

INTERNATIONAL STANDARD

IEC
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First edition
1999-03

Evaluation and routine testing in medical imaging departments –

Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems

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

*Partie 3-1:
Essais d'acceptation –
Performance d'imagerie des appareils
à rayonnement X pour systèmes radiographiques
et radioscopiques*



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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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**EVALUATION AND ROUTINE TESTING
IN MEDICAL IMAGING DEPARTMENTS –**

**Part 3-1: Acceptance tests –
Imaging performance of X-ray equipment
for radiographic and radiosopic systems**

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical 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 61223-3-1 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/361/FDIS	62B/365/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.

Annex A forms an integral part of this standard.

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

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: smaller roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN IEC 60788, IN IEC 60601-1 OR IN THE IEC 61223 SERIES: SMALL CAPITALS (SEE ANNEX A).

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

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (for example diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.

Some provisions or statements in this standard require additional information. Such information is presented in annex D. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopy systems

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which influence the image quality and PATIENT dose of diagnostic X-ray systems using radiographic and radioscopy imaging systems.

This standard applies to the performance of X-RAY EQUIPMENT in the ACCEPTANCE TEST on the following medical diagnostic X-RAY EQUIPMENT and ASSOCIATED EQUIPMENT:

- radiography equipment, for example:
 - stationary radiography EQUIPMENT;
 - mobile radiography EQUIPMENT;
 - skull radiography EQUIPMENT;
 - lung radiography EQUIPMENT;
 - TOMOGRAPHY EQUIPMENT – excluding COMPUTED TOMOGRAPHY;
 - radiography devices (SPOTFILM DEVICES) in RADIOSCOPY EQUIPMENT;
 - angiography EQUIPMENT (excluding DSA function);
 - CINERADIOGRAPHY equipment;
- RADIOSCOPY EQUIPMENT, including:
 - combined radiographic and radioscopy EQUIPMENT.

This standard applies to the generation of X-RADIATION and ACCESSORIES of digital systems. It does not apply to any digital image acquisition or image processing parts of the above mentioned diagnostic X-RAY EQUIPMENT.

NOTE – Since the characterization of digital detectors and image processing is still under development, this will be included in a later edition of this standard.

This standard does not apply to mammographic X-RAY EQUIPMENT, RADIOTHERAPY simulators, nor to dental X-RAY EQUIPMENT.

1.2 Object

This standard defines:

- a) the parameters which describe the performance of X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;
- b) methods of testing whether measured quantities related to those parameters comply with the specified tolerances.

These methods rely mainly on non-invasive measurements, using appropriate test equipment, performed during or after the installation is completed. Signed statements covering steps of product testing at the MANUFACTURER's site or during the installation procedure can be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications relating to the image quality and PATIENT dose, and to detect malfunctions that are not in agreement with those specifications.

This standard does not specify tolerances for the parameters under investigation. Nor does it consider:

- c) aspects of mechanical and electrical safety,
- d) aspects of mechanical, electrical and software performance unless they are essential to the performance of the tests directly affecting image quality and PATIENT dose.

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 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60417-1:1998, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60522:1976, *Inherent filtration of an X-ray tube assembly*

IEC 60580:1977, *Area exposure product meter*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

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 60601-2-7:1998, *Medical electrical equipment – Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60878:1988, *Graphical symbols for electrical equipment in medical practice*

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

IEC 61267:1994, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

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 with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60601-1, IEC 60788, IEC 61223-1 and in 3.3 of this standard (see annex A).

NOTE – Attention is drawn to the fact, that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

3.3 Defined terms

3.3.1

ARTIFACT

apparent structure visible in the image which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

3.3.2

LINE PAIR RESOLUTION

highest spatial frequency of the specified line-group test pattern imaged under specified conditions which is distinguishable in the image. The unit is lp/mm

NOTE – LINE PAIR RESOLUTION is used here as a practical substitute for spatial resolution.

3.3.3

LOW CONTRAST RESOLUTION

lowest contrast detail object of a specified shape and area that can be resolved from an uniform background

3.3.4

RADIATION OUTPUT

AIR KERMA per CURRENT TIME PRODUCT (mGy/mAs) at a given distance from the FOCAL SPOT in the primary X-RAY BEAM

3.3.5

TRANSMISSION KERMA (TRANSMISSION KERMA RATE)

AIR KERMA (AIR KERMA RATE) in the central X-RAY BEAM behind the specified attenuating layer

4 General aspects of ACCEPTANCE TESTS

4.1 General conditions to be considered in test procedures

The aim of an ACCEPTANCE TEST is to demonstrate that the specified characteristics of the equipment lie within the specified tolerances. Some requirements are enforced by legislation. Other requirements and specifications may be in the order contract, in the supplier's brochure or in other standards, for example in the IEC 60601 series.

Before any ACCEPTANCE TEST according to this standard is carried out, the EQUIPMENT has to be installed and put into service according to the set-up procedure as given in the MANUFACTURER's documentation.

An inventory of the EQUIPMENT under test, the ACCOMPANYING DOCUMENTS, and the test protocols shall be compiled. Each item shall be identified by its MODEL OR TYPE REFERENCE (type number) and SERIAL NUMBER, and the entire inventory shall be compared with the order contract.

RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS, RADIOGRAPHIC FILMS and film processing are vital parts in the imaging chain. It is the responsibility of the USER to show that these components perform in an acceptable way, based upon information given by MANUFACTURERS of RADIOGRAPHIC FILMS and INTENSIFYING SCREENS, for example with respect to sensitivity, contrast and absence of ARTIFACTS.

Non-invasive measurements are preferred for ACCEPTANCE TESTS. Whenever invasive tests are part of the programme, it shall be shown that the EQUIPMENT has been restored to its pre-test condition after the test.

4.2 Documents and data for the tests

The following documentation is required:

- statements of compliance with applicable parts of IEC 60601;
- list of EQUIPMENT or EQUIPMENT parts ordered and the actual delivery list;
- performance specification as agreed upon between the purchaser and the supplier;
- results from tests performed at the MANUFACTURER's site or during installation covering items of importance to quality, such as NOMINAL FOCAL SPOT VALUE;
- INSTRUCTIONS FOR USE, including guidance for the operation of the EQUIPMENT;
- details of the actual operating conditions under which the X-RAY EQUIPMENT is to be used in medical practice and whether this results in a limitation of the scope of the tests or of the functionality of the EQUIPMENT. If certain functions are disabled, only those used need to be tested;
- guidance as to the extent and frequency of maintenance procedures;
- reports on previous tests where applicable;
- list of agreed technical modifications in the meantime between the order contract and the ACCEPTANCE TEST.

4.3 Test conditions

Different categories of tests can be identified:

- visual inspection;
- functional tests;
- system performance;
- check of the uncertainty in the values of variables.

The measuring arrangements which may be used for performing tests are illustrated in figures 1 and 2.

Figure 1 includes the measuring arrangement for the TRANSMISSION KERMA, K_T , or the TRANSMISSION KERMA RATE, \dot{K}_T , and the X-RAY IMAGE RECEPTOR AIR KERMA, K_B , or the X-RAY IMAGERECEPTOR AIR KERMA RATE, \dot{K}_B , and the test parameters derived from them.

Figure 2 includes the measuring arrangement to test geometry and resolutions.

The arrangements in figures 1 and 2 are indicative only. The test may be carried out in the vertical or the horizontal position according to the mode of operation of the EQUIPMENT. Not every component in the figures is needed in every test.

The X-RAY FIELD size shall be the minimum size required for each measurement.

The distance between the additional attenuating layer and the detector of the KERMAMETER (KERMA RATEMETER) shall be not less than 250 mm.

NOTE – For the effects of SCATTERED RADIATION, see 4.5.4.

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

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

4.4 Test parameters

The following items are subject to ACCEPTANCE TESTING:

- identification of EQUIPMENT;
- check of documents;
- visual and functional tests;
- X-RAY TUBE VOLTAGE;
- CURRENT TIME PRODUCT;
- LOADING TIME;
- limitation and indication of the extent of the X-RAY BEAM;
- FOCAL SPOT;
- TOTAL FILTRATION;
- RADIATION OUTPUT;
- TRANSMISSION KERMA (TRANSMISSION KERMA RATE);
- function of the AUTOMATIC EXPOSURE CONTROL;
- ATTENUATION RATIO;
- AIR KERMA (AIR KERMA RATE);
- AIR KERMA (AIR KERMA RATE) at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER;
- LINE PAIR RESOLUTION;
- LOW CONTRAST RESOLUTION;
- optical density (for AUTOMATIC EXPOSURE CONTROL test).

Annex B lists symbols and units for some of the above items.

4.5 Test equipment including PHANTOMS (ATTENUATION devices) and TEST DEVICES

4.5.1 General

Measuring equipment used for ACCEPTANCE TESTS shall be certified (for example calibration according to national or international regulations, if applicable).

The uncertainty of measuring instruments shall be less than one-third of the specified tolerances for the quantities being measured.

4.5.2 High-voltage measuring instrument

The high-voltage measuring instrument shall measure the value of X-RAY TUBE VOLTAGES within the specified range. Instruments based on either direct or indirect measurements may be used.

4.5.3 KERAMETER

The KERAMETER (KERMA RATEMETER) shall have a range sufficient to measure the AIR KERMA (AIR KERMA RATE) within the required accuracy for the system under test and shall be calibrated for the applied beam qualities.

If legal regulations require the use of other dosimetric quantities, they may be applied.

4.5.4 PHANTOMS (ATTENUATION devices) and TEST DEVICES

PHANTOMS and TEST DEVICES may consist of attenuating layers (PHANTOM part of the object) and/or structural elements (TEST DEVICE part of the object) which can be arranged in combination or separately.

The following requirements apply:

a) External dimensions

PHANTOM dimensions shall be at least large enough to intercept the entire RADIATION BEAM for all test conditions applicable; see figures 1 and 2.

b) ATTENUATION and hardening

The attenuating layers of the PHANTOMS shall be in aluminium of at least 99,5 % purity (Al 99,5 according to ISO 2092) and a material thickness of 25 mm \pm 0,5 mm; see IEC 61267.

Some, but not all, tests will need an additional homogeneous attenuating layer of about 1,5 mm copper.

A PHANTOM of low atomic number material (for example TISSUE EQUIVALENT MATERIAL) is used to test the function of the AUTOMATIC EXPOSURE CONTROL, for example 10 cm, 15 cm or 20 cm of water.

For some tests lead layers (1 mm to 2 mm thick) are needed to make lead masks or for the shielding of direct and indirect RADIATION.

c) Effects of SCATTERED RADIATION with various measuring arrangements

In all tests care shall be taken to reduce SCATTERED RADIATION to a minimum. If it is likely that SCATTERED RADIATION will significantly affect the measurement, the correction factor shall be determined and used in calculating the results.

d) Beam limiting TEST DEVICE

The beam limiting TEST DEVICE shall comprise structural elements for testing the centring, limitation and indication of the extent of the X-RAY BEAM as marking elements and a matrix with intervals of 1 cm made of RADIATION absorbing material.

These structural elements should be of such material and arranged in such a way that the function of the AUTOMATIC EXPOSURE CONTROL is unaffected.

e) LINE PAIR RESOLUTION TEST DEVICE

The TEST DEVICE shall comprise line-group test patterns with a lead thickness of 0,05 mm and grid groups with local frequencies of 0,6 lp/mm to 5,0 lp/mm with a gradation of less than or equal to 20 % from group to group. The outer dimensions are for example 55 mm × 65 mm; see figure 3.

f) LOW CONTRAST RESOLUTION TEST DEVICE

There are many devices available to measure the LOW CONTRAST RESOLUTION. If this parameter is measured, the results should be recorded together with the description of the TEST DEVICE used.

The detail diameters shall be such that their resolution is neither enhanced nor degraded by the frequency response of the X-RAY IMAGE INTENSIFIER-television system (imaging system). For examples, see annex C.

4.5.5 Lens

A magnifying lens shall be available. A 2 × to 6 × magnification is usually suitable.

4.5.6 Densitometer

The densitometer shall cover the optical density range 0 to 3,5.

4.5.7 Additional inspection and TEST DEVICES for TOMOGRAPHY X-RAY EQUIPMENT

The following TEST DEVICES are required:

– TEST DEVICE to test the layer height adjustment:

Holder for metallic slab with holes drilled at constant intervals (or the TEST DEVICE described above with additional holes; see figure 4) with an inclination of the short axis of the test pattern of 20° to 45° to the plane of the PATIENT SUPPORT. The holes in each row of the test pattern shall be at such intervals as to give an interval of 1 mm in the direction of height;

– TOMOGRAPHY movement TEST DEVICE:

Pinhole DIAPHRAGM for displaying the tomographic movement;

– TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE:

A line-group test pattern with a lead thickness of between 0,05 mm and 0,10 mm and grid groups with local frequencies of 0,5 lp/mm to 4 lp/mm with a gradation of less than or equal to 40 % from group to group. The outer dimensions are for example 42 mm × 110 mm; see figure 4.

4.6 Evaluating the test results

Whenever specified limiting values or tolerances are not met, verify the results by making at least two additional measurements.

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

5 Test methods for RADIOGRAPHY EQUIPMENT

5.1 Visual and functional tests

5.1.1 Requirements

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

All OPERATOR accessible controls shall be labelled with a graphical symbol, for example IEC 60417-1 or IEC 60878, and/or in plain language. The colour of indicator lamps shall comply with applicable standards, for example IEC 60601-1. The marking on the X-RAY TUBE ASSEMBLY shall comply with IEC 60601-2-28. The LIGHT FIELD shall be recognizable in the specified ambient illumination.

The INSTRUCTIONS FOR USE shall describe comprehensively how the X-RAY EQUIPMENT under test is to be operated. The function of each OPERATOR accessible control, indicator and display shall be described and all symbols shall be illustrated with their significance. Reproductions in the INSTRUCTIONS FOR USE shall be in agreement with the actual X-RAY EQUIPMENT, with respect to position, labels and symbols. The INSTRUCTIONS FOR USE shall be written in the language that is required locally or specified in the order contract.

5.1.2 Test methods

The tests are performed by visual inspection and functional check. They comprise:

- *inventory of EQUIPMENT under test;*
- *check on the presence of all documents according to 4.2;*
- *functional test of the mechanical and electrical adjustment devices (including check of the accuracy of FOCAL SPOT TO IMAGE RECEPTOR DISTANCE indicator and any detent positions, where this parameter is variable);*
- *functional test and identification of the control elements;*
- *visual inspection of the labelling of control elements;*
- *visual inspection of the markings on the X-RAY SOURCE ASSEMBLY;*
- *visual inspection of the brightness of the LIGHT FIELD;*
- *visual inspection of the INSTRUCTIONS FOR USE (see IEC 60601-1).*

5.2 *X-RAY TUBE VOLTAGE

5.2.1 Requirements

The MEASURED VALUES of the X-RAY TUBE VOLTAGE shall agree with the values indicated at the control panel within the specified tolerances.

5.2.2 Test methods

The measurements should be carried out using the arrangement in figure 1 without the attenuating layer. The tests are preferably performed using a non-invasive method.

Place the detector of the high-voltage measuring instrument in the centre of the RADIATION BEAM.

At least three standard X-RAY TUBE VOLTAGE measurements shall normally be performed, at 60 kV, 80 kV and 100 kV or at voltages close to these values, at 50 % or more of the highest available X-RAY TUBE CURRENT and a LOADING TIME of approximately 0,1 s. At 80 kV, the measurement shall be carried out also at the lowest and the highest available X-RAY TUBE CURRENT settings.

NOTE 1 – The suggested LOADING FACTORS given above are a minimum recommendation. The choice of LOADING FACTORS should be made considering the nature of the EQUIPMENT under test and its clinical application, so as to explore enough of the X-RAY TUBE VOLTAGE/LOADING TIME/X-RAY TUBE CURRENT relationship to establish the conformance of the EQUIPMENT to its specification and the needs of the USER.

NOTE 2 – At no time during testing should the maximum ratings of the X-RAY TUBE ASSEMBLY be exceeded.

Compare the MEASURED VALUES of the X-RAY TUBE VOLTAGE with the values indicated at the control panel and the specified tolerances.

NOTE – The LOADING FACTORS should be recorded because the X-RAY TUBE VOLTAGE measured may vary with the LOADING FACTOR.

5.3 *TOTAL FILTRATION

5.3.1 Requirements

The minimum TOTAL FILTRATION shall be as specified.

5.3.2 Test method

Compliance with the specification is checked by inspection of the markings on the X-RAY SOURCE ASSEMBLY and by examination of the ACCOMPANYING DOCUMENTS. The QUALITY EQUIVALENT FILTRATION may be determined according to clauses 3 and 4 of IEC 60522, if necessary.

NOTE – This requires measuring the HALF-VALUE LAYER under NARROW BEAM CONDITIONS with the X-RAY EQUIPMENT operating at appropriate values of X-RAY TUBE VOLTAGE and corresponding LOADING FACTORS, and to compare with the HALF-VALUE LAYER from an X-RAY TUBE with the same TARGET material and TARGET ANGLE.

A simplified HALF-VALUE LAYER measurement may be carried out with the arrangement in figure 1, without the attenuating layer. Measure the first HALF-VALUE LAYER with the X-RAY EQUIPMENT operating at appropriate values of X-RAY TUBE VOLTAGE with suitable LOADING FACTORS in the range of NORMAL USE. This test gives only an approximate estimate of the TOTAL FILTRATION because these test conditions do not fully comply with IEC 60522.

State either the compliance of the TOTAL FILTRATION with the specification, or the compliance of the measured HALF-VALUE LAYER with the requirements according to IEC 60601-1-3.

5.4 *FOCAL SPOT of the X-RAY TUBE

5.4.1 Requirements

The actual FOCAL SPOT dimensions for the stated NOMINAL FOCAL SPOT VALUES shall comply with the dimensions specified in IEC 60336. Additional specifications, for example concerning dimensions, direction of the REFERENCE AXIS or LOADING FACTORS, are subject to testing within the scope of this standard only if these specifications also state the test method.

5.4.2 Test method

The compliance of the ACTUAL FOCAL SPOT dimensions for the stated NOMINAL FOCAL SPOT VALUES with IEC 60336 shall be confirmed by the MANUFACTURER.

NOTE – FOCAL SPOT measuring procedures by SLIT CAMERA, PINHOLE CAMERA, star pattern evaluation and Fourier transform of images of TEST DEVICES all give different results concerning size and resolution. The standard FOCAL SPOT measurement is specified according to IEC 60336 by SLIT CAMERA under specified projection conditions and optical density.

5.5 *Limitation and indication of the extent of the X-RAY BEAM

5.5.1 Accuracy of marked and written indications of the X-RAY FIELD size

5.5.1.1 Requirements

The actual size of the X-RAY FIELD shall comply with what is indicated on the EQUIPMENT within the specified tolerances.

5.5.1.2 Test methods

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS. Where appropriate, measure the dimensions of the X-RAY FIELD along its two major axes at selected indicated settings of the BEAM LIMITING SYSTEM, and the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, as available for NORMAL USE and at the commonly used X-RAY BEAM angulation.

Other test procedures than those described here may be used if they lead to comparable results.

Use the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE at the value indicated on the EQUIPMENT or stated in the ACCOMPANYING DOCUMENTS, for the setting used.

Make the measurements with a RADIOGRAPHIC CASSETTE arranged in the tray or on the top of the PATIENT SUPPORT in the centre of the X-RAY FIELD and using the arrangement in figure 2, without the attenuating layer.

Produce RADIOGRAMS with two field sizes, for example 18 cm × 24 cm and 24 cm × 30 cm, under these conditions, with LOADING FACTORS so as to give an optical density D in the range 0,5 to 2,0 on the RADIOGRAPHIC FILM.

Measure the X-RAY FIELD size on the processed RADIOGRAPHIC FILMS and note the discrepancies with the displayed indication(s) on the X-RAY EQUIPMENT. If the RADIOGRAPHIC CASSETTES had been exposed on the top of the PATIENT SUPPORT, this field size must be corrected to correspond to that at the cassette tray.

Discrepancies between the measured X-RAY FIELD size and the displayed indications shall be within the specified tolerances.

5.5.2 Accuracy of indication of the LIGHT FIELD-INDICATOR

5.5.2.1 Requirements

The discrepancies in the indication of the LIGHT FIELD and the X-RAY FIELD shall comply with the tolerances specified.

5.5.2.2 Test methods

Site a RADIOGRAPHIC CASSETTE, for example 24 cm × 30 cm, on top of the PATIENT SUPPORT in the centre of the X-RAY FIELD and manually set a LIGHT FIELD of for example 18 cm × 24 cm. Mark the corners of the LIGHT FIELD with radio-opaque markers, for example metal wires. Choose LOADING FACTORS so as to give an optical density D in the range 0,5 to 2,0 on the RADIOGRAPHIC FILM.

Measure the X-RAY FIELD limits on the processed RADIOGRAPHIC FILM and the discrepancies from the indicated LIGHT FIELD.

In figure 5, 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 FOCAL SPOT to the plane of the LIGHT FIELD distance is r_L , then, for compliance, the following relationships are true:

$$|a_1| + |a_2| \leq X \times r_L$$

$$|b_1| + |b_2| \leq X \times r_L$$

where

X is the tolerance specified.

5.5.3 Correspondence between the X-RAY FIELD and IMAGE RECEPTION AREA with automatic adjustment of the RADIATION APERTURE

5.5.3.1 Requirements

The discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall comply with the tolerances specified.

5.5.3.2 Test methods

Compliance with the relevant requirements is checked by inspection of the EQUIPMENT, by examination of the INSTRUCTIONS FOR USE and by measurement of the X-RAY FIELDS, where appropriate.

Allow a period of at least 5 s for the automatic mechanism to complete any adjustment occurring during the tests.

Use two cassette sizes for this test, for example 18 cm × 24 cm and 24 cm × 30 cm.

Use the arrangement of figure 2, without the attenuating layer. Put a non-screen RADIOGRAPHIC CASSETTE or a RADIOGRAPHIC FILM in a light-proof envelope on the PATIENT SUPPORT. Then insert a loaded RADIOGRAPHIC CASSETTE into the cassette holder. The automatic BEAM LIMITING DEVICE will automatically adjust the X-RAY FIELD size to the format of the RADIOGRAPHIC CASSETTE used. Choose LOADING FACTORS so as to give an optical density D in the range 0,5 to 2,0 on both RADIOGRAPHIC FILMS.

Measure, on the processed RADIOGRAPHIC FILMS, the X-RAY FIELD limits and the discrepancies from the IMAGE RECEPTION AREA.

As shown in figure 6, the measured discrepancies in the IMAGE RECEPTOR PLANE are represented by c_1 and c_2 on one axis, and by d_1 and d_2 on the other.

If the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE is r_B , then for compliance, the following relationships are true:

$$|c_1| + |c_2| \leq Y \times r_B$$

$$|d_1| + |d_2| \leq Y \times r_B$$

$$|c_1| + |c_2| + |d_1| + |d_2| \leq Z \times r_B$$

where

Y and Z are the tolerances specified.

NOTE – If the above requirements are fulfilled, the X-RAY EQUIPMENT complies with the X-RAY FIELD centring requirements.

5.6 *Linearity and reproducibility of TRANSMISSION KERMA OR RADIATION OUTPUT

5.6.1 Requirements

The following requirements are applied alternatively (for TRANSMISSION KERMA or for RADIATION OUTPUT) according to the regional requirements.

The linearity of the TRANSMISSION KERMA with the CURRENT TIME PRODUCT and the reproducibility shall comply with the tolerances or values specified.

The RADIATION OUTPUT and the TRANSMISSION KERMA per CURRENT TIME PRODUCT at a given distance for a given setting of X-RAY TUBE VOLTAGE should be independent of the X-RAY TUBE CURRENT selection for each FOCAL SPOT.

If the TRANSMISSION KERMA index, TK_i , is specified at a specified X-RAY TUBE VOLTAGE, it shall comply with the values and tolerances specified.

The RADIATION OUTPUT shall comply with the values and tolerances specified.

5.6.2 Test method

Carry out the measurements using the arrangement in figure 1, with the attenuating layer in position. Measure the linearity and reproducibility of the TRANSMISSION KERMA with the CURRENT TIME PRODUCT (AIR KERMA per CURRENT TIME PRODUCT) for a specific value of the X-RAY TUBE VOLTAGES. The detector of the KERMA METER is to be placed in the RADIATION BEAM behind the attenuating layer at a sufficient distance.

Measure the AIR KERMA for the following settings:

- a) at least five values of X-RAY TUBE CURRENT, including the lowest and the highest value, at an X-RAY TUBE VOLTAGE of about 80 kV or as specified and a LOADING TIME of about 0,1 s;*
- b) select the same value of X-RAY TUBE VOLTAGE and measure the AIR KERMA at a low value of X-RAY TUBE CURRENT for the lowest and the highest available value of LOADING TIME;*
- c) make at least five measurements at a specific combination of the CURRENT TIME PRODUCT and X-RAY TUBE VOLTAGE.*

In case of RADIATION OUTPUT the above measurements are done in the primary beam without the attenuating layer.

NOTE 1 – The combinations of LOADING FACTORS specified for the tests are limited in number but chosen from experience as being appropriate in most cases.

NOTE 2 – At no time during testing should the maximum ratings of the X-RAY TUBE ASSEMBLY be exceeded.

Evaluate the results as follows:

- for a) and b) calculate the deviations and the TRANSMISSION KERMA index, TK_i , if specified;*
- for c) calculate the mean value and the maximum deviation.*

For the calculation of the TRANSMISSION KERMA index, TK_i , the following applies:

$$TK_i = K_T \times \frac{r_T^2}{Q_a^2}$$

where

K_T is the TRANSMISSION KERMA;

TK_i is the TRANSMISSION KERMA index;

r_T is the distance between FOCAL SPOT and measuring plane;

Q_a is the indicated CURRENT TIME PRODUCT (mAs).

Compare the results with the specified values and tolerances.

5.7 *ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR

5.7.1 Requirements

The ATTENUATION RATIO, T_R , of material between the PATIENT and the X-RAY IMAGE RECEPTOR shall not exceed the specified values.

5.7.2 Test method

Check that the parts delivered are as ordered (for example type of ANTI-SCATTER GRID).

Measure the ATTENUATION RATIO, T_R , using the arrangement in figure 1 within the specified range of the X-RAY TUBE VOLTAGES, for example 80 kV, and with the attenuating layer, for example 25 mm aluminium, in position. The measurement should be made in NARROW BEAM CONDITION.

Measure the TRANSMISSION KERMA (TRANSMISSION KERMA RATE), K_T (\dot{K}_T), and the X-RAY IMAGE RECEPTOR AIR KERMA (AIR KERMA RATE), K_B (\dot{K}_B), if accessible.

Calculate the ATTENUATION RATIO:

$$T_R = \frac{K_T}{K_B} \times \frac{r_T^2}{r_B^2}$$

where

K_T and K_B are the values for AIR KERMA above and below the PATIENT SUPPORT;

r_T and r_B are the corresponding distances from the FOCAL SPOT.

Compare the results of these measurements with the specified values.

5.8 *AUTOMATIC EXPOSURE CONTROL (AEC)

5.8.1 NOMINAL SHORTEST IRRADIATION TIME with AUTOMATIC EXPOSURE CONTROL

5.8.1.1 Requirements

The NOMINAL SHORTEST IRRADIATION TIME (see IEC 60601-2-7) shall be specified in the ACCOMPANYING DOCUMENTS together with the test conditions.

5.8.2 * Performance of the AEC

5.8.2.1 Requirements

The adjustment of the AEC is usually made by the installing engineer in consultation with the USER, based upon dedicated information given by MANUFACTURERS of RADIOGRAPHIC FILMS, INTENSIFYING SCREENS and film processing.

Both parties, the installing engineer and the USER, should be signatories to a statement of compliance.

If this statement of compliance cannot be provided, the following tests are applicable.

The AEC shall perform within the tolerances specified under the following conditions:

- a) IRRADIATIONS using AEC at specified X-RAY TUBE VOLTAGES, with a specified PHANTOM, for example water, and with specified X-RAY IMAGE RECEPTORS, for example film-screen systems, shall give optical densities within the specified range;

- b) specified variations of PHANTOM thickness and X-RAY TUBE VOLTAGE shall lead to optical densities within the specified range for a specified film-screen system and a specified technique, for example ANTI-SCATTER GRID/non-ANTI-SCATTER GRID technique;
- c) adjacent correction steps shall lead to changes in AIR KERMA values, LOADING FACTORS or optical densities for the specified film-screen system within the tolerances specified.

5.8.2.2 Test methods

5.8.2.2.1 Constancy of the optical density with variation of X-RAY TUBE VOLTAGE and PHANTOM thickness (RADIOGRAPHIC FILM method)

Check that the AEC has been set up for the specified film-screen system used in the test.

Carry out the measurements using the arrangement in figure 1 with the PHANTOM on the PATIENT SUPPORT. Use a PHANTOM of 15 cm of water as reference thickness, see 4.5.4. For each measurement made, use the same RADIOGRAPHIC CASSETTE, for example 24 cm × 30 cm, the same type of RADIOGRAPHIC FILM and the same radiographic screens. The film-screen system used in the test shall be the same as that used in medical practice. A test of the performance of the film processing shall precede any of these tests; see 4.1. The film processing shall be carried out under normal and stable conditions, for example with respect to sensitivity, contrast and absence of ARTIFACTS.

Select a voltage of 80 kV. Adjust the AEC dose level and density correction according to the instruction manual. Produce a basic RADIOGRAM using the AEC under reference conditions.

After processing the RADIOGRAPHIC FILM, measure the optical density, D , in the specified area of the RADIOGRAPHIC FILM with a densitometer. If the optical density is in accordance with the USER's expectation, investigate the compensation for different PHANTOM thicknesses over the specified range, at constant X-RAY TUBE VOLTAGE. Repeat this test for phantom thicknesses of 10 cm and 20 cm of water.

If the AEC meets the specification at 80 kV, use another RADIOGRAPHIC FILM to demonstrate the effect of X-RAY TUBE VOLTAGE variation upon the optical density. Use the lowest and highest specified values of X-RAY TUBE VOLTAGE.

The constancy of the optical densities D for combinations of measuring fields may be checked at the reference PHANTOM thickness.

NOTE 1 – If the AEC has more than one sensor area (measuring field), not all sensor areas may have the same sensitivity and produce the same optical density. This depends on the specified anatomical REGION OF INTEREST for the RADIOGRAMS; see the INSTRUCTIONS FOR USE.

NOTE 2 – If using PHANTOM material other than water, for example polymethyl-methacrylate (PMMA), the absolute values of the optical density and the AIR KERMA can be different from the values with a water PHANTOM.

5.8.2.2.2 Reproducibility test of the AEC (KERMAMETER method)

Carry out the AIR KERMA measurements using the same arrangement as in figure 1 and AEC reference conditions, for example standard position of available range of density correction steps and dose steps as appropriate to the film-screen system.

Place the detector of the KERMAMETER in the X-RAY BEAM.

Select one sensor (usually the centre sensor). Make five measurements and calculate the reproducibility.

Compare the results of these measurements with the values specified.

5.8.3 Back-up timer and security cut-out

5.8.3.1 Requirements

The back-up timer shall terminate the IRRADIATION when the specified X-RAY TUBE LOAD or LOADING TIME has been reached. In the presence of a security cut-out, no separate test of the back-up timer shall be carried out.

5.8.3.2 Test methods

Cover the sensor for the AEC with at least 2 mm of lead and operate the X-RAY EQUIPMENT under the AEC mode with the specified setting for the X-RAY TUBE VOLTAGE (for example a low value of about 60 kV). Record the X-RAY TUBE LOAD or the LOADING TIME and compare with the values specified.

NOTE – A malfunctioning back-up timer may lead to excess X-RAY TUBE LOAD resulting in the damage of the X-RAY TUBE. The OPERATOR should be aware of this possibility.

5.9 LINE PAIR RESOLUTION for DIRECT RADIOGRAPHY

NOTE – There is no requirement and no test included here because the LINE PAIR RESOLUTION is either determined by the FOCAL SPOT size (see 5.4) and the measuring arrangement, or limited by the characteristic for the film-screen system used.

5.10 * AIR KERMA area product indicator

5.10.1 Requirements

The indicated AIR KERMA area product shall be within the tolerances specified.

5.10.2 Test method

Carry out the measurement using the arrangement in figure 1.

Measure the X-RAY FIELD size using a radiographic method.

Arrange the RADIOGRAPHIC CASSETTE, for example 18 cm × 24 cm, in the centre of the X-RAY FIELD. Make the collimated field size about 15 cm × 15 cm. Choose LOADING FACTORS so as to give an optical density in the range 0,5 to 2,0. Measure the field size on the processed RADIOGRAPHIC FILM.

Then remove the attenuating layer and put the detector of the KERMAMETER in the same position as the RADIOGRAPHIC CASSETTE and make an IRRADIATION with the same field size.

Compare the product of the value of the X-RAY FIELD size measured on the RADIOGRAPHIC FILM, and the measured AIR KERMA with the INDICATED VALUE of the AIR KERMA area product.

6 Test methods for RADIOSCOPY EQUIPMENT

6.1 Visual and functional tests

6.1.1 Requirements

The requirements are given in 5.1.1, if applicable.

6.1.2 Test methods

The test methods are given in 5.1.2, if applicable.

6.2 X-RAY TUBE VOLTAGE

6.2.1 Requirements

The value of the X-RAY TUBE VOLTAGE is controlled through the AUTOMATIC EXPOSURE RATE CONTROL (AERC) when the attenuating layer/PHANTOM is placed in the X-RAY BEAM. This displayed value at the OPERATOR'S console shall comply with the measured value within the specified tolerance.

6.2.2 Test methods

The AERC may be influenced by the detector of the high-voltage measuring instrument. The attenuating layer/PHANTOM is therefore first placed in the X-RAY BEAM according to the arrangement in figure 1, and the values of the LOADING FACTORS which are controlled by the AERC are recorded. These values are stored with the "lock-in" button. If there is no "lock-in" button, and if there is no possibility to select these values manually, the order contract shall specify the test procedure.

Place the detector of the high-voltage measuring instrument in the X-RAY BEAM and measure the X-RAY TUBE VOLTAGE.

Compare the results of the measurements with the values indicated at the control panel.

NOTE – Modern radioscopic systems with X-RAY IMAGE INTENSIFIER-television systems are equipped with an AERC. This control system consists of a kV or mA control or a combined kV/mA control. Separate measurement of the individual LOADING FACTORS is only possible with invasive measurements.

6.3 TOTAL FILTRATION

6.3.1 Requirements

The requirements given in 5.3.1 are applicable.

6.3.2 Test method

The test method given in 5.3.2 is applicable.

6.4 FOCAL SPOT of the X-RAY TUBE

6.4.1 Requirements

The requirements given in 5.4.1 are applicable.

6.4.2 Test method

The test method given in 5.4.2 is applicable.

6.5 Functioning of the AUTOMATIC EXPOSURE RATE CONTROL (AERC)

6.5.1 Requirements

The AERC shall function as specified.

NOTE – An AUTOMATIC EXPOSURE RATE CONTROL (AERC) is intended to maintain constant average image brightness independent of the X-ray absorption of the objects being examined by adjusting the LOADING FACTORS. This function may be linked with that of an automatic brightness control (ABC) or an automatic gain control (AGC) of the television chain.

6.5.2 Test method

Select the AERC mode of operation.

To demonstrate compliance with the required LOADING FACTOR charts or diagrams when the ATTENUATION of a test object is varied, use the procedure specified in the MANUFACTURER'S installation instructions.

Record the LOADING FACTORS.

Check that the AERC functions correctly for all X-RAY IMAGE INTENSIFIERS formats (zoom formats), and for all selectable AIR KERMA RATES.

Record that the AERC functions correctly, according to the above tests.

6.6 Limitation of the extent of the X-RAY BEAM

These tests should be performed at a typical FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and commonly used angle of the PATIENT SUPPORT. Alternatively, other test procedures than those described in this subclause may be used if they lead to comparable results.

6.6.1 Correspondence between the X-RAY FIELD, the IMAGE RECEPTION AREA of X-RAY IMAGE INTENSIFIERS and the image display

6.6.1.1 Requirements

The discrepancies between the X-RAY FIELD, the corresponding IMAGE RECEPTION AREA of the X-RAY IMAGE INTENSIFIER and the displayed image shall comply with the tolerances specified.

6.6.1.2 Test methods

Compliance is checked by inspection of the EQUIPMENT, by examination of the INSTRUCTIONS FOR USE and by measurement of the X-RAY FIELDS, where appropriate.

When automatic adjustment of the RADIATION APERTURE is provided, before making any measurements, allow a period of at least 5 s for the automatic mechanism to complete any adjustments.

When determining compliance with the requirements, carry out the measurements with the REFERENCE AXIS normal to the IMAGE RECEPTOR PLANE within $\pm 3^\circ$.

Carry out the measurements using the arrangement of figure 2, without the attenuating layer.

Adjust the BEAM LIMITING DEVICE to maximum field size. Check whether the limitation due to the BEAM LIMITING DEVICE is visible on the video display unit (VDU), both in vertical and horizontal direction.

If not all four blades are visible, perform the following test steps.

- a) *Put a RADIOGRAPHIC CASSETTE on the PATIENT SUPPORT, for undertable X-RAY TUBE units on the rear panel of the SPOTFILM DEVICE. Use, if possible, a film-screen system with a lower speed than normally used or a RADIOGRAPHIC FILM in a light-proof envelope.*
- b) *Adjust the BEAM LIMITING DEVICE to a small field size. Centre the beam limiting TEST DEVICE under RADIOSCOPY or with the light field indication.*

NOTE – The test film IRRADIATION will not affect the test results.

- c) *Adjust the BEAM LIMITING DEVICE to maximum field size. Measure the visible X-RAY FIELD SIZE under radiosopic conditions by noting the matrix intervals in all four directions displayed on the VDU.*
- d) *Operate the radiosopic mode so as to produce on the RADIOGRAPHIC FILM an optical density D in the range 0,5 to 2,0.*
- e) *Evaluate the processed RADIOGRAPHIC FILM. Measure the X-RAY FIELD limits in four directions and define the discrepancies to the noted matrix intervals.*

Repeat this procedure with all X-RAY IMAGE INTENSIFIERS formats (zoom formats), for example 36 cm/25 cm/17 cm.

If an INDIRECT RADIOGRAPHY system is used, make a documentation for one image format.

For compliance, the requirements given in 5.5.3 are applicable.

6.6.2 Correspondence between the X-RAY FIELD and the IMAGE RECEPTION AREA using a SPOTFILM DEVICE

6.6.2.1 Requirements

The discrepancies between the X-RAY FIELD and the corresponding IMAGE RECEPTION AREA in connection with a SPOTFILM DEVICE shall comply with the tolerances specified.

6.6.2.2 Test methods

The test method given in 5.5.3.2 is applicable.

6.7 ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR

6.7.1 Requirements

The requirements given in 5.7.1 are applicable.

6.7.2 Test method

The test method given in 5.7.2 is applicable.

A test is not necessary if this parameter has been tested in RADIOGRAPHY operation; see 5.7.

6.8 *AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for RADIOSCOPY

6.8.1 Requirements

The AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER shall comply with the values specified. The measurements shall be made under the conditions specified by the operating modes provided.

This test uses an homogeneous PHANTOM and applies to systems with mean value controls. The use of an homogeneous PHANTOM for other systems, for example peak value control, will give different absolute values. In each case, compliance is tested against the values specified by the MANUFACTURER.

6.8.2 Test method

Carry out the measurements using the arrangement in figure 1, with the attenuating layer, for example 25 mm aluminium, in position and the KERMAMETER as close as possible to the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER; see 4.5.4.

Select an X-RAY TUBE VOLTAGE of 70 kV to 80 kV. If the X-RAY TUBE VOLTAGE selection is automatic, add sufficient attenuating layer, for example 1,5 mm copper, to drive the X-RAY TUBE VOLTAGE to within this range.

Measure the AIR KERMA RATE, \dot{K}_B , at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER behind the ANTI-SCATTER GRID.

If the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER is not directly accessible, measure the TRANSMISSION KERMA RATE, \dot{K}_T , and calculate \dot{K}_B from the relationship:

$$\dot{K}_B = \frac{\dot{K}_T}{T_R} \times \frac{r_T^2}{r_B^2}$$

using the value of T_R specified by the MANUFACTURER.

Measure \dot{K}_B or \dot{K}_T at each AIR KERMA RATE selection with the X-RAY BEAM collimated to the full X-RAY IMAGE INTENSIFIER format.

Compare the results of this measurement with the specified values.

6.9 *Entrance AIR KERMA RATE for RADIOLOGY with X-RAY IMAGE INTENSIFIER

6.9.1 Requirements

The entrance AIR KERMA RATE shall comply with the values specified.

The measurements shall be carried out under the conditions specified in the operating modes provided.

NOTE – These measurements give an indication of the effectiveness of additional X-RAY BEAM filtering devices and of the PATIENT SURFACE AIR KERMA.

This is especially important for cardiac radioscopic systems using high dose rate RADIOLOGY.

In some countries, the limitation of the entrance AIR KERMA RATE to a defined maximum value has to be proved.

6.9.2 Test method

Carry out the measurements using the arrangement in figure 1, with the PHANTOM (for example 20 cm water) on the PATIENT SUPPORT and the KERMAMETER at the entrance plane of the PHANTOM.

Select a voltage of 70 kV to 80 kV.

If the voltage selection is automatic, further attenuating layers may be needed to drive the operating voltage to within this range.

Measure the AIR KERMA RATE at the entrance plane of the PHANTOM, at the specified AIR KERMA RATE selection and with the X-RAY BEAM collimated to the full X-RAY IMAGE INTENSIFIER format.

Compare the results with the specified values.

6.9.3 Test method for maximum entrance AIR KERMA RATE

If the maximum value of entrance AIR KERMA RATE are to be measured, the X-RAY IMAGE INTENSIFIER shall be covered by a high absorbing layer, for example by 2 mm of lead. The AUTOMATIC EXPOSURE RATE CONTROL will increase the AIR KERMA RATE to the maximum value.

Measure the maximum entrance AIR KERMA RATE at the reference point as defined for the X-RAY EQUIPMENT under test by the MANUFACTURER.

NOTE – International Standards and some regional regulations define as reference point:

> 30 cm above the PATIENT SUPPORT for C-arm units and overtable tube equipment;

> 1 cm above PATIENT SUPPORT for undertable tube equipment.

Compare the results with the specified values.

6.10 AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

6.10.1 Requirements

The AIR KERMA per image, under the specified conditions, shall be as specified.

6.10.2 Test method

Carry out the measurements using the same conditions as in 6.8.2.

Measure K_B per image at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER. If the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER is not directly accessible, measure the TRANSMISSION KERMA, K_T , and calculate K_B from the relationship:

$$K_B = \frac{K_T}{T_R} \times \frac{r_T^2}{r_B^2}$$

using the value of T_R specified by the MANUFACTURER.

If a film is used, the optical density D shall be $1,0 \pm 0,2$, unless some other figure is specified.

For AUTOMATIC EXPOSURE CONTROL (kV/mA control), for example with CINERADIOGRAPHY technique, sufficient FILTRATION (for example 1,5 mm copper) may be needed as an attenuating layer in addition to the 25 mm of aluminium used in the arrangement of figure 1, to achieve an X-RAY TUBE VOLTAGE of about 70 kV.

Calculate the AIR KERMA per image from the total AIR KERMA of a series of images (for example cine-runs) divided by the number of irradiated images. Make the measurement in the stable phase.

Compare the results of these measurements with the specified values.

6.11 Entrance AIR KERMA for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

6.11.1 Requirements

The entrance AIR KERMA shall comply with the values specified.

Measurements shall be carried out under the conditions specified in the operating modes provided.

NOTE – These measurements give an indication of the effectiveness of additional X-RAY BEAM filtering devices and of the PATIENT SURFACE AIR KERMA.

This is especially important for cardiac radioscopy systems using high power RADIOSCOPY.

6.11.2 Test method

Carry out the measurements using the arrangement in figure 1, with the PHANTOM (for example 20 cm water) on the PATIENT SUPPORT and the KERMA METER at the entrance plane of the PHANTOM.

Measure the AIR KERMA per image at the entrance plane of the PHANTOM, at the specified AIR KERMA RATE selection and with the X-RAY BEAM collimated to the full X-RAY IMAGE INTENSIFIER format.

For AUTOMATIC EXPOSURE CONTROL (kV/mA control), for example with CINERADIOGRAPHY technique, sufficient ATTENUATION (for example 1,5 mm copper) may be needed, as an attenuating layer additional to the PHANTOM used in the arrangement of figure 1, to achieve an X-RAY TUBE VOLTAGE of about 70 kV.

Calculate the AIR KERMA per image from the total AIR KERMA of a series of images (for example cine-runs) divided by the number of irradiated images. Make the measurement in the stable phase.

Compare the results with the specified values.

6.12 *LINE PAIR RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

6.12.1 Requirements

The LINE PAIR RESOLUTION, R , for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for INDIRECT RADIOGRAPHY systems shall comply with the specified values under the specified conditions.

NOTE – The LINE PAIR RESOLUTION is a subjective measurement for judging only one aspect of image quality.

6.12.2 Test method

Carry out the measurements using the arrangement in figure 2 with the LINE PAIR RESOLUTION TEST DEVICE, oriented at 45° to the video scan lines and ANTI-SCATTER GRID lines.

NOTE – If measurements are made with the ANTI-SCATTER GRID removed, different performance figures will be produced.

The test shall be carried out with one of the following conditions, as specified.

a) Detector resolution without attenuating layer/PHANTOM

Place the LINE PAIR RESOLUTION TEST DEVICE near the centre of the X-RAY BEAM as close as possible to the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER. Use an X-RAY BEAM at the lowest available X-RAY TUBE VOLTAGE and a high AIR KERMA RATE.

The AIR KERMA RATE used to reduce the effect of quantum noise shall not saturate the brightest parts of the image.

b) System resolution with attenuating layer/PHANTOM

Place the LINE PAIR RESOLUTION TEST DEVICE near the centre of the X-RAY BEAM at a distance to the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER as specified by the MANUFACTURER.

NOTE – Test a) gives information mainly about the function of the X-RAY IMAGE INTENSIFIER-television system. It represents the highest possible LINE PAIR RESOLUTION (without PATIENT).

Test b) gives information mainly about the function of the X-RAY EQUIPMENT including the X-RAY IMAGE INTENSIFIER-television system under practical diagnostic conditions (PATIENT simulated by a PHANTOM; geometry).

For RADIOSCOPY, when an attenuating layer or PHANTOM is used, select a voltage for this measurement of 70 kV to 80 kV.

If the voltage selection is automatic, further ATTENUATION may be needed to drive the X-RAY TUBE VOLTAGE to within this range.

For INDIRECT RADIOGRAPHY with AUTOMATIC EXPOSURE RATE CONTROL (kV/mA control), for example with CINERADIOGRAPHY technique, sufficient ATTENUATION (for example water, aluminum or copper according to the MANUFACTURER's instructions) may be needed in addition to the PHANTOM used in the arrangement of figure 1 to achieve an X-RAY TUBE VOLTAGE of about 70 kV.

If the image is recorded on film, the optical density D shall be $1,0 \pm 0,2$, unless some other figure is specified.

Measure the light level on the face of the monitor under normal working conditions. If necessary, adjust the ambient light level so that the light on the face of the (unilluminated) monitor is as specified by the MANUFACTURER (for example less than 1 Cd/m^2).

Before using the LINE PAIR RESOLUTION TEST DEVICE, adjust the video display unit (VDU) without X-RADIATION.

The area surrounding the circular radiosopic area on the screen should show the minimum brightness (background brightness).

Then adjust with X-RADIATION the VDU contrast control for maximum visibility of the LINE PAIR RESOLUTION TEST DEVICE.

When examining the RADIOGRAPHIC FILM images of the LINE PAIR RESOLUTION TEST DEVICE a magnifying lens may be required.

Record the smallest line-group (highest LINE PAIR RESOLUTION) of the specified LINE PAIR RESOLUTION TEST DEVICE which can be resolved in the image. The lines of a group shall be detectable over the major part of the total length.

Compare the values with the specified values under specified conditions.

6.13 *LOW CONTRAST RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

NOTE – These tests are subjective and cannot give the degree of independent accuracy needed for objective decisions or to compare one system with another.

6.13.1 Requirements

The LOW CONTRAST RESOLUTION at the specified AIR KERMA and X-RAY TUBE VOLTAGE should be as specified.

There are many TEST DEVICES available or that can be made to measure the LOW CONTRAST RESOLUTION. If the LOW CONTRAST RESOLUTION is measured, the result shall be recorded, together with a description of the TEST DEVICE used.

6.13.2 Test method

For the determination of the LOW CONTRAST RESOLUTION and the AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER, use the measuring arrangement in figure 2.

Set the X-RAY BEAM parameters as specified for the TEST DEVICE (X-RAY TUBE VOLTAGE, for example 70 kV, and AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER).

The AIR KERMA RATE used to reduce the effect of quantum noise shall not saturate the brightest parts of the image.

Use the specified TEST DEVICES with contrast detail objects (steps, step wedges or disks); see annex C. Place the TEST DEVICE in the X-RAY BEAM at a suitable position and distance (see TEST DEVICE specification).

NOTE – The observed contrast details are related to the degree of contrast loss and noise of the system.

With AUTOMATIC EXPOSURE RATE CONTROL, depending on the PHANTOM, a specified AIR KERMA RATE results at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER.

Adjust the ambient lighting to normal working conditions.

Before using the LOW CONTRAST RESOLUTION TEST DEVICE, adjust the video display unit (VDU) without X-RADIATION as described in 6.12.2.

Then adjust with X-RADIATION the VDU contrast control with the LOW CONTRAST RESOLUTION TEST DEVICE until the low contrast details are equally visible.

Carry out these measurements at a constant distance from the VDU, for example three or four times the screen diagonal of the VDU.

NOTE – If the video chain has variable integration characteristics, a longer time constant may produce a noticeable improvement in low contrast discrimination.

At the specified AIR KERMA RATE, count the number of visible contrast details discernible from the background. The observed values should be based upon the average observations of at least two people. If there is doubt about the visibility of the last contrast detail, this may be recorded as a half value.

Record the values and compare with the specification.

6.14 AIR KERMA area product indicator

6.14.1 Requirements

The requirements given in 5.10.1 are applicable.

6.14.2 Test method

The test method given in 5.10.2 is applicable.

7 Additional tests required for TOMOGRAPHY EQUIPMENT

7.1 *Requirements

The accuracy of the tomographic height indication at 100 mm above the PATIENT SUPPORT shall be within the specified tolerances of the INDICATED VALUE.

The deviation between the light indicator of the tomographic plane and the displayed layer shall not exceed the specified tolerances.

The symmetry of the tomographic movement and angle shall be checked.

The movement figures of the tomographic unit and the LINE PAIR RESOLUTION at approximately 100 mm to 150 mm above the PATIENT SUPPORT shall be as specified.

7.2 Test method

a) Tomographic height indication

Use the TEST DEVICE for the layer height adjustment, described in 4.5.7, placed on top of the PATIENT SUPPORT with the centre at the indicated height for the tomographic plane, oriented with the long axis to the main direction of the FOCAL SPOT movement. From the irradiated and processed RADIOGRAPHIC FILMS, derive the position of the hole in a row that is sharply imaged, and calculate the deviation from the centre hole.

b) Tomographic figure

Place the pinhole DIAPHRAGM approximately 100 mm to 150 mm above the PATIENT SUPPORT and select a tomographic plane of approximately 50 mm height. Collimate the X-RAY BEAM so that it is completely intercepted by the lead DIAPHRAGM at all positions in the tomographic figure. Make an IRRADIATION selecting appropriate LOADING FACTORS.

This RADIOGRAM may be superimposed with a pinhole RADIOGRAM from the centred X-RAY TUBE to mark the geometrical centre of the tomographic movement.

Examine the irradiated and processed RADIOGRAPHIC FILM and compare with specifications.

c) LINE PAIR RESOLUTION

The LINE PAIR RESOLUTION is measured using the IRRADIATION of a TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE (see figure 4) in the tomographic plane at approximately 100 mm above the PATIENT SUPPORT. The lead bar test pattern shall be mounted in a holder at an angle of 20° to 45° to the tomographic plane on the PATIENT SUPPORT plate, oriented with the long axis to the main direction of the FOCAL SPOT movement.

When examining RADIOGRAPHIC FILM images of the TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE on the FILM ILLUMINATOR, to determine the LINE PAIR RESOLUTION, a magnifying lens may be required.

Record the values and compare with the specification.

8 Test report and statement of compliance

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

- description of the X-RAY EQUIPMENT tested, including individual identification data for all components;
- compilation of relevant performance and functioning specifications;
- description of the test equipment including film-screen system(s) and processing data;
- test results;
- statement of compliance or non-compliance of the X-RAY EQUIPMENT with its specifications, including the location, the date and the names of the persons performing the tests.

The result recorded in the test report shall indicate whether the X-RAY EQUIPMENT under test fulfils the requirements.

NOTE – The relevant results of the acceptance testing, including film processing, can be used as reference data for the initial CONSTANCY TEST.

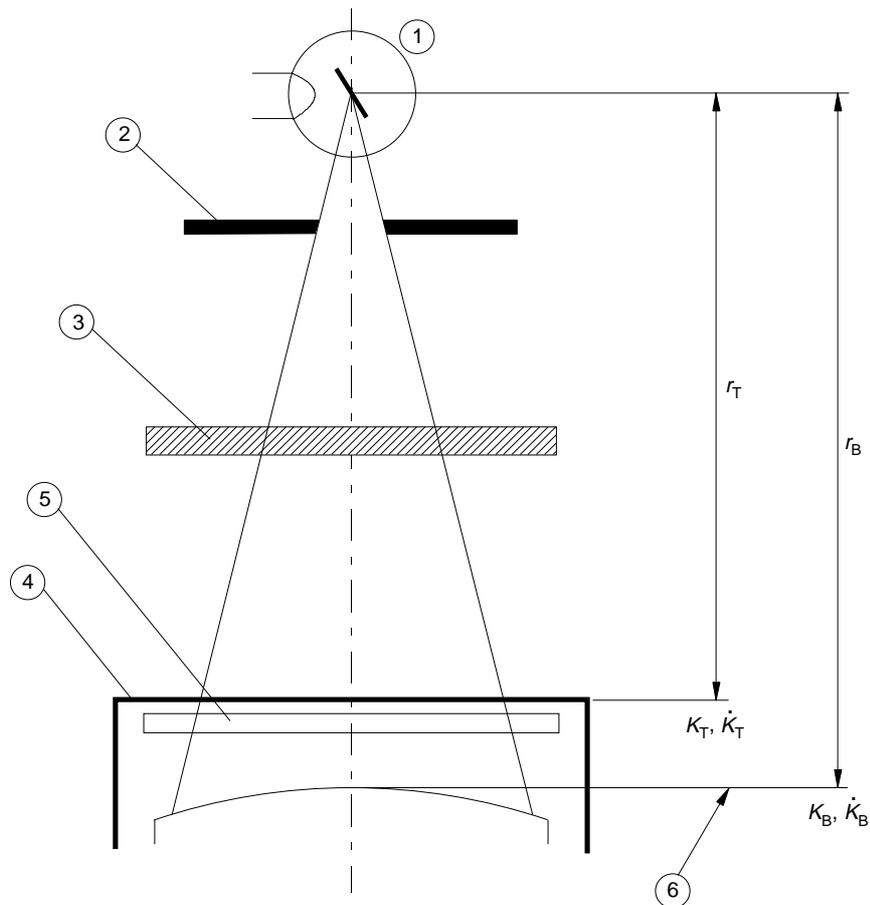
The test report shall be headed:

**Test report
on acceptance tests of X-ray equipment for radiographic
and radiosopic systems
according to IEC 61223-3-1:1999**

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

Imaging performance of X-ray equipment for radiographic and radiosopic systems,* ,
complies with IEC 61223-3-1:1999.

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



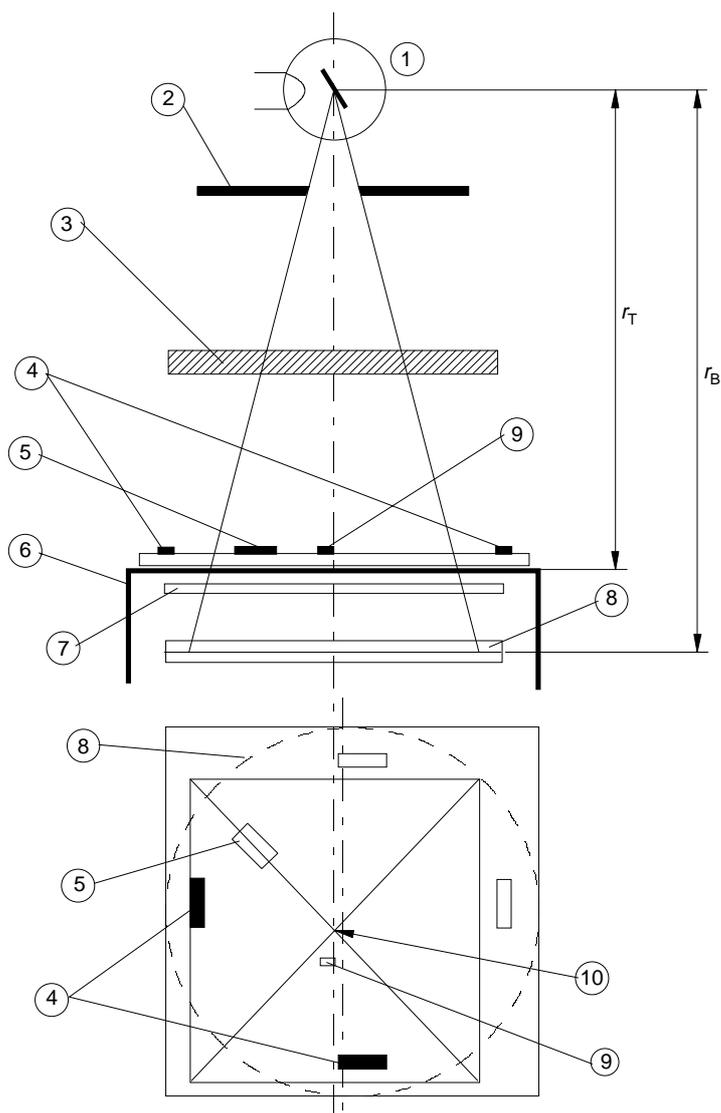
IEC 331/99

Key

1	X-RAY TUBE
2	DIAPHRAGM (BEAM LIMITING DEVICE)
3	Additional attenuating layer/phantom (25 mm aluminium, sometimes 1,5 mm copper added)
4	PATIENT SUPPORT
5	ANTI-SCATTER GRID
6	IMAGE RECEPTOR PLANE (RADIOGRAPHIC FILM cassette or X-RAY IMAGE INTENSIFIER housing)
r_T	FOCAL SPOT to PATIENT SUPPORT distance
r_B	FOCAL SPOT to IMAGE RECEPTOR PLANE distance
K_T (\dot{K}_T)	TRANSMISSION KERMA (TRANSMISSION KERMA RATE)
K_B (\dot{K}_B)	X-RAY IMAGE RECEPTOR AIR KERMA (AIR KERMA RATE)

NOTE – For explanations, see table B.1.

**Figure 1 – Measuring arrangement for RADIOGRAPHY and RADIOSCOPY EQUIPMENT
for AIR KERMA measurements**



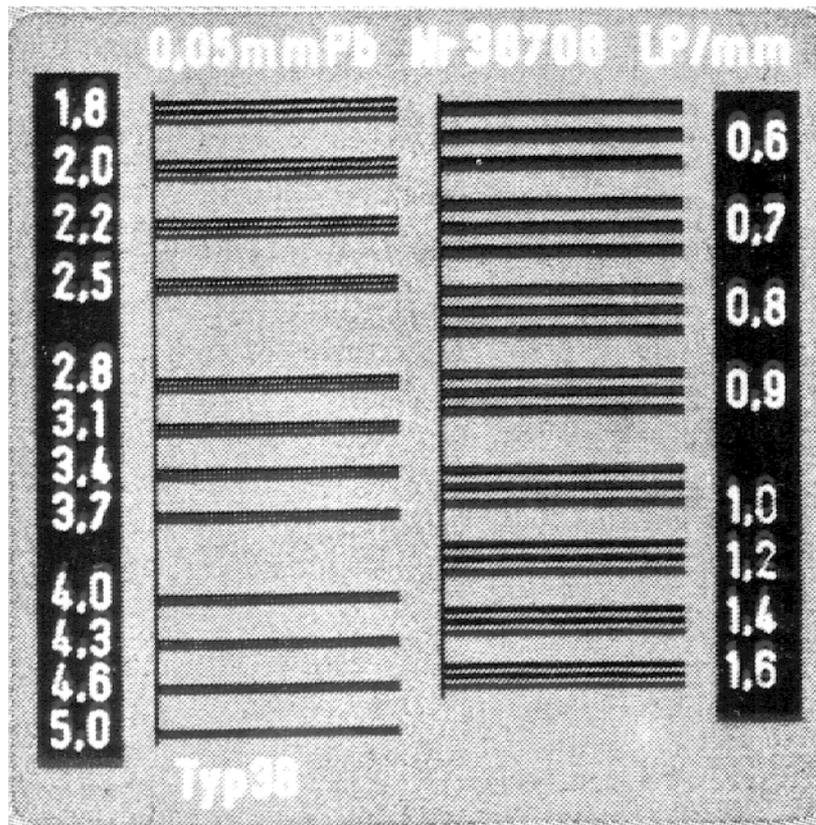
IEC 332/99

Key

- 1 X-RAY TUBE
- 2 DIAPHRAGM (BEAM LIMITING DEVICE)
- 3 Additional attenuating layer/PHANTOM (25 mm aluminium, sometimes 1,5 mm copper added)
- 4 Beam limiting TEST DEVICE with markings for field geometry (LIGHT FIELD – structural elements)
- 5 LINE PAIR RESOLUTION TEST DEVICE
- 6 PATIENT SUPPORT
- 7 ANTI-SCATTER GRID
- 8 IMAGE RECEPTOR PLANE (RADIOGRAPHIC FILM cassette or X-RAY IMAGE INTENSIFIER housing)
- 9 Contrast details
- 10 Offset for clarity
- r_T FOCAL SPOT to PATIENT SUPPORT distance
- r_B FOCAL SPOT to IMAGE RECEPTOR PLANE distance

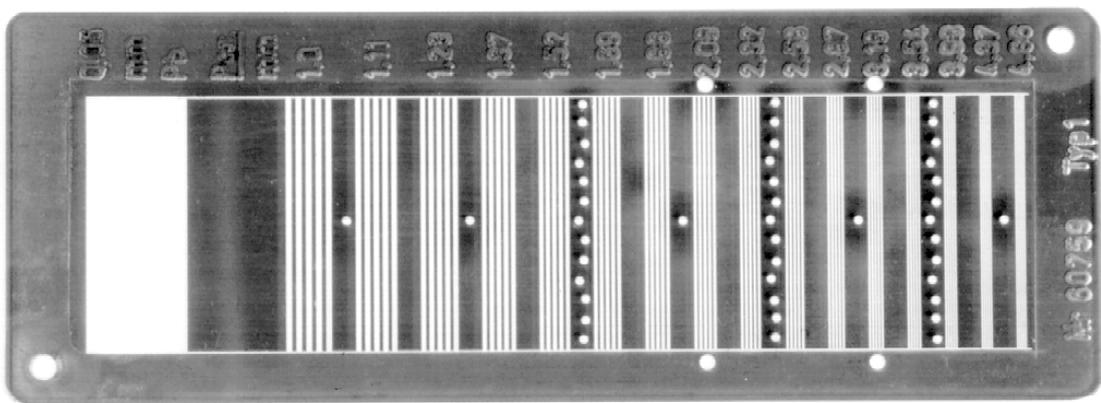
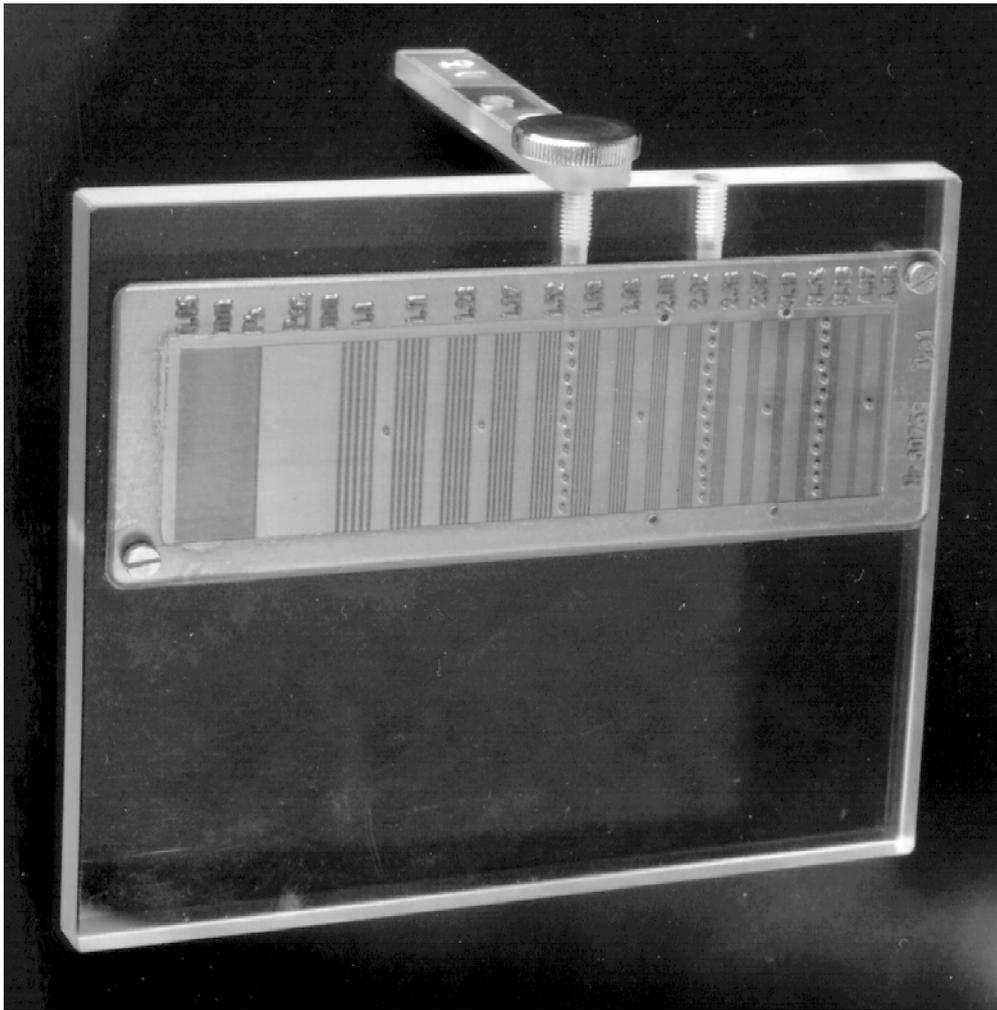
NOTE – For explanations, see table B.1.

Figure 2 – Measuring arrangement for RADIOGRAPHY and RADIOSCOPY EQUIPMENT to test geometry and resolutions



IEC 333/99

Figure 3 – LINE PAIR RESOLUTION TEST DEVICE



IEC 334/99

Figure 4 – TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE

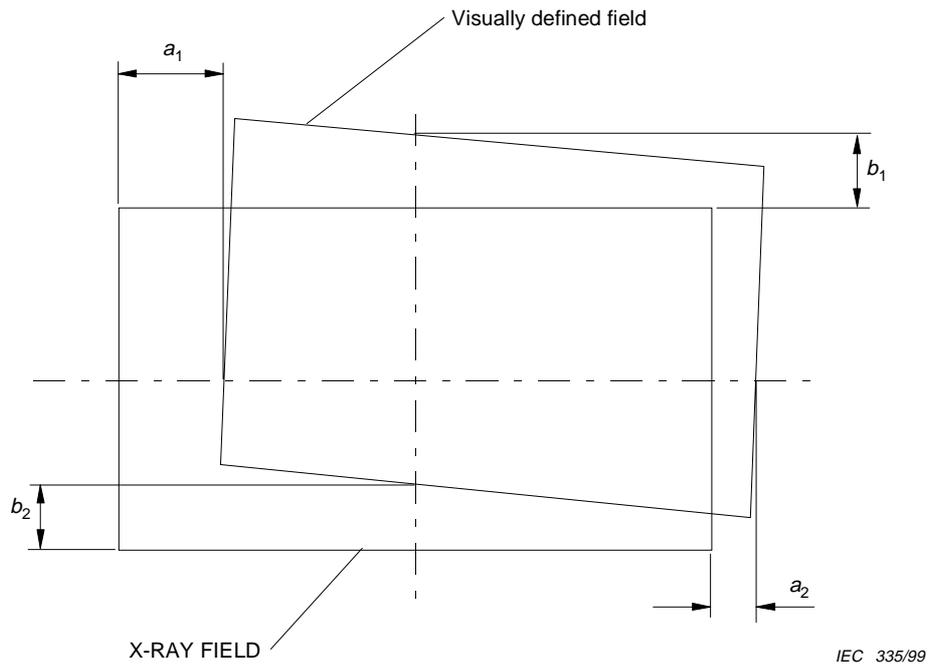


Figure 5 – Discrepancies in visual indication of the X-RAY FIELD

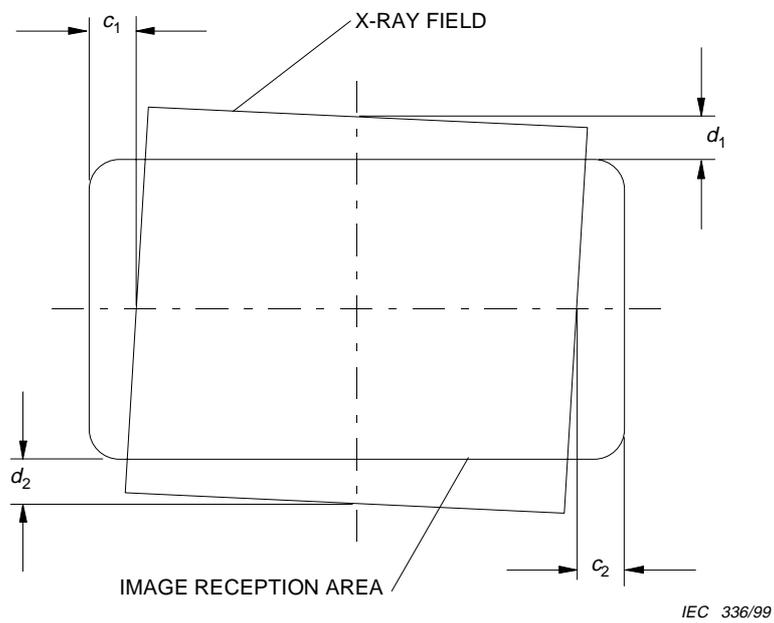


Figure 6 – Discrepancies in covering the IMAGE RECEPTION AREA

Annex A
(normative)

Terminology – Index of defined terms

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Term without definition	rm-...-
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X-RAY TUBE VOLTAGE	rm-36-02

Annex B (informative)

Test parameters, symbols and units

Table B.1 – Test parameters, symbols and units

Measured quantities	Symbol	Unit
X-RAY TUBE VOLTAGE	U	kV
X-RAY TUBE CURRENT	I	mA
LOADING TIME	t	s, ms
CURRENT TIME PRODUCT	Q	mAs
TRANSMISSION KERMA (TRANSMISSION KERMA RATE)	K_T (\dot{K}_T)	mGy (mGy/s)
X-RAY IMAGE RECEPTOR AIR KERMA (AIR KERMA RATE)	K_B (\dot{K}_B)	mGy (mGy/s)
TRANSMISSION KERMA index	TK_i	(mGy m ²)/mAs
RADIATION OUTPUT	K_R	mGy/mAs
ATTENUATION RATIO	T_R	–
FILTER value (QUALITY EQUIVALENT FILTRATION)	–	mm Al
LINE PAIR RESOLUTION	R	lp/mm
LOW CONTRAST RESOLUTION		–
Optical density	D	–
Distance from FOCAL SPOT to PATIENT SUPPORT respectively SPOTFILM DEVICE at undertable tube systems	r_T	cm
FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	r_B	cm

Annex C (informative)

Examples of low contrast TEST DEVICES

Example 1

UAB low contrast TEST DEVICE (UAB = University of Alabama at Birmingham, USA)

These TEST DEVICES consist of a copper attenuator plate, for example 2 mm, and two 6,1 mm thick aluminium target plates. Each target plate has a gradation of 1,1 cm diameter circular ATTENUATION differences or holes. The outer dimensions of the target plates are 15,2 cm × 15,2 cm. The plates have three rows of three targets with a contrast increment of about 3 % between adjacent targets in the same row. The two outer rows have increasing target contrast increments while the middle row is offset and has decreasing increments. To achieve 0,5 % LOW CONTRAST RESOLUTION, two test plates are used, one with targets ranging in contrast from about 1 % to 9 % (integer TEST DEVICE) and the second with targets ranging from about 0,5 % to 8,5 % (half integer TEST DEVICE), both with 1 % contrast increments.

With these test objects, an AUTOMATIC EXPOSURE RATE CONTROL of radioscopic units may be driven to comparable values, for example about 70 kV to 80 kV. The LOW CONTRAST RESOLUTION can be determined to a 0,5 % precision by selecting the lower value obtained by the sequential use of the two plates. According to the reference, the measured threshold contrast is independent of X-RAY TUBE VOLTAGE.

For more detailed information, see reference [12] in annex E.

Example 2

DIN low contrast TEST DEVICE

In this PHANTOM, which consists of attenuating layers (for example 25 mm aluminium) and structural elements (for example a polymethyl-methacrylate (PMMA) layer with structural elements), one contrast step is integrated. Using this PHANTOM and an X-RAY TUBE VOLTAGE of about 70 kV under radioscopic conditions this contrast step shall produce an X-ray contrast of 4 %.

For more detailed information, see reference [4] in annex E.

Example 3

Leeds X-ray test objects for RADIOGRAPHY/RADIOSCOPY systems

A special test object for low contrast sensitivity consists of a circular array of 19 low contrast disks, each 11 mm in diameter. The X-ray contrast ranges from 0,16 to 0,007. The outer dimensions are 180 mm in diameter.

For more detailed information, see reference [6] in annex E.

Example 4

IEC low contrast TEST DEVICE

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

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 these steps can be measured on a RADIOGRAPHIC FILM, but the TEST DEVICE should be so constructed as to give these values theoretically with the RADIATION QUALITIES used in normal medical practice.

For more detailed information, see IEC 61223-2-9 (to be published).

C.1 Reference document

IEC 61223-2-9, — *Evaluation and routine testing in medical imaging departments – Part 2-9: Constancy tests – Equipment for indirect radioscopy and indirect radiography* (to be published)

Annex D
(informative)

**Examples of requirements (accuracy, tolerances, discrepancies)
according to actual IEC standards or state of the art**

Concerning 5.2 X-RAY TUBE VOLTAGE

See subclause 50.102.1 of IEC 60601-2-7: $\pm 10\%$.

Concerning 5.3 TOTAL FILTRATION

See IEC 60601-1-3:

subclause 29.201.5: QUALITY EQUIVALENT FILTRATION: not less than 2,5 mm aluminium

or

table 204 – HALF-VALUE LAYERS in X-RAY EQUIPMENT: 2,3 mm aluminium at 80 kV.

Concerning 5.4 FOCAL SPOT of the X-RAY TUBE

Table D.1 – Typical values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES (see IEC 60336)

NOMINAL FOCAL SPOT VALUE <i>f</i>	FOCAL SPOT dimensions Permissible values mm	
	Width	Length
0,25	0,25 0,38	0,25 0,38
0,3	0,30 0,45	0,45 0,65
0,4	0,40 0,60	0,60 0,85
0,5	0,50 0,75	0,70 1,10
0,6	0,60 0,90	0,90 1,30
0,7	0,70 1,10	1,00 1,50
0,8	0,80 1,20	1,10 1,60
0,9	0,90 1,30	1,30 1,80
1,0	1,00 1,40	1,40 2,00
1,1	1,10 1,50	1,60 2,20
1,2	1,20 1,70	1,70 2,40
1,3	1,30 1,80	1,90 2,60
1,4	1,40 1,90	2,00 2,80
1,5	1,50 2,00	2,10 3,00
1,6	1,60 2,10	2,30 3,10
1,7	1,70 2,20	2,40 3,20

Concerning 5.5 Limitation and indication of the extent of the X-RAY BEAM

See 29.202.8, 29.202.9 and 29.203.4 of IEC 60601-1-3.

Table D.2 – Values for the discrepancy parameters X, Y and Z according to IEC 60601-1-3

Discrepancy parameter	Discrepancy value (see note 1) %
X	2
Y (see note 2)	3
Z (see note 3)	4
<p>NOTE 1 – Requirements for discrepancy values according to IEC 60601-1-3.</p> <p>NOTE 2 – Along each of the two major axes of the IMAGE RECEPTION AREA, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall not exceed 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTOR PLANE is normal to the REFERENCE AXIS.</p> <p>NOTE 3 – The sum of the discrepancies on both axes shall not exceed 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.</p>	

Concerning 5.6 Linearity and reproducibility of TRANSMISSION KERMA

See IEC 60601-2-7:

subclause 50.101 Linearity $\pm 20\%$

subclause 50.101.1 Reproducibility $\pm 10\%$

Table D.3 – Typical values for the TRANSMISSION KERMA index TK_i

TRANSMISSION KERMA index * TK_i $\mu\text{Gy m}^2 (\text{mAs})^{-1}$	X-RAY TUBE VOLTAGE kV			
	Direct voltage, 12-pulse, 12-pulse equivalent or converter technique	6-pulse with smoothing or 6-pulse equivalent	6-pulse without smoothing	2-pulse
0,6	62	63	67	71
0,9	66	68	72	76
1,3	71	73	77	82
1,6	74	75	81	86
2,0	77	79	85	91
2,3	79	81	88	94
2,8	82	85	92	99
3,5	87	89	97	104
<p>* Measured behind an attenuating layer of 25 mm aluminium, referred to a FOCAL SPOT to RADIATION DETECTOR distance of 100 cm and free from SCATTERED RADIATION with a tungsten-rhenium compound ANODE and TOTAL FILTRATION of 2,5 mm aluminium QUALITY EQUIVALENT FILTRATION.</p> <p>For more detailed information, see reference [4] in annex E.</p>				

Concerning 5.7 ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR

Table D.4 – Typical values for the ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR

Material (components of X-RAY EQUIPMENT)	ATTENUATION RATIO *
PATIENT SUPPORT	1,25
Front panel of FILM CHANGER	1,25
ANTI-SCATTER GRID	1,43
AUTOMATIC EXPOSURE CONTROL (AEC) detector	1,11
* Measuring parameters are 80 kV and an attenuating layer of 25 mm aluminium. For more detailed information, see reference [4] in annex E.	

Concerning 5.8 AUTOMATIC EXPOSURE CONTROL (AEC)

Concerning 5.8.2 Performance of the AEC

In IEC 60601-2-7 the following value is included:

Constancy of optical density for variation of
X-RAY TUBE VOLTAGE and object thickness: $|D| < 0,2$

NOTE – This density tolerance refers to a mean gradient of about 3,0

Concerning 5.10 AIR KERMA area product indicator

See 6.4 of IEC 60580: Total accuracy $\pm 25 \%$.

Concerning 6.8 AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for RADIOSCOPY

No standard values exist.

Practical values according to the described
test method are: $0,2 \mu\text{Gy/s}$ to $1,0 \mu\text{Gy/s}$

Concerning 6.10 AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

No standard values exist.

Practical values according to the described test methods are:

INDIRECT RADIOGRAPHY systems with
25 cm X-RAY IMAGE INTENSIFIER: $< 2,0 \mu\text{Gy}$
CINERADIOGRAPHY per image: $< 0,2 \mu\text{Gy}$

Concerning 6.12 LINE PAIR RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)

No standard values exist.

Practical values according to the described test method b) (with attenuating layer) are:

RADIOSCOPY

with 25 cm X-RAY IMAGE INTENSIFIER: 0,9 lp/mm to 1,4 lp/mm

with 45 cm X-RAY IMAGE INTENSIFIER: 0,5 lp/mm to 0,8 lp/mm

(depending on the video bandwidth)

INDIRECT RADIOGRAPHY, 25 cm X-RAY IMAGE INTENSIFIER: 2,0 lp/mm

CINERADIOGRAPHY per image, 25 cm X-RAY IMAGE INTENSIFIER: 1,6 lp/mm

(Values are valid within the central two-thirds of the NOMINAL ENTRANCE FIELD SIZE diameter of the X-RAY IMAGE INTENSIFIER, LINE PAIR TEST DEVICE close to the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER.)

Concerning 6.13 LOW CONTRAST RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY (excluding digital systems)

No standard values exist.

Practical values depend on the specified test methods.

Concerning 7.1 Requirements

No standard values exist.

Practical values according to the described test methods are:

Tomographic movement figures:	see specifications.
Height indication:	the deviation between the light indicator for the tomographic plane and the displayed layer should not be more than ± 5 mm.
Minimum LINE PAIR RESOLUTION:	1,8 lp/mm.

Annex E (informative)

Bibliography

- [1] Bronder, Th., Jakschik, J., and DGMP-Arbeitskreis
A Proposed Performance test of X-Ray radiographic equipment for quality assurance in diagnostic radiology, PTB-MM-3/DGMP-Bericht Nr 3, 1985
A Proposed Performance test of X-ray fluoroscopic equipment for quality assurance in diagnostic radiology, PTB-MM-4/DGMP-Bericht Nr 4, 1987
 Physikalische Technische Bundesanstalt, Germany, DGMP-und PTB-Bericht, Deutsche Gesellschaft für Medizinische Physik e.V.
- [2] Drexler, G., Eriskat, H., Schibilla,: Criteria and Methods for Quality Assurance in Medical X-Ray Diagnosis, Scientific Seminar, Udine, Italy, 1984, H.
British Journal of Radiology, Supplement No.18, British Institute of Radiology, London 1985
- [3] DIN 6868 Part 1: *Image quality assurance in X-ray departments; General*.
 Beuth Verlag GmbH, Burggrafenstrasse 6, 10787 Berlin, Germany
- [4] DIN 6868 Part 50: *Image quality assurance in X-ray departments; Acceptance testing for radiography, radioscopy and film processing*.
 Beuth Verlag GmbH, Burggrafenstrasse 6, 10787 Berlin, Germany
 Translation available by ©Technical Help to Exporters, British Standards Institution, Linford Wood, Milton Keynes, MK14 6LE
- [5] Gray, J.E., Winkler, N.T., Stears, J. and Frank, E.D.: *Quality Control in Diagnostic Imaging*, University Park Press, Baltimore, 1983
- [6] Hospital Physicists' Association 1980, *Measurement of the Performance Characteristics of Diagnostic X-Ray Systems Used in Medicine*
Part 1: X-Ray Tubes and Generators
Part 2: X-Ray Image Intensifier Television Systems
 TGR 32, (HPA, 47 Belgrave Square, London), (now IPEMB, 4 Camleshon Road, York YO2 1PE)
- [7] MDD Evaluation Report (MEDICAL DEVICES DIRECTORATE) Number MDD/94/07:
The Testing of X-Ray Image Intensifier-Television Systems, 4th Edition of a DH Working Group report, Department of Health, medical devices directorate, (MDD/DEP), 14 Russell Square, London, (now Medical Devices Agency, Hannibal House, Elephant & Castle, London SE1)
- [8] Moores, B.M., Henshaw, E.T., Watkinson, S.A., Percy, B.J.:
Practical guide to quality assurance in medical imaging
- [9] Stender, H.-S., Stieve, F.-E.: *Praxis der Qualitätskontrolle in der Röntgendiagnostik*, Gustav Fischer Verlag, Stuttgart-New York, 1986
- [10] *Quality Assurance in Diagnostic Radiology*
 A Guide prepared following a workshop held in Neuherberg (Germany) Oct 1980, World Health Organization, Geneva (Switzerland) 1982
- [11] Quality Control and Radiation Protection of the Patient in Diagnostic Radiology and Nuclear Medicine; Proceedings of a workshop, Grado, Italy, 1993; *Radiation Protection Dosimetry* **57** Nos. 1 – 4, 1995

- [12] Wagner A.J., Barnes, G.T., and WU, Xizeng: Assessing fluoroscopic contrast resolution: A practical and quantitative test tool; *Medical Physics* **18** (5), Sept/Oct 1991
- [13] B.M. Moores, F.E. Stieve, H. Eriscat and H. Schibilla: *Technical and Physical Parameters for Quality Assurance in Medical Diagnostic Radiology, Tolerances, Limiting Values and Appropriate Measuring Methods*; British Institute of Radiology, BIR Report 18, London, 1989
- [14] *European guidelines on quality criteria for diagnostic radiographic images*, EUR 16260, Feb 1996
- [15] ICRU Report 54: *Medical imaging – The assessment of image quality*, International Commission on Radiation Units and measurements, USA, 1996
- [16] NCRP Report No. 99: *Quality Assurance for Diagnostic Imaging Equipment*, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814, USA

See also annex B, Bibliography in IEC 61223-1.



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