INTERNATIONAL STANDARD

IEC 61223-2-9

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

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

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

Partie 2-9: Essais de constance – Dispositifs de radioscopie et de radiographie indirectes

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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.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-9: Constancy tests – Equipment for indirect radioscopy and indirect 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.
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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 61223-2-9 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/371/FDIS	62B/383/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 2-9 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 2-9: Constancy tests – Equipment for indirect radioscopy and indirect radiography

1 Scope and object

1.1 Scope

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

a) generate, influence the propagation of, and detect X-RADIATION, and

b) process, present and store diagnostic X-ray images in RADIOLOGICAL INSTALLATIONS with diagnostic X-ray systems for INDIRECT RADIOSCOPY and INDIRECT RADIOGRAPHY which use X-RAY IMAGE INTENSIFIERS in conjunction with analogue and/or digital storage systems:

   – closed-circuit television display systems:
   – cut film cameras
   – cine cameras.

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 sub-systems 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 equipment for indirect radioscopy and indirect 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, and
– 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.

These methods are based upon assessment of radiological information using appropriate TEST DEVICES.

The purpose of the methods is

– to establish a reference level of performance when such equipment is accepted;
– to detect or verify any significant variation in functional parameters which may then require corrective actions.

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 is not intended to 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 61223-2-4:1994, *Evaluation and routine testing in medical imaging departments – Part 2-4: Constancy tests – Hard copy cameras*

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 purposes, or the parameters or conditions associated with its use or 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 imaging 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.

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

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.

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 the influence of environmental changes on the results. Variations in mains voltage and, when IMAGE DISPLAY DEVICE images are evaluated, 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.

4.2 Establishment of BASELINE VALUES

When new X-RAY EQUIPMENT is brought into use, 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 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;
– BEAM LIMITING DEVICES;
– PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;
– ANTI-SCATTER GRID;
– RADIOGRAPHIC FILM type and emulsion number;
– video chain (camera, video unit and monitor);
– FILM PROCESSOR;
– HARD COPY CAMERAS;

together with items of test instrumentation, such as

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

and settings of variables such as

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
– AUTOMATIC CONTROL SYSTEM density control and sensor position;
– window levels of digital imaging systems;
– LOADING FACTORS;
– nominal FOCAL SPOT size, if applicable;

shall be marked or recorded so that the items and settings used in the initial CONSTANCY TEST can be used with the equipment under subsequent testing.

NOTE 1 – It is preferable that all settings chosen for the initial CONSTANCY TEST reflect typical clinical use of the equipment.

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. If more than one type of radiographic material is processed in the FILM PROCESSOR, CONSTANCY TESTS should be conducted on each type in order to allow for differences in response of each material.

4.5 Measured functional parameters

The imaging performance of a system for INDIRECT RADIOSCOPY is considered to be constant if the variations of the following functional parameters are found to meet acceptable criteria:

– RADIATION output from the X-RAY SOURCE ASSEMBLY; see 5.1;
– grey-scale image and AUTOMATIC INTENSITY CONTROL; see 5.2;
– threshold contrast for detail of large size; see 5.3;
– limiting resolution for detail of high contrast for X-RADIATION; see 5.4.

The imaging performance of a system for INDIRECT RADIOGRAPHY is considered to be constant if the variations of the following functional parameters are found to meet acceptable criteria:

– RADIATION output from the X-RAY SOURCE ASSEMBLY; see 5.1;
– grey-scale image and AUTOMATIC INTENSITY CONTROL; see 5.2;
– threshold contrast for detail of large size; see 5.3;
– limiting resolution for detail of high contrast for X-RADIATION; see 5.4.

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 INTENSITY CONTROL, depending upon the type and use of the X-RAY EQUIPMENT.

5.1.2 Test equipment

Measurements are performed using a RADIATION METER having an overall systematic error of ±5 % including long-term stability, instrument noise and read-out ability.

As a substitute for the PATIENT when testing under AUTOMATIC INTENSITY CONTROL, the ATTENUATION PHANTOM shall be used. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. A detailed description of the 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; and*

– *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. Use the same RADIATION FIELD size.

Whenever possible, carry out this test under both manual and AUTOMATIC INTENSITY CONTROL.

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 INTENSITY 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.

5.1.4 Data evaluation

Compare 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 normally be within ±20 % of the BASELINE VALUES.

5.1.5.2 Testing under AUTOMATIC INTENSITY CONTROL

The criteria to be applied depend on the 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 RADIATION output should be within ±25 % of the BASELINE VALUES.

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 – For testing under manual control, 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. However, for AUTOMATIC INTENSITY CONTROL, a decrease in the RADIATION output is compensated for 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 every two weeks for 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 annually.

5.2 Grey-scale image and AUTOMATIC INTENSITY CONTROL

5.2.1 Summary

In order to ensure that the performance of the X-ray imaging equipment is constant, a TEST DEVICE containing details of specific contrasts for X-RADIATION is imaged. In addition, imaging of the TEST DEVICE under AUTOMATIC INTENSITY CONTROL enables a check to be carried out of the constancy of performance of the AUTOMATIC INTENSITY CONTROL system.

5.2.2 Test equipment

An ATTENUATION PHANTOM; see annex D;

A grey-scale TEST DEVICE; see annex D.

5.2.3 Test procedure

a) *Place the grey-scale* TEST DEVICE *as close as possible to the input surface of the X-*RAY IMAGE INTENSIFIER. *Ensure that the* TEST DEVICE *is in the centre of the field of the X-*RAY IMAGE INTENSIFIER *and has the same orientation with respect to the X-*RAY IMAGE INTENSIFIER *as that used in the initial* CONSTANCY TEST. *If necessary, temporarily affix the* TEST DEVICE *to the underside of the* SERIAL CHANGER *or the housing of the X-*RAY IMAGE INTENSIFIER.

b) *Set the distance between the* FOCAL SPOT *and the input surface of the X-*RAY IMAGE INTENSIFIER *to that specified for the most recent initial* CONSTANCY TEST.

c) *Select the largest field size available of the X-*RAY IMAGE INTENSIFIER *and collimate the X-*RAY BEAM *to the main dimensions of the test object.*

d) *Place the* ATTENUATION PHANTOM *in the X-*RAY BEAM *as close as possible to the X-*RAY TUBE ASSEMBLY.

e) *Operate the radioscopic unit*

   – *at the manual settings of X-*RAY TUBE VOLTAGE *and X-*RAY TUBE CURRENT *specified for the initial* CONSTANCY TEST;

   – *with window levels and image handling parameters (edge enhancement etc.) as specified in the initial* CONSTANCY TEST;

   NOTE – Normally, settings are chosen which are similar to those used in clinical practice.

   – *under* AUTOMATIC INTENSITY CONTROL.

f) *Stand directly in front of the* IMAGE DISPLAY DEVICE *and observe the image detail visible on the* IMAGE DISPLAY DEVICE *under the room lighting conditions used during the initial* CONSTANCY TEST.

5.2.4 Data evaluation

a) *Check the visibility of both the white and black spots on the* IMAGE DISPLAY DEVICE.

b) *Record the* INDICATED VALUES *of X-*RAY TUBE VOLTAGE *and X-*RAY TUBE CURRENT *during* RADIOSCOPY *under* AUTOMATIC INTENSITY CONTROL.

5.2.5 Criteria to be applied

a) Both the black and white spots shall be equally visible on the IMAGE DISPLAY DEVICE.

b) The INDICATED VALUE of X-RAY TUBE VOLTAGE, if provided by the equipment, shall be within ±5 kV of the BASELINE VALUE.

c) The INDICATED VALUE of X-RAY TUBE CURRENT, if provided by the equipment, shall be within ±20 % of the BASELINE VALUE.

5.2.6 Action to be taken

If both the black and white spots are not equally visible, the desired degree of visibility may be restored by minor adjustments to the brightness and contrast controls of the IMAGE DISPLAY DEVICE. If this action fails, or if the system fails to meet any of the other criteria, the guidance given in annex C should be followed.

5.3 Threshold contrast for detail of large size

5.3.1 Summary

The constancy of the threshold level of contrast visible under standard test conditions is determined using an appropriate TEST DEVICE containing a series of large attenuating disks. If used with an appropriate X-RAY BEAM quality similar to that used in clinical practice, the disks will generate a suitable range of contrasts for X-RADIATION.

5.3.2 Test equipment

An ATTENUATION PHANTOM; see annex D;

A low-contrast TEST DEVICE; see annex D.

5.3.3 Test procedure

Repeat the test procedure described in 5.2.3 but, instead of using a grey-scale TEST DEVICE, use a low-contrast TEST DEVICE.

Where applicable, repeat the test procedure using the image storage system operating at the same settings as used in the initial CONSTANCY TEST.

5.3.4 Data evaluation

Count the number of disks which are just perceptible:

– *on THE IMAGE DISPLAY DEVICE during RADIOSCOPY;*

– *on the IMAGE DISPLAY DEVICE when using the storage facility.*

5.3.5 Criterion to be applied

The number of disks visible shall not differ by more than one from the number recorded at the initial CONSTANCY TEST.

5.3.6 Action to be taken

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

5.4 Limiting resolution for detail of high contrast for X-RADIATION

5.4.1 Summary

The limiting resolution of the system is tested by imaging a TEST DEVICE such as a lead bar test pattern containing details covering an appropriate range of spatial frequencies.

5.4.2 Test equipment

A high-contrast TEST DEVICE; see annex D;

A correction FILTER TEST DEVICE may be required; see annex D.

5.4.3 Test procedure

a) *If possible without making use of tools, remove the* ANTI-SCATTER GRID. *Place the high contrast* TEST DEVICE *as close as possible to the input surface of the X-*RAY IMAGE INTENSIFIER. *The test pattern shall be adjusted so that the main direction of the bars in the image makes an angle of approximately 45° with the lines on the* IMAGE DISPLAY DEVICE.

b) *Set the distance between the* FOCAL SPOT *of the X-*RAY TUBE *and the input surface of the X-*RAY IMAGE INTENSIFIER *to that specified for the initial* CONSTANCY TEST.

c) *Select the same field sizes of the X-*RAY IMAGE INTENSIFIER *as were used in the initial* CONSTANCY TEST *and collimate the X-*RAY BEAM *to the main dimensions of the test object.*

NOTE – For the purposes of this test, the ATTENUATION PHANTOM shall not be present in the X-RAY BEAM.

d) *Operate the radioscopic unit under manual control with the settings of the X-*RAY TUBE VOLTAGE *and X-*RAY TUBE CURRENT *specified in the initial* CONSTANCY TEST.

If the system cannot be operated under manual control, perform the test under AUTOMATIC INTENSITY CONTROL.

*The X-*RAY TUBE VOLTAGE *should be set at about 70 kV, with the X-*RAY TUBE CURRENT *at the highest possible setting that does not cause the image on the* IMAGE DISPLAY DEVICE *to become too bright, for example to "white-out". If "white-out" occurs, place a correction* FILTER TEST DEVICE *(see annex D) in the X-*RAY BEAM *close to the X-*RAY SOURCE ASSEMBLY.

e) *Stand directly in front of the* IMAGE DISPLAY DEVICE *and observe the image detail visible on the* IMAGE DISPLAY DEVICE *under room lighting conditions as used in the initial* CONSTANCY TEST.

f) *If available, repeat the procedures in a) to e) above while using the image storage system operating at the settings used in the initial* CONSTANCY TEST.

5.4.4 Data evaluation

Count the number of line pair groups which are adequately resolved

– *on the* IMAGE DISPLAY *device during* RADIOSCOPY;

– *on the* IMAGE DISPLAY *device while the image storage facility is being used;*

– *on the* RADIOGRAM.

5.4.5 Criterion to be applied

The number of groups of the resolution pattern that are visible should not be more than two and shall not be more than three less than in the initial CONSTANCY TEST.

5.4.6 Action to be taken

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

5.5 Frequency of CONSTANCY TESTS

All the CONSTANCY TESTS described in 5.1, 5.2, 5.3 and 5.4 should 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 under conditions specified in 4.3.

6 Statement of compliance

The test report shall be headed:

Test report

on constancy test of equipment for indirect radioscopy and indirect radiography

according to IEC 61223-2-9:1999

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

The equipment for indirect radioscopy and indirect radiography,....*), complies with IEC 61223-2-9: 1999.

———————

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

Annex A
(normative)

Terminology – Index of defined terms

Annex B
(informative)

Example of a form for the standardized test report

Test report
on constancy test of equipment for indirect radioscopy and indirect radiography according to IEC 61223-2-9:1999

Identifications

Person performing test Identification:

Equipment under test Identification:

IMAGE DISPLAY DEVICE, according to IEC 61223-2-5 Identification:
– all user selectable settings

Test equipment Identification:
– RADIOGRAPHIC CASSETTE Identification:
– RADIATION METER
– ATTENUATION PHANTOM
– grey-scale TEST DEVICE
– low-contrast TEST DEVICE
– high-contrast TEST DEVICE
– correction FILTER TEST DEVICE, if needed

Standard test conditions (including environmental influences)

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

According to 5.1.4:
– RADIATION output
– IRRADIATION TIME
– CURRENT TIME PRODUCT

According to 5.2.4:
– X-RAY TUBE VOLTAGE
– X-RAY TUBE CURRENT
– optical density of test films

According to 5.3.4:

– number of disks visible during RADIOSCOPY
– number of disks visible using storage facility
– number of disks visible on RADIOGRAM

According to 5.4.4:

– number of line pairs resolved during RADIOSCOPY
– number of line pairs resolved using storage facility
– number of line pairs resolved on RADIOGRAM

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

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 PHANTOM

The ATTENUATION PHANTOM is used

– as a substitute for the PATIENT;

– to provide appropriate hardening of the X-RAY BEAM for the use of the grey-scale TEST DEVICE;

– where applicable, to provide appropriate ATTENUATION and hardening of the X-RAY BEAM interacting with the AUTOMATIC CONTROL SYSTEM.

For example, the ATTENUATION PHANTOM may consist of 40 mm PMMA plus a 1 mm thick copper layer.

Grey-scale TEST DEVICE

The grey-scale TEST DEVICE contains two objects of attenuating material, each of which produces an image of a disk of at least 1 cm in diameter within a square of at least 2 cm $\times$ 2 cm. If the grey-scale TEST DEVICE is used with an X-RAY BEAM which has been hardened by the ATTENUATION PHANTOM, these two objects produce two contrast steps of 5 % each, i.e. the X-RAY images of these two objects should then appear on the IMAGE DISPLAY DEVICE as

a) a white spot (95 % TRANSMISSION) surrounded by an even whiter background (100 % TRANSMISSION); and

b) a dark spot (5 % TRANSMISSION) surrounded by an even darker background (0 % TRANSMISSION), respectively.

The grey-scale TEST DEVICE contains at least two radio-opaque markers of circular shape which will identify the specific points on the RADIOGRAM where measurements of optical density are to be made.

Low-contrast TEST DEVICE

The low-contrast TEST DEVICE contains disks of attenuating material of at least 1 cm in diameter. The TEST DEVICE shall be so constructed that, if used with an X-RAY BEAM hardened by the ATTENUATION PHANTOM, these disks shall produce contrasts for X-RADIATION varying from 1 % to 20 % in steps similar to the following:

0,5 %, 1,0 %, 1,4 %, 1,8 %, 2,3 %, 2,7 %, 3,3 %, 3,9 %, 4,5 %, 5,5 %, 6,6 %, 7,6 %, 8,6 %, 10,8 %, 12,3 %, 14,5 %, 16,0 %, 18,0 %, 20,0 %.

NOTE – Not all of them can be measured on the same film simultaneously, but the TEST DEVICE should be so constructed as to give these values theoretically with the RADIATION QUALITIES used in normal clinical practice.

High-contrast TEST DEVICE

The high-contrast TEST DEVICE is a 50 μm to 100 μm thick lead bar test pattern which contains groups of line pairs (lp) with five line pairs in each group and resolutions of the groups of

0,50 lp/mm, 0,56 lp/mm, 0,63 lp/mm, 0,71 lp/mm, 0,80 lp/mm, 0,90 lp/mm, 1,00 lp/mm, 1,12 lp/mm, 1,25 lp/mm, 1,40 lp/mm, 1,60 lp/mm, 1,80 lp/mm, 2,00 lp/mm, 2,24 lp/mm, 2,50 lp/mm, 2,80 lp/mm, 3,15 lp/mm, 3,55 lp/mm, 4,00 lp/mm, 4,50 lp/mm, 5,00 lp/mm.

Correction FILTER TEST DEVICE

The correction FILTER TEST DEVICE is used in conjunction with the high-contrast TEST DEVICE. Its material, for example aluminium, and thickness are to be chosen in such a way that, when placed in the X-RAY BEAM, will permit the high contrast TEST DEVICE to be imaged with a low X-RAY TUBE VOLTAGE while preventing the image on the IMAGE DISPLAY DEVICE from becoming too bright due to "white-out".

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