured values of density in accordance with the procedure referred to in 4.4 to allow for any changes in film batch or processing conditions.

5.5.4 Data evaluation

Examine the RADIOGRAM and compare it with that produced in the initial CONSTANCY TEST. This will reveal gross variations in the distribution of optical density throughout the RADIOGRAM.

Determine the differences in optical density measured at specific points on the RADIOGRAM, indicated by the images of the radio-opaque markers, and that measured at the reference point, and compare with the established initial CONSTANCY TEST. Make additional measurements and determine the differences in optical density at any other points on the RADIOGRAM where visual inspection indicates that a significant change may have occurred.

5.5.5 Criteria to be applied

The optical density differences should be within ±0,10 of the BASELINE VALUES.

5.5.6 Action to be taken

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

5.5.7 Frequency of variation in optical densities CONSTANCY TESTS

The tests shall be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at least quarterly.

6 Statement of compliance

The test report shall be headed

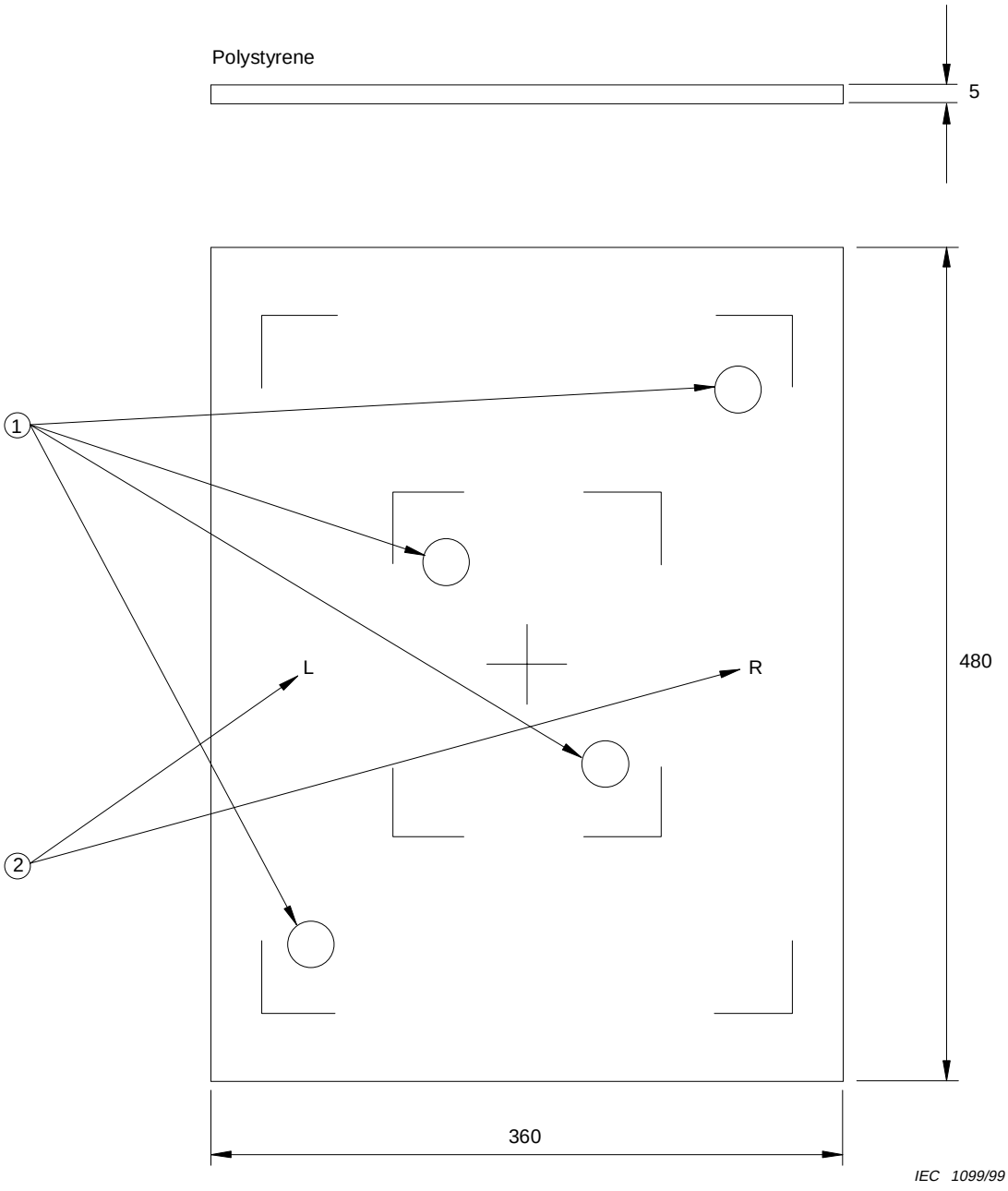
Test report
on constancy test of equipment for general direct radiography
according to IEC 61223-2-11:1999

If compliance with this standard is to be stated, this shall be done as follows:

The equipment for general direct radiography, ...*), complies with IEC 61223-2-11:1999.

———————

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



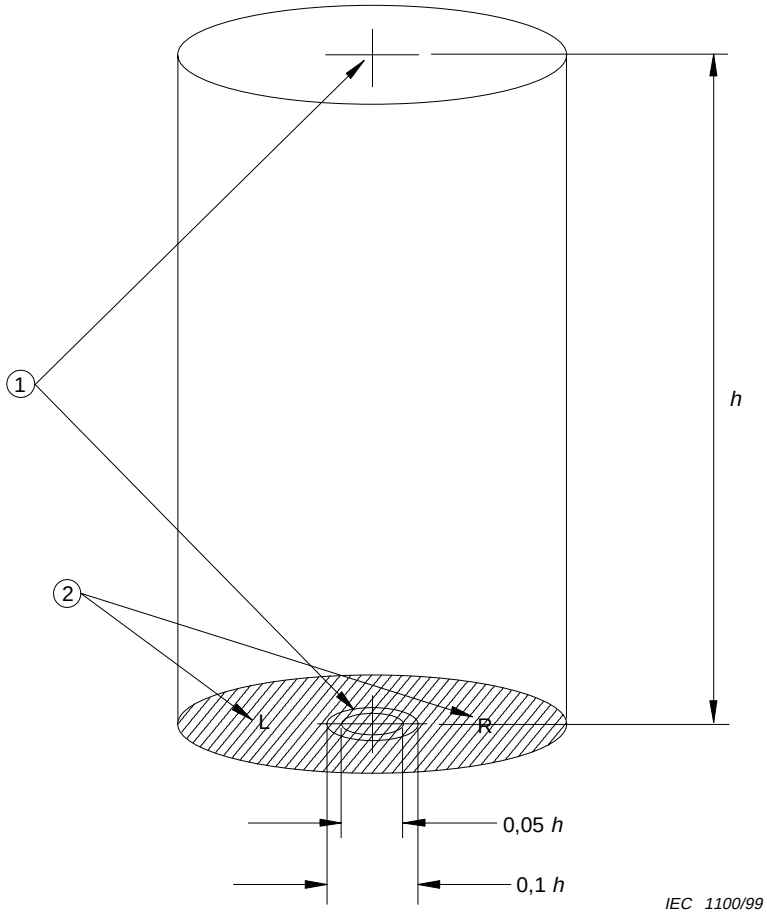
Key

1 Radio opaque wire markers

2 Radio opaque letters

Dimensions in millimetres

Figure 1 – Example of a film marker TEST DEVICE



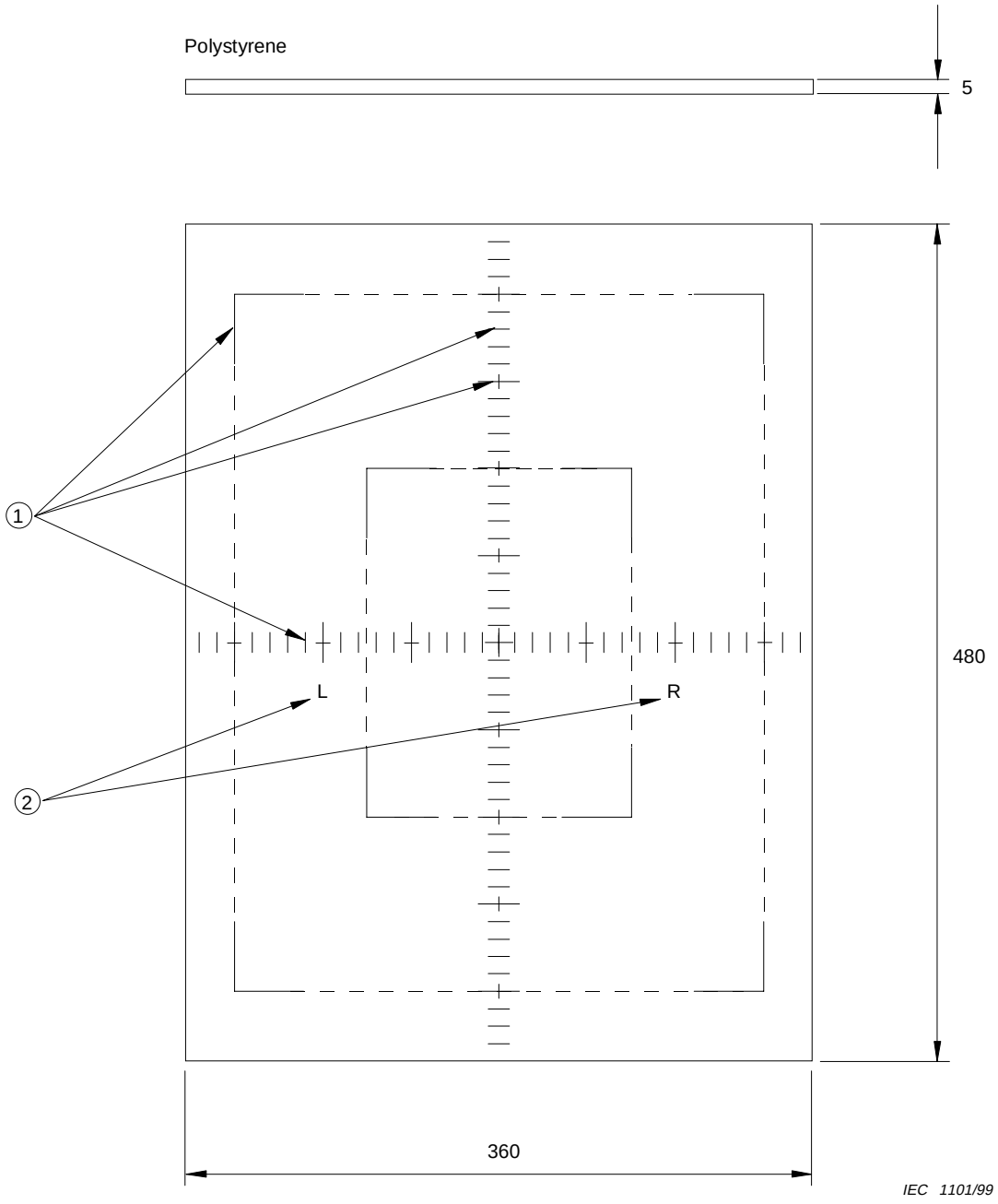
Key

1 Radio opaque wire markers

2 Radio opaque letters

Dimensions in millimetres

Figure 2 – Example of a TEST DEVICE for perpendicular position



Key

1 Radio opaque wire markers

2 Radio opaque letters

Dimensions in millimetres

Figure 3 – Example of an alignment TEST DEVICE

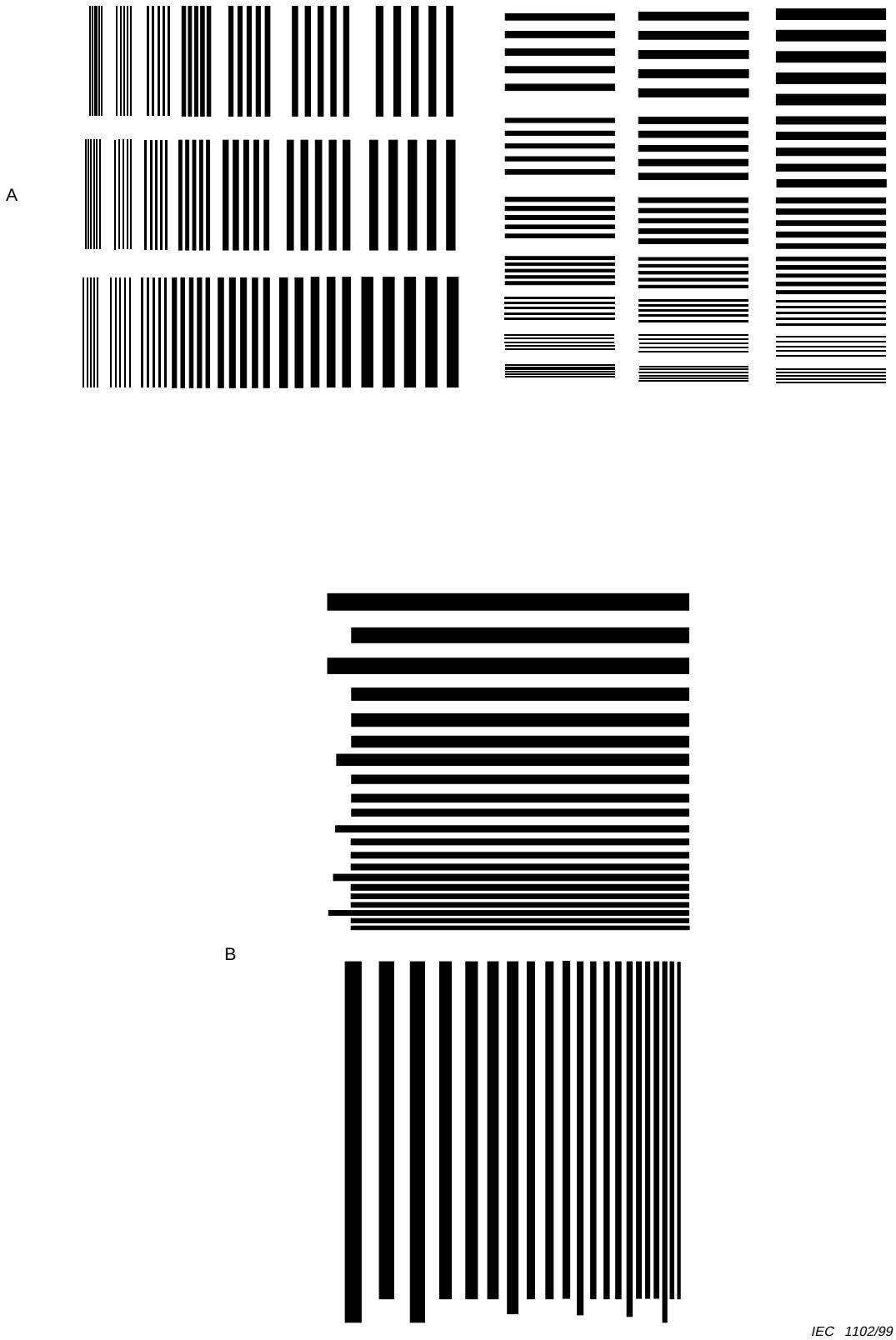
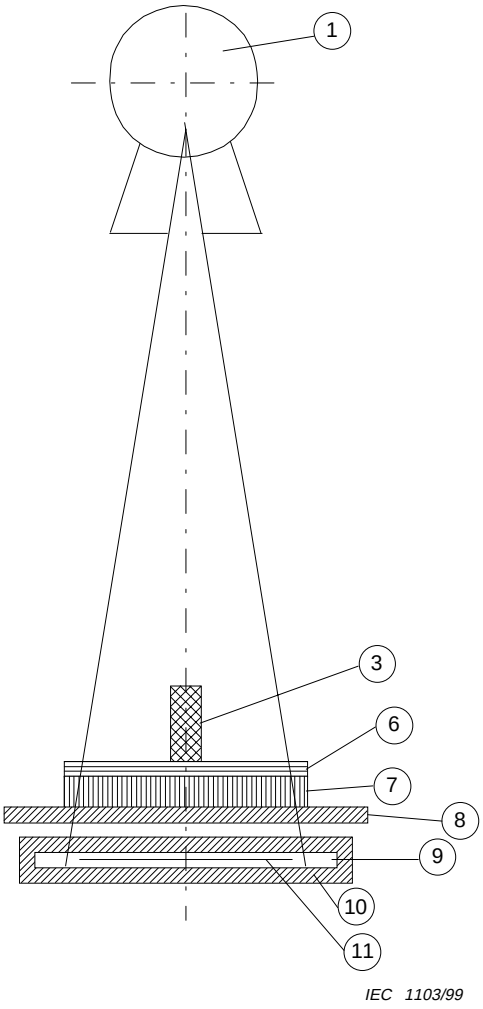


Figure 4 – Examples of a high-contrast TEST DEVICE



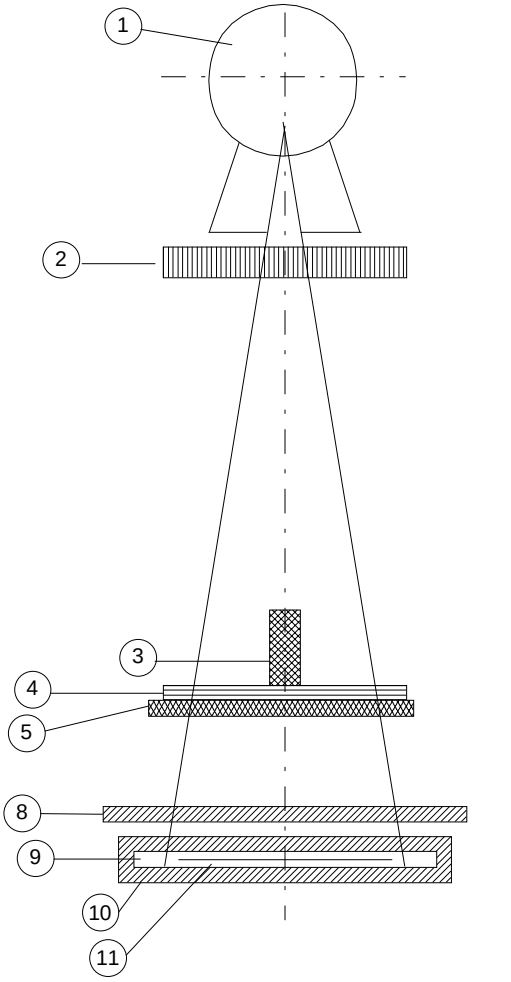


Figure 5a – Over-couch arrangement

Figure 5b – Over-couch arrangement

Key

1 X-RAY SOURCE ASSEMBLY
2 ATTENUATION PHANTOM
3 TEST DEVICE for perpendicular position
4 Alignment TEST DEVICE
5 CASSETTE Q
6 Alignment TEST DEVICE
7 ATTENUATION PHANTOM
8 PATIENT SUPPORT
9 CASSETTE P
10 X-RAY IMAGE RECEPTOR
11 IMAGE RECEPTOR AREA

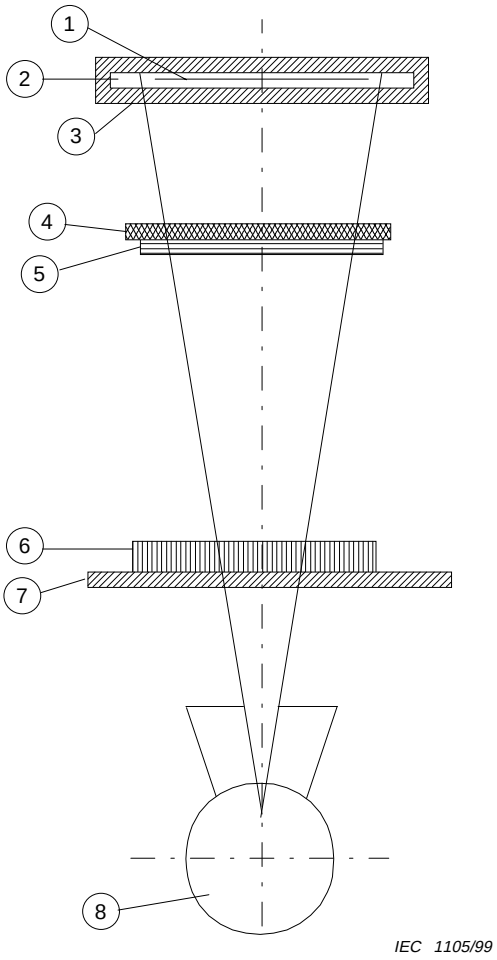
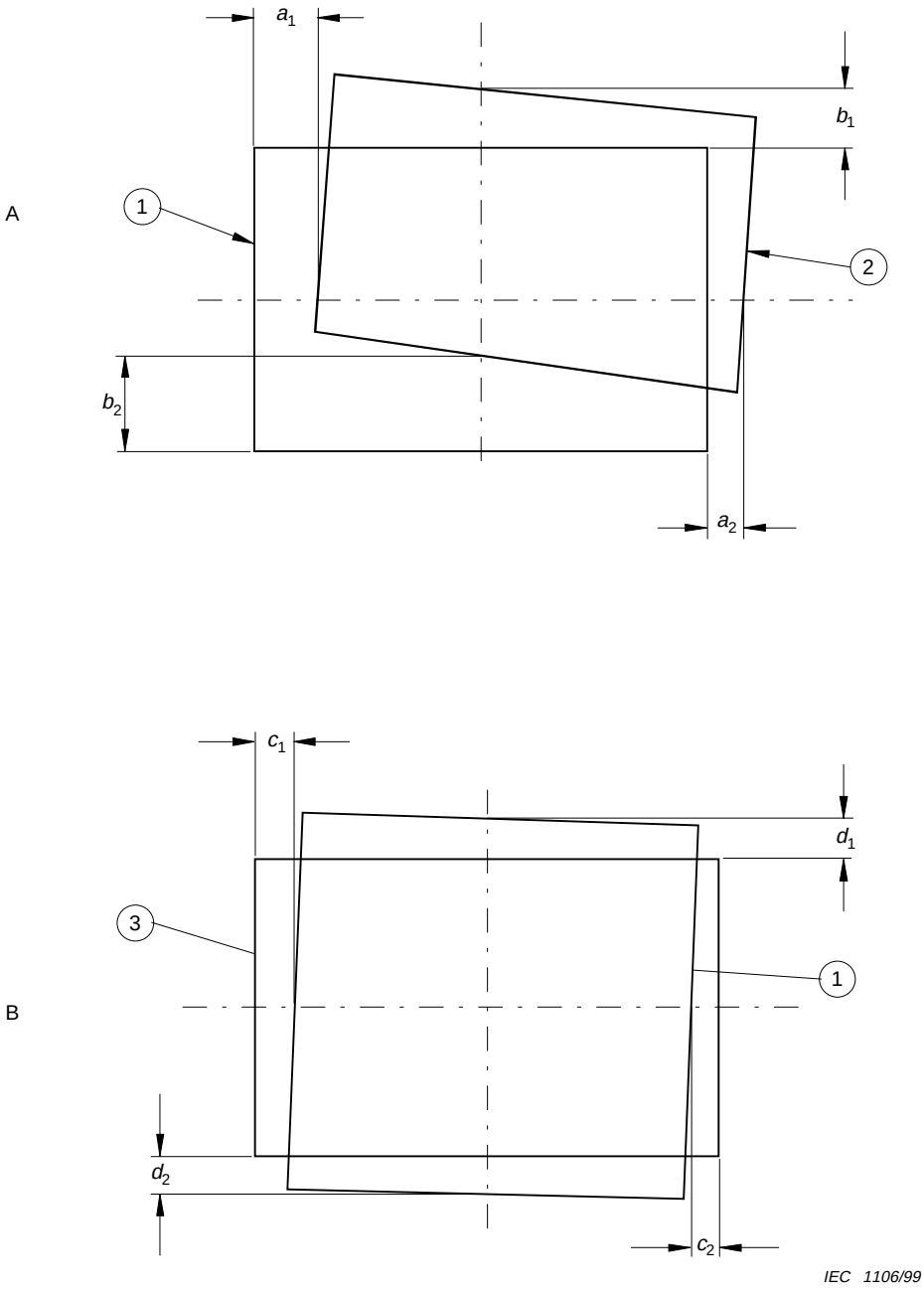


Figure 5c – Under-couch arrangement

Key

1	IMAGE RECEPTOR AREA	5	Alignment TEST DEVICE
2	CASSETTE P	6	ATTENUATION PHANTOM
3	X-RAY IMAGE RECEPTOR	7	PATIENT SUPPORT
4	CASSETTE Q	8	X-RAY SOURCE ASSEMBLY

Figure 5 – Arrangements for testing geometric conditions



Key

1 RADIATION FIELD

2 LIGHT FIELD

3 IMAGE RECEPTION AREA

Figure 6 – Geometric coincidences

Annex A
(normative)

Terminology – Index of defined terms

IEC 60788 ..... rm.-..-..
Name of unit in the International System SI ..... rm.-..-..*
Derived term without definition ..... rm.-..-..+
Term without definition ..... rm.-..-..-
Name of earlier unit ..... rm.-..-..·
Shortened term ..... rm.-..-..s
Clause 3 of IEC 61223-1 ..... AG-3...
Clause 3 of IEC 61223-2-XY ..... XY-3...

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ACCOMPANYING DOCUMENTS rm-82-01
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RADIATION BEAM rm-37-05
RADIATION BEAM AXIS rm-37-06
RADIATION DETECTOR rm-51-01
RADIATION FIELD rm-37-07
RADIATION METER rm-50-01
RADIOGRAM rm-32-02
RADIOGRAPHIC CASSETTE rm-35-14
RADIOGRAPHIC FILM rm-32-32
RADIOLOGICAL INSTALLATION rm-20-24
REFERENCE DIRECTION rm-37-02

SCATTERED RADIATION rm-11-13
Specific rm-74-01
Specified rm-74-02
SPOTFILM DEVICE rm-31-05
STATUS TEST AG-3.2.5

TARGET rm-20-08
TEST DEVICE rm-71-04
TISSUE EQUIVALENT MATERIAL rm-35-16
TOTAL FILTRATION rm-13-48

USER rm-85-01

X-RADIATION rm-11-01-
X-RAY BEAM ..... rm-37-05+
X-RAY EQUIPMENT rm-20-20
X-RAY IMAGE RECEPTOR rm-32-29
X-RAY SOURCE ASSEMBLY ..... rm-20-05+
X-RAY SPECTRUM ..... rm-13-34+
X-RAY TUBE rm-22-03
X-RAY TUBE ASSEMBLY rm-22-01
X-RAY TUBE CURRENT rm-36-07
X-RAY TUBE VOLTAGE rm-36-02

Annex B
(informative)

Example of a form for the standardized test report

Test report
on constancy test of equipment for general direct radiography according to IEC 61223-2-11:1999

Identifications

Person performing test Identification:

Equipment and subsystems Identification :

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

Components and accessories

– ADDED FILTERS
– PATIENT SUPPORT
– IONIZATION CHAMBER (AUTOMATIC CONTROL SYSTEM)
– ANTI-SCATTER GRID
– RADIOGRAPHIC FILM (type, emulsion number, date of first use (batch))
– RADIOGRAPHIC CASSETTE
– INTENSIFYING SCREENS

Darkrooms

Film processing equipment

Test equipment Identification:

– ATTENUATION PHANTOM, film marker TEST DEVICE, TEST DEVICE for perpendicular position, TEST DEVICE for alignment, high-contrast TEST DEVICE
– RADIATION METER
– densitometer
– lead sheet

Test arrangement

– distance between FOCAL SPOT and RADIATION DETECTOR
– BEAM LIMITING DEVICE position
– orientations of
  • RADIOGRAPHIC CASSETTE
  • RADIATION METER
  • ANTI-SCATTER GRID
  • TEST DEVICE for perpendicular position

Test conditions

– X-RAY TUBE ASSEMBLY selected
– FOCAL SPOT selected
– TOTAL FILTRATION of the X-RAY SOURCE ASSEMBLY
– set field indicated by light
– set RADIATION FIELD
– X-RAY TUBE VOLTAGE selected
– X-RAY TUBE CURRENT selected/measured
– measuring field of AUTOMATIC CONTROL SYSTEM
– programme step of AUTOMATIC CONTROL SYSTEM
– time selected for manual IRRADIATION

NOTE – Manual settings of LOADING FACTORS should be approached from one direction and the same direction of the range of the scale.

History of tests

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

Test results

Results for testing under manual control

– magnitude RADIATION output (RADIATION METER)
– magnitude RADIATION input
  • optical density
  • RADIATION METER
– geometric characteristics
  • FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
  • alignment of RADIATION FIELD edges
  • centre coincidence RADIATION FIELD with LIGHT FIELD
– resolution of high-contrast detail
  • maximum spatial frequency visible parallel to X-RAY TUBE axis
  • maximum spatial frequency visible perpendicular to X-RAY TUBE axis

– variation in optical density throughout a RADIOGRAM
  - optical density difference

Results for testing under AUTOMATIC EXPOSURE CONTROL

– magnitude RADIATION output (RADIATION METER)
– magnitude RADIATION input
  - optical density
  - RADIATION METER

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) action is initiated as specified in the QUALITY ASSURANCE PROGRAMME for the equipment tested;

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

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

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
(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 ATTENUATION and 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 four TEST DEVICES are needed, the main characteristics of which are described in detail below.

Although each PHANTOM and TEST DEVICE may be manufactured and used individually and separately, it may be more appropriate and convenient to combine some or all of these characteristics into a single TEST DEVICE.

ATTENUATION PHANTOMS

Either device A1, A2 or A3 described below may be adopted as the ATTENUATION PHANTOM. Each of these options will involve a compromise. It is highly recommended that the ATTENUATION PHANTOM A1 be used routinely whenever possible, and exclusively for performance of those CONSTANCY TESTS requiring a clinically realistic transmitted primary X-RAY SPECTRUM and the presence of clinically significant quantities of scattered PRIMARY RADIATION. The ATTENUATION PHANTOM A1 requires test objects of large dimensions and thus of large mass, which may be unacceptable under certain conditions. Should the use of the ATTENUATION PHANTOM A1 prove impractical, it is recommended that the ATTENUATION PHANTOM A2 be used for those CONSTANCY TESTS in which the spectral distribution of transmitted PRIMARY RADIATION is important, but the lack of scattered PRIMARY RADIATION will not negatively affect performance of the CONSTANCY TEST. The ATTENUATION PHANTOM A3 is recommended only for those CONSTANCY TESTS in which extreme difficulty is encountered with the use of the ATTENUATION PHANTOM A1 and in which the lack of a clinically realistic spectral distribution of transmitted primary X-RADIATION and the presence of scattered primary X-RADIATION are unimportant.

No definite recommendation is made with respect to the material or design to be used for the ATTENUATION PHANTOMS A1, A2 and A3. Any material may be used, but the implications resulting from the choice must be borne in mind.

ATTENUATION PHANTOM A1

The ATTENUATION PHANTOM A1 is designed as a substitute for the PATIENT by providing appropriate ATTENUATION and hardening of the RADIATION BEAM. The length and width of the ATTENUATION PHANTOM A1 depend on the distance from the FOCAL SPOT at which it is positioned in the RADIATION BEAM. It shall be large enough so that the projection of its edges in the plane distance from the FOCAL SPOT onto the plane of the IMAGE RECEPTION AREA falls at least by 15 % outside the nominal dimensions of the greatest IMAGE RECEPTION AREAS used for the CONSTANCY TESTS (for example a RADIOGRAPHIC CASSETTE 35 cm × 43 cm).

If the CONSTANCY TESTS are performed at more than one X-RAY TUBE VOLTAGE, the ATTENUATION PHANTOM A1 shall be comprised of two or more single layers.

The choice of material, the thickness and the conditions under which the ATTENUATION PHANTOM A1 is used should simulate as far as practicable the radiological procedures currently used in clinical practice. PHANTOMS which will attenuate, harden and scatter the incident X-RADIATION to the same degree as the PATIENT shall be manufactured of TISSUE EQUIVALENT MATERIALS (for example water, polymethyl-methacrylate (PMMA), polytetrafluoroethylene (PTFE) or aluminium to simulate bone) and shall be positioned as close as possible to the X-RAY IMAGE RECEPTOR.

ATTENUATION PHANTOM A2

The ATTENUATION PHANTOM A2, which ideally is composed of TISSUE EQUIVALENT MATERIAL and is of a similar design to the ATTENUATION PHANTOM A1, is intended to be attached to the LIGHT FIELD INDICATOR and, therefore, can be kept small in area and low in mass. The transmitted primary X-ray spectral distribution will be equivalent to the spectral distribution of the ATTENUATION PHANTOM A1, but the amount of SCATTERED RADIATION reaching the X-RAY IMAGE RECEPTOR is greatly reduced due to the gap between the ATTENUATION PHANTOM A2 and the X-RAY IMAGE RECEPTOR. By use of the ATTENUATION PHANTOM A2, however, many problems associated with the ATTENUATION PHANTOM A3 (see below), which is made of heavy metal materials, can be avoided. Additional problems may be encountered with checking X-RAY EQUIPMENT with X-RAY SOURCE ASSEMBLIES under the PATIENT SUPPORT owing to the difficulties in positioning the ATTENUATION PHANTOM A2 and the RADIATION DETECTOR relative to the X-RAY SOURCE ASSEMBLY.

ATTENUATION PHANTOM A3

The ATTENUATION PHANTOM A3, which is composed of heavy metal materials (having an atomic number much higher than tissue, for example copper, lead), will reduce the thickness needed for the ATTENUATION PHANTOM A and will thus reduce the mass of the PHANTOM. The amount of SCATTERED RADIATION produced by these heavy metal materials, however, is much smaller than for TISSUE EQUIVALENT MATERIALS.

Furthermore, the equivalent thickness of the ATTENUATION PHANTOM A3 can either match the ATTENUATION or can equally harden the RADIATION BEAM to the same extent as a PHANTOM of TISSUE EQUIVALENT MATERIAL, but not both. This results in values for RADIATION dose, IRRADIATION TIME and optical densities which may differ considerably from those encountered in normal clinical practice. Variation in some of the measured quantities as a result of changes in the X-RAY TUBE VOLTAGE will be amplified to a much greater extent than those arising from changes in the values of other parameters of the equipment.

In many cases, the production of SCATTERED RADIATION is relatively unimportant because changes in the performance of components influenced by SCATTERED RADIATION to the IMAGE RECEPTION AREA are normally negligible. Therefore, the choice of PHANTOM should be dictated by the practicability of using a particular PHANTOM on the CONSTANCY TEST.

Film marker TEST DEVICE

The film marker TEST DEVICE is used to identify specific measuring points in the RADIOGRAM where measurements of the optical density shall be made.

The film marker TEST DEVICE is comprised of a thin, X-RADIATION-translucent template containing at least two rings, of radio-opaque wire, to identify points at which a comparison of differences in optical density is made.

The markers shall be arranged in a manner which enables the orientation of the film marker TEST DEVICE on the RADIOGRAM to be unambiguously identified.

The film marker TEST DEVICE should be suitable for enabling the CONSTANCY TEST to be performed at two specific RADIATION FIELD sizes (for example 15 cm × 20 cm and 30 cm × 40 cm).

The incident surface of the film marker TEST DEVICE shall be so marked as to permit it to be centred in the LIGHT FIELD and to permit the LIGHT FIELD to be limited to the dimensions chosen for the CONSTANCY TEST.

An example of a film marker TEST DEVICE is shown in figure 1.

TEST DEVICE for perpendicular position

The TEST DEVICE for perpendicular position is used to check the position of the RADIATION BEAM AXIS to the IMAGE RECEPTOR PLANE.

The TEST DEVICE consists of two thin parallel plates of X-RADIATION-translucent and transparent material (for example polycarbonate, acrylic) arranged to form an upper and a lower base, separated by a hollow straight-sided (for example cylindrical) structure of at least 200 mm in length. Radio-opaque wire markers of wire of approximately 1 mm in diameter are attached to both plates and arranged so that the centres of both markers lie in the same line perpendicular to the plane of both bases. Typical markers may consist of

– a cross-wire with arms of approximately 15 mm length on the upper base;
– two concentric rings on the lower base having internal diameters of 5 % and 10 % of the distance separating the upper and lower bases.

An example of a TEST DEVICE TO TEST THE PERPENDICULAR POSITION is shown in figure 2.

Alignment TEST DEVICE

The alignment TEST DEVICE is used to test those aspects of the geometric characteristics other than the perpendicular position.

The alignment TEST DEVICE consists of a thin, rigid, X-RADIATION-translucent template containing radio-opaque wire markers similar to those used in the TEST DEVICE for the perpendicular position to identify on the RADIOGRAM the edges and the centre of the LIGHT FIELD and the unambiguous orientation of the alignment TEST DEVICE.

The alignment TEST DEVICE should be designed to permit the CONSTANCY TEST to be performed at two specific RADIATION FIELD sizes (for example 15 cm × 20 cm and 30 cm × 40 cm) and shall also be marked on the incident surface, so as to permit it to be appropriately centred to the LIGHT FIELD and the LIGHT FIELD to be limited to the dimensions chosen for the CONSTANCY TEST.

An example of an alignment TEST DEVICE is shown in figure 3.

High-contrast TEST DEVICE

The high-contrast TEST DEVICE is used to test the constancy of performance of the X-RAY EQUIPMENT with regard to the ability to resolve small details of high contrast.

The high-contrast TEST DEVICE should contain periodic patterns in two directions perpendicular to each other, composed of bars cut from thin foil of high atomic number material (for example lead of 0,05 mm). The periodic pattern should give a square wave response and provide a range of spatial frequencies from at least 0,5 to 10 line pairs per millimetre, either continuously or in groups of at least three line pairs with increments spatial frequencies not exceeding 20 % between adjacent groups.

The bar pattern should be fixed on a supporting plate made of plastic, for example PMMA, of a maximum thickness of 2 mm. The bars should be orientated through a minimum of two perpendicular directions. The whole pattern should be contained within an area not exceeding 70 mm × 70 mm. The device shall also include markings on the external surface which permit the LIGHT FIELD to be centred and limited for the purpose of the test.

The bar pattern should be attached to a spacer which supports the pattern parallel to the surface on which the spacer is placed and at a distance of 200 mm from this surface. In this way, the arrangement relates to clinical conditions and takes into account any possible variations related to the FOCAL SPOT of the X-RAY TUBE.

An example of a high-contrast TEST DEVICE is shown in figure 4.

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