INTERNATIONAL STANDARD

IEC 61223-3-4

First edition
2000-03

Evaluation and routine testing in medical imaging departments –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

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

Partie 3-4: Essais d'acceptation – Performance d'imagerie des appareils de radiographie dentaire

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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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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

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 specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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International Standard IEC 61223-3-4 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/393/FDIS	62B/402/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.

Annex A forms an integral part of this standard.

Annexes B and C 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 type;

– *test specifications: italic type;*

– TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN IEC 61223-1 OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX A: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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- withdrawn;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

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

INTRODUCTION

This part of IEC 61223 is part of a series of International Standards which gives methods of acceptance testing and constancy testing for subsystems and systems (for example, diagnostic X-RAY EQUIPMENT) including film processing.

Some provisions or statements in this standard require additional information. Such information is presented in annex B. 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 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

1 Scope and object

1.1 Scope

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

This standard applies to the performance of the ACCEPTANCE TEST on dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR and dental X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR (for example, dental panoramic X-RAY EQUIPMENT or cephalometric X-RAY).

This standard applies to dental film and digital image acquisition and processing.

1.2 Object

This standard defines

a) the essential parameters which describe the performance of the above-mentioned dental X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;

b) methods of testing and 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 in the installation procedure may be used as part of the acceptance testing.

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

This standard does not in itself specify tolerances for the parameters under investigation. Neither is it intended to 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 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 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 60417-2:1998, *Graphical symbols for use on equipment – Part 2: Symbol originals*

IEC 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

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

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2-28: 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 in accordance with their definitions in IEC 60601-1, in IEC 60788, in IEC 61223-1, or in this standard.

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.

An index of defined terms used in this standard is given in annex A.

3.3 Defined terms

For the purpose of this part of IEC 61223, the following additional definitions apply.

3.3.1
ARTEFACT
apparent structure visible in the image which does not represent a structure within the object.

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 Another term for LINE PAIR RESOLUTION used in literature is spatial resolution.

3.3.3
LOW CONTRAST RESOLUTION
the lowest contrast detail object of a specified object that can be resolved from a 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.

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 purchase contract, in the supplier's brochure or in other standards, for example in the IEC 60601 series.

An inventory of the EQUIPMENT under test, the ACCOMPANYING DOCUMENTS, and the test protocols, shall be compiled before any ACCEPTANCE TESTS are carried out. 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 purchase contract.

The response of non-screen dental X-ray film (NON-SCREEN FILM, rm-32-35) to a visible-light sensitometer does not match its response to X-RADIATION. It is therefore most practicable to assess the performance of a dedicated dental film processing system when EQUIPMENT is available for testing the X-RAY EQUIPMENT. A suitable test procedure is given in annex C.

RADIOGRAPHIC FILMS and film processing are vital parts in the imaging chain. It is the responsibility of the USER to ensure that these components perform in an acceptable way, for example with respect to sensitivity, contrast and absence of ARTEFACTS. A test of the performance of these components shall precede any ACCEPTANCE TEST measurements involving the IRRADIATION of RADIOGRAPHIC FILMS using the dental X-RAY EQUIPMENT.

The performance of the IMAGE DISPLAY DEVICE will affect the measured performance of a digital dental imaging system. Before any ACCEPTANCE TESTS are carried out on the X-RAY EQUIPMENT, the IMAGE DISPLAY DEVICE shall be set up, by following the MANUFACTURER'S instructions and using the MANUFACTURER'S electronic test image, to deliver its specified performance.

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:

– statement of compliance with applicable parts of IEC 60601;
– list of EQUIPMENT or EQUIPMENT parts ordered and the actual delivery list (IEC 60601-1);
– 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 dental X-RAY EQUIPMENT is to be used;
– guidance as to the extent and frequency of maintenance procedures;
– reports on previous tests where applicable;
– data on technical changes.

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,

a) for intra-oral application (see figures 1 and 2);
b) for panoramic application (see figures 3 and 4);
c) for cephalometric application (see figure 5).

The arrangement in figure 1 is indicative only. Not every component is needed in every test.

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 dental X-RAY EQUIPMENT tested, identification of the test equipment used, geometrical set-up, operating characteristics, correction factors and test results of the ASSOCIATED EQUIPMENT (RADIOGRAPHIC FILM, 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 Scope of tests

The following are subject to ACCEPTANCE TESTING:

– identification of dental X-RAY EQUIPMENT;
– check of documents;
– visual and functional tests;
– X-RAY TUBE VOLTAGE;
– TOTAL FILTRATION;
– FOCAL SPOT;
– limitation and alignment of the X-RAY BEAM;
– LINE PAIR RESOLUTION;
– LOW CONTRAST RESOLUTION;
– RADIATION OUTPUT;
– optical density.

4.5 Test equipment including PHANTOMS and TEST DEVICES

4.5.1 General

Measuring equipment used for ACCEPTANCE TESTS shall be certified as calibrated against a national standard or an International Standard where such a standard exists.

The uncertainty of measuring instruments shall be less than the tolerance stated for the MEASURED VALUES.

4.5.2 High-voltage measuring instrument

Wherever practicable, the X-RAY TUBE VOLTAGE should be measured by a radiographic penetrameter.

NOTE If it is necessary to use an electronic high-voltage measuring instrument, the USER should evaluate the significance of any deviation between the INDICATED VALUES and MEASURED VALUES.

In some types of dental X-RAY EQUIPMENT, there is a variation of X-RAY TUBE VOLTAGE at the beginning of the LOADING TIME, which is of no clinical consequence.

Some panoramic equipment is designed so that the X-RAY TUBE VOLTAGE is deliberately varied during the LOADING TIME.

No general guidance can be given as different types of "digital kV meter" respond to different aspects of the voltage/time characteristic.

4.5.3 KERMAMETER

Dental radiography uses X-RAY BEAMS with smaller dimensions, lower energy and lower AIR KERMA RATES than general medical radiography. It shall be ensured that the KERMAMETER used for these tests is suitable for the purpose and calibrated for the energy and KERMARATE in use and that the detector is smaller than the nominated beam dimensions.

4.5.4 PHANTOMS and TEST DEVICES

These TEST DEVICES may consist of structural elements which can be arranged in combination or separately.

The test device shall contain a grid group with a spatial frequency equal to, or higher than, the spatial frequency to be resolved. The following requirements apply:

a) External dimensions

The dimensions of these PHANTOMS shall be at least large enough to intercept the entire RADIATION BEAM for all test conditions applicable:

1) for intra-oral application (see figures 6 and 7);

2) for panoramic application;

3) for cephalometric application.

b) ATTENUATION and hardening

The aluminium PHANTOMS shall be of at least 99,5 % purity (Al 99,5 % according to ISO 2092) and a material thickness of 6 mm ± 0,1 mm (see IEC 61267).

c) TEST DEVICE for LINE PAIR RESOLUTION for digital imaging

Suitable TEST DEVICES may comprise line-group test patterns with a lead thickness of 0,05 mm and grid groups with local frequencies

1) for intra-oral application of 4,0 lp/mm to 8,0 lp/mm

2) for panoramic application of 1,6 lp/mm to 3,0 lp/mm

3) for cephalometric application of 1,6 lp/mm to 3,0 lp/mm

with a gradation of ≤20 % from group to group.

d) TEST DEVICE for LOW CONTRAST RESOLUTION for digital imaging

The TEST DEVICE shall contain one minimal contrast object with a contrast lower or equal to the contrast to be detected. A suitable TEST DEVICE is one with holes in a 0,5 mm Al foil (see figure 7):

1) for intra-oral application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter;

2) for panoramic application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter;

3) for cephalometric application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter.

4.5.5 Lens

A magnifying lens shall be available. A 2,5 × magnification is usually suitable.

4.5.6 Densitometer

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

4.6 Evaluating the test results

Whenever specified limiting values or tolerances are exceeded, verify the results by making at least two additional measurements.

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

5 Test methods for dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR

5.1 Visual and functional tests

5.1.1 Requirements

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

All OPERATOR accessible controls shall be labelled with a graphical symbol, for example according to IEC 60417 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 INSTRUCTIONS FOR USE shall describe comprehensively how the dental 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 dental X-RAY EQUIPMENT, with respect to position, labels and symbols. The INSTRUCTIONS FOR USE shall be in the language that is required locally.

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;*
– *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 TUBE ASSEMBLY;*
– *visual inspection of the INSTRUCTIONS FOR USE (according to IEC 60601-1).*

5.2 *X-RAY TUBE VOLTAGE

5.2.1 Requirement

The MEASURED VALUES for the X-RAY TUBE VOLTAGE shall comply with the INDICATED VALUES within the specified tolerances.

5.2.2 Test methods

The measurements shall be carried out with the arrangement in figure 1. The tests are preferably performed using a non-invasive method.

Place the penetrameter or the detector of the high-voltage measuring instrument in the centre of the PRIMARY RADIATION BEAM at the IMAGE RECEPTOR PLANE.

Make the measurements at the fixed X-RAY TUBE VOLTAGES or at the X-RAY TUBE VOLTAGE normally used.

Compare the MEASURED VALUES of the X-RAY TUBE VOLTAGE with the INDICATED VALUES and the specified tolerances.

5.3 *TOTAL FILTRATION

5.3.1 Requirements

The TOTAL FILTRATION arising from materials in the X-RAY BEAM incident to the PATIENT shall be as specified. The TOTAL FILTRATION is stated as QUALITY EQUIVALENT FILTRATION in thickness of aluminium or other suitable reference material, together with the RADIATION QUALITY used for its determination.

5.3.2 Test method

The compliance with the specification is checked by inspection of the markings on the X-RAY SOURCE ASSEMBLY and by examination of the ACCOMPANYING DOCUMENTS. If this information is not given, the TOTAL FILTRATION is not measured directly but the QUALITY EQUIVALENT FILTRATION is determined according to clauses 3 and 4 of IEC 60522, if necessary (see below).

NOTE This requires measuring the HALF VALUE LAYER under NARROW BEAM CONDITIONS with the dental X-RAY EQUIPMENT operating at fixed values of X-RAY TUBE VOLTAGE and corresponding LOADING FACTORS, and for comparison with the HALF-VALUE LAYER from an X-RAY TUBE with the same TARGET material and TARGET angle.

A simplified measurement may be carried out with the arrangement in figure 1. Measure the first HALF VALUE LAYER with the dental X-RAY EQUIPMENT operating at the fixed X-RAY TUBE VOLTAGE and the CURRENT TIME PRODUCT normally used. This test gives only an approximation of the TOTAL FILTRATION because these test conditions do not comply with IEC 60522. Failure of compliance shown by this modified measurement shall not be used as a reason for non-acceptance of the dental X-RAY EQUIPMENT. It is only valuable as indicating the need for a more rigorous test.

5.4 *FOCAL SPOT of the X-RAY TUBE

5.4.1 Requirements

The ACTUAL FOCAL SPOT dimensions for the stated NOMINAL FOCAL SPOT VALUE shall comply with 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 method of testing.

5.4.2 Test method

The compliance of the ACTUAL FOCAL SPOT dimensions for the stated NOMINAL FOCAL SPOT VALUE with IEC 60336 shall be certified and demonstrated 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. The inspection procedure may be specified in the purchase contract.

5.5 Limitation and alignment of the X-RAY BEAM

5.5.1 Requirements

The accuracy of marked and written indications of the size of the X-RAY FIELD on the EQUIPMENT and the actual size of the X-RAY FIELD shall comply with the tolerances specified.

5.5.2 Test methods

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS. Measure the dimensions of the X-RAY FIELD at the end of the dental BEAM APPLICATOR.

Examine the RADIOGRAM and evaluate whether or not the REFERENCE AXIS and the BEAM LIMITING DEVICE are aligned correctly.

NOTE For a circular beam-limiting device and dental beam applicator, there will be a change in the optical density across the image of the radiogram when the reference axis is not parallel to the dental beam applicator. Also when the beam-limiting device is not aligned correctly with the reference axis at the radiation head, the image on the radiogram will appear oval in shape.

Make the measurements with a RADIOGRAPHIC FILM (dental film) in a lightproof envelope or a RADIOGRAPHIC CASSETTE or a suitable X-RAY IMAGE RECEPTOR arranged at the end of the DENTAL BEAM APPLICATOR and the arrangement in figure 1.

Produce RADIOGRAMS under these conditions with LOADING FACTORS so as to give on the processed RADIOGRAPHIC FILM an optical density D in the range 0,5 to 2,0.

Measure the X-RAY FIELD size and note any discrepancies from the specified value. If there is no film-processing available, it is possible to test the limitation of the X-ray beam with the digital sensor by taking four exposures at 90° rotation.

The discrepancies between the measured X-RAY FIELD size and the specified value shall be within the specified tolerances.

5.6 FOCAL SPOT TO SKIN DISTANCE

5.6.1 Requirement

The accuracy of marked and written indications of the distance from the indicated FOCAL SPOT to the end of the DENTAL BEAM APPLICATOR shall comply with the tolerances specified.

5.6.2 Test methods

Compliance is checked by inspection of the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

Measure the distance from the FOCAL SPOT to the end of the DENTAL BEAM APPLICATOR.

The discrepancies between the measured distance and the indications shall be within the specified tolerances.

5.7 *Reproducibility of RADIATION OUTPUT

5.7.1 Requirements

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

5.7.2 Test method

Make the measurements with the arrangement in figure 1. The detector of the KERMAMETER is placed in the PRIMARY RADIATION BEAM close to the DENTAL BEAM APPLICATOR. Ensure that the beam completely covers the detector. Measure the reproducibility of the RADIATION OUTPUT at the specified X-RAY TUBE VOLTAGES and the CURRENT TIME PRODUCT normally used preferably 3 mAs to 5 mAs.

NOTE Dental X-RAY EQUIPMENT is designed for use at very low duty cycles. Sufficient cooling time should be allowed between test IRRADIATIONS for the system to remain within its operating temperature limits, and to ensure that the results represent the intended performance of the EQUIPMENT. If the MANUFACTURER's instructions do not specify a duty cycle, restrict the LOADING TIME to less than 0,5 s per minute.

The suggested LOADING TIME has been chosen so that initial transient effects, and the effects of heating during the IRRADIATION, should not affect the result.

Make at least five measurements of AIR KERMA at the specific combination of CURRENT TIME PRODUCT and X-RAY TUBE VOLTAGE.

Calculate the mean value and the coefficient of variation and check whether all individual measurements are in the specified range.

Compare the results of these calculations with the specified tolerances.

5.8 LINE PAIR RESOLUTION

a) Without digital imaging acquisition or processing parts

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 geometry or limited by the characteristic of the film type used.

b) With digital imaging acquisition or processing parts

With the arrangement of figure 2, vary the IRRADIATION TIME setting to obtain an IRRADIATION in the detector plane that is recommended by the MANUFACTURER to produce the maximum dynamic range in the image.

Use this IRRADIATION TIME setting to produce an image of the TEST DEVICE shown in figure 7.

Compare the LINE PAIR RESOLUTION with the specified value.

5.9 LOW CONTRAST RESOLUTION

a) Without digital imaging acquisition or processing parts

Not applicable.

b) With digital imaging acquisition or processing parts

The test image generated in 5.8 b) includes low contrast steps. Note the value of the lowest contrast step that is discernible from its background, and compare this with the specified value.

6 Test methods for dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR

6.1 Visual and functional tests

The requirements and tests given in 5.1 are applicable.

6.2 X-RAY TUBE VOLTAGE

6.2.1 Requirements

The requirements given in 5.2 are applicable.

6.2.2 Test method

Either a penetrameter or the detector of a suitable high-voltage measuring instrument may be attached to the secondary diaphragm or to the digital sensor.

6.3 TOTAL FILTRATION

6.3.1 Requirements

The TOTAL FILTRATION arising from materials in the X-RAY BEAM incident to the PATIENT shall be as specified. The TOTAL FILTRATION is stated as QUALITY EQUIVALENT FILTRATION in thickness of aluminium or other suitable reference material, together with the RADIATION QUALITY used for its determination.

6.3.2 Test method

The compliance with the specification is checked by inspection of the markings on the X-RAY SOURCE ASSEMBLY and by examination of the ACCOMPANYING DOCUMENTS. If this information is not given, the TOTAL FILTRATION is not measured directly, but the QUALITY EQUIVALENT FILTRATION is determined according to clauses 3 and 4 of IEC 60522, if necessary (see below).

NOTE This requires measuring the HALF VALUE LAYER under NARROW BEAM CONDITIONS with the dental X-RAY EQUIPMENT operating at values of X-RAY TUBE VOLTAGE and corresponding LOADING FACTORS, and for comparison with the HALF-VALUE LAYER from an X-RAY TUBE with the same TARGET material and TARGET angle.

A simplified measurement may be carried out with the arrangement in figure 1. Measure the first HALF VALUE LAYER with the dental X-RAY EQUIPMENT operating at the X-RAY TUBE VOLTAGE and the CURRENT TIME PRODUCT normally used. This test gives only an approximation of the TOTAL FILTRATION because these test conditions do not comply with IEC 60522. Failure of compliance shown by this modified measurement shall not be used as a reason for non-acceptance of the dental X-RAY EQUIPMENT. It is only valuable as indicating the need for a more rigorous test.

6.4 FOCAL SPOT of the X-RAY TUBE

The requirements and test methods of 5.4 are applicable.

6.5 Limitation and alignment of the X-RAY BEAM

6.5.1 Requirements

The accuracy of marked and written indications of the size of the X-RAY FIELD on the dental X-RAY EQUIPMENT and the actual size of the X-RAY FIELD and the alignment shall comply with the tolerances specified.

6.5.2 Test methods

One applicable test procedure is listed below.

Compliance is checked by inspection of the dental X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS. Measure the dimensions of the slot in the secondary DIAPHRAGM. Make the measurement with RADIOGRAPHIC FILM in lightproof envelopes or a suitable X-RAY IMAGE RECEPTOR placed both in front of and behind the secondary DIAPHRAGM with the arrangement in figure 3. Ensure that the X-RAY IMAGE RECEPTORS extend several centimetres above and below the slot in the secondary DIAPHRAGM and that there will be no interference with the rotational movement of the dental panoramic X-RAY EQUIPMENT. Produce RADIOGRAMS using suitable LOADING FACTORS so as to give on the processed film an optical density D in the range 0,5 to 2,0.

Measure the X-RAY FIELD size on the film from in front of the secondary DIAPHRAGM and note the discrepancies from the specified value. The discrepancies between the measured X-RAY FIELD size and the specified value shall be within the specified tolerances.

Measure the X-RAY FIELD size on the film from behind the secondary DIAPHRAGM and note the discrepancies from the specified value and the dimensions of the slot in the secondary DIAPHRAGM. Examine the film and ensure that the alignment of the X-RAY BEAM and the slot in the secondary DIAPHRAGM are satisfactory. The discrepancies between the measured X-RAY FIELD size and the specified value shall be within the specified tolerances.

6.6 FOCAL SPOT TO SKIN DISTANCE

No requirements for this test.

6.7 Reproducibility of RADIATION OUTPUT

If the RADIATION OUTPUT is possible in both clockwise and counter-clockwise directions then the reproducibility needs to be measured using both directions.

6.7.1 Requirements

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

6.7.2 Test method

Make the measurements with the arrangement in figure 3. The detector of the KERMAMETER is placed in the PRIMARY RADIATION BEAM close to the secondary diaphragm. Measure the reproducibility of the RADIATION OUTPUT at the specified X-RAY TUBE VOLTAGES and the CURRENT TIME PRODUCT normally used.

Make at least five measurements of AIR KERMA at the specific combination of CURRENT TIME PRODUCT and X-RAY TUBE VOLTAGE.

Calculate the mean value and the coefficient of variation and check whether all individual measurements are in the specified range.

Compare the results of these calculations with the specified tolerances.

6.8 LINE PAIR RESOLUTION

a) Without digital imaging acquisition or processing parts

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 geometry or limited by the characteristics of the film type used.

b) With digital imaging acquisition or processing parts

With the arrangement in figure 4 and with an additional attenuating layer of 0,8 mm Cu in the X-RAY BEAM to simulate the ATTENUATION of the skull, vary the X-RAY TUBE VOLTAGE setting to obtain an IRRADIATION in the detector plane that is recommended by the MANUFACTURER to produce the maximum dynamic range in the image.

Use this X-RAY TUBE VOLTAGE setting to produce an image of the TEST DEVICE shown in figure 7.

Compare the LINE PAIR RESOLUTION with the specified value.

6.9 LOW CONTRAST RESOLUTION

a) Without digital imaging acquisition or processing parts

Not applicable.

b) With digital imaging acquisition or processing parts

The test image generated in 6.8 b) includes low contrast steps. Note the value of the lowest contrast step that is discernible from its background, and compare this with the specified value.

6.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS

6.10.1 Requirement

RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS shall be lightproof and free from ARTEFACTS and defects.

6.10.2 Test method

The cassettes shall undergo a visual and performance test. INTENSIFYING SCREENS shall be checked for defects and ARTEFACTS. All cassettes shall be tested for light impermeability.

6.11 Image homogeneity

The X-RAY TUBE during the IRRADIATION rotation shall not undulate or hesitate.

6.11.1 Test procedure

Make RADIOGRAMS using the arrangement in figure 3 using a TEST DEVICE which produces parallel horizontal stripes. Use LOADING FACTORS so as to give on the processed RADIOGRAPHIC FILM an optical density D in the range 0,5 to 2,0.

6.11.2 Evaluation of the RADIOGRAM

a) *Vertical undulations of the stripes shall not be apparent to the unaided eye.*

b) *Vertical striations caused by backlash and variations in speed or rotation may not affect the diagnostic value of the image. They commonly occur at one extreme (usually at the start) of the image. Striations that are near the centre of the image are very dense, or have sharp boundaries, indicate a mechanical problem that should be investigated before the EQUIPMENT is accepted.*

6.12 Indicators for patients' positioning

Check that the indicators are correctly adjusted according to the MANUFACTURER's test procedure.

6.13 Panoramic layer

6.13.1 Requirements

DENTAL PANORAMIC TOMOGRAPHY is a technique used to produce a RADIOGRAM of the dental arch. The shape and amplitude of the arch varies between children and adults, therefore it is necessary to test the effectiveness of the panoramic dental X-RAY EQUIPMENT to produce on one RADIOGRAM an acceptable image of the different curved surfaces.

6.13.2 Test method

Use the test device delivered by the manufacturer for this purpose.

7 Test methods for dental cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR

7.1 Visual and functional tests

The requirements and test methods given in 5.1 are applicable.

7.2 X-RAY TUBE VOLTAGE

The requirements and test methods given in 6.2 are applicable.

7.3 TOTAL FILTRATION

The requirements and test methods given in 6.3 are applicable.

7.4 FOCAL SPOT of the X-RAY TUBE

The requirements and test methods given in 5.4 are applicable.

7.5 Limitation and alignment of the X-RAY BEAM

7.5.1 Requirements

The field of the X-RAY BEAM shall be equal to, or smaller than, the size of the image receptor in the image receptor plane.

7.5.2 Test methods

Position a FILM cassette or the digital image receptor in the image receptor holder at the appropriate position. If there are no applicable test procedures from the manufacturer, cover the diaphragm at the X-RAY TUBE with an attenuation layer of 0,8 mm Cu. Irradiate the image receptor using LOADING FACTORS appropriate to cephalometry. The acceptance criteria is satisfied if all edges of the image are visible on the radiogram. One applicable procedure to test the beam alignment is using a fluorescent screen.

7.6 FOCAL SPOT TO SKIN DISTANCE

No requirements for this test.

7.7 Reproducibility of RADIATION OUTPUT

The requirements and test methods given in 6.7 are applicable.

7.8 LINE PAIR RESOLUTION

The requirements and test methods given in 5.8 are applicable.

7.9 LOW CONTRAST RESOLUTION

The requirements and test methods given in 5.9 are applicable.

7.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS

The requirements and test methods given in 6.10 are applicable.

7.10.1 Test method

The cassettes shall undergo a visual and performance test. INTENSIFYING SCREENS shall be checked for defects and ARTEFACTS. All cassettes shall be tested for light impermeability.

8 Test report and statement of compliance

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

– description of the dental 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 and processing data;
– test results;
– statement whether the tested dental X-RAY EQUIPMENT complies with the specified parameters, including the location, the date and the names of the persons performing the tests.

The results recorded in the test report shall indicate whether the X-RAY EQUIPMENT tested fulfils the requirements of this standard.

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

The test report shall be headed:

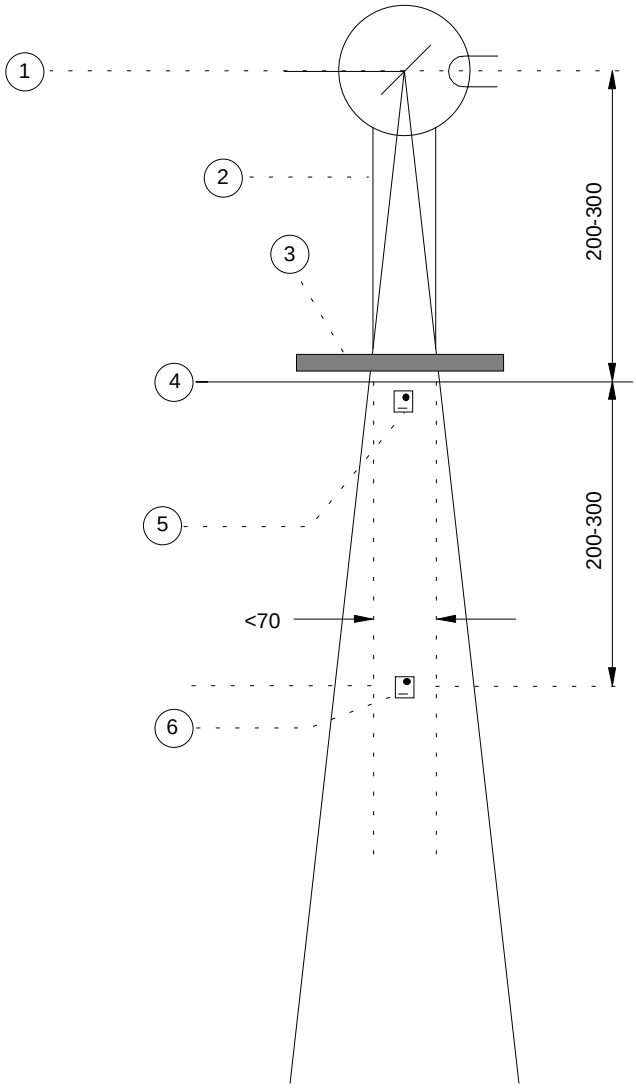
Test report
on acceptance test of dental X-ray equipment
according to IEC 61223-3-4: **)

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

Imaging performance of dental X-ray equipment, ...*), complies with IEC 61223-3-4: ... **)

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

**) Year of publication of this standard.

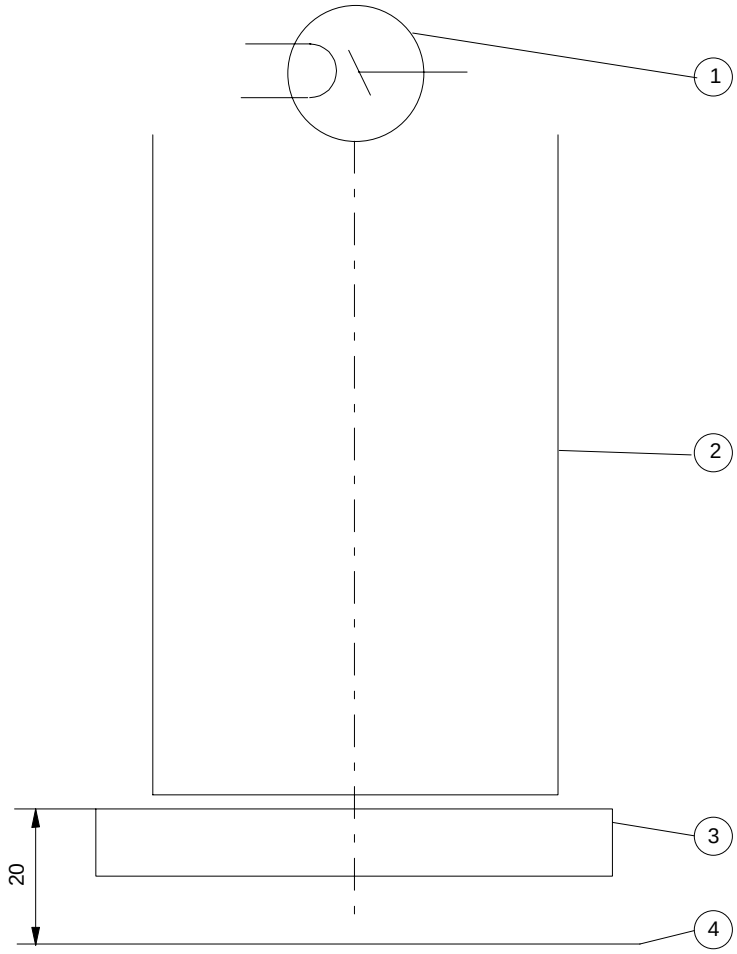


Dimensions in millimetres

Key

1 FOCAL SPOT
2 Dental beam applicator
3 Half-value layer measuring device
4 Image receptor plane
5 Kermameter detector for reproducibility
6 Kermameter detector for HVL

Figure 1 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution



Dimensions in millimetres

Key

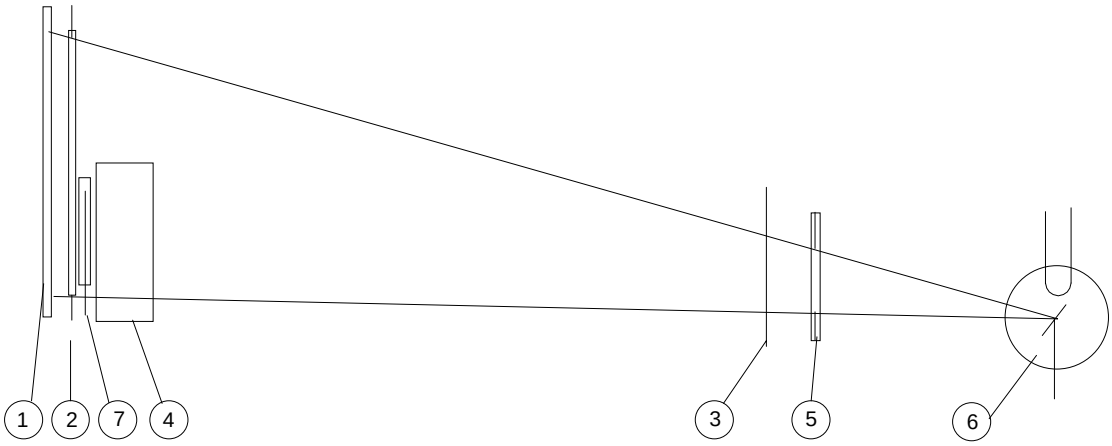
1 X-RAY TUBE

2 DENTAL BEAM APPLICATOR

3 Additional attenuating layer (6 mm aluminium)
or dental PHANTOM (see figure 6)
or dental PHANTOM for digital image acquisition (see figure 7)

4 X-RAY IMAGE RECEPTOR or KERMAMETER

Figure 2 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

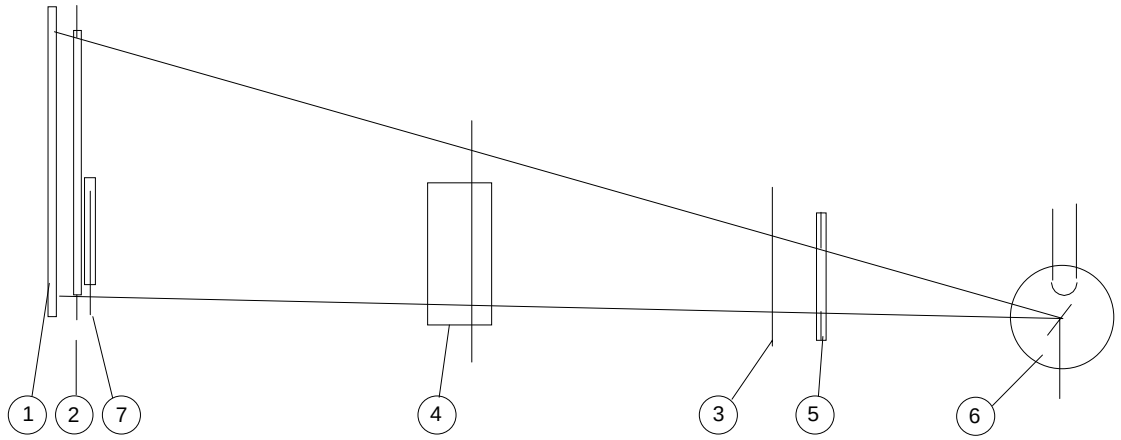


IEC 302/2000

Key

1 Film-screen system
2 Secondary DIAPHRAGM
3 Additional attenuating layer/PHANTOM (for example 0,8 mm copper)
4 Dental PHANTOM (see figure 6)
5 Primary DIAPHRAGM
6 X-RAY TUBE
7 KERMAMETER detector

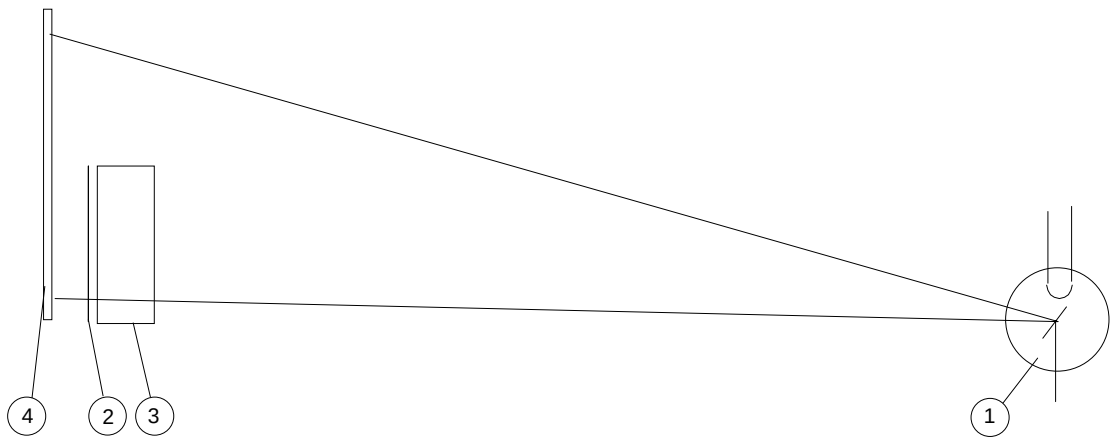
Figure 3 – Dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution



Key

1 Digital sensor
2 Secondary DIAPHRAGM
3 Additional attenuating layer/PHANTOM (for example 0,8 mm copper)
4 Dental PHANTOM for digital acquisition (see figure 7)
or TEST DEVICES for panoramic layers (see figure 8)
5 Primary DIAPHRAGM
6 X-RAY TUBE
7 KERMAMETER detector

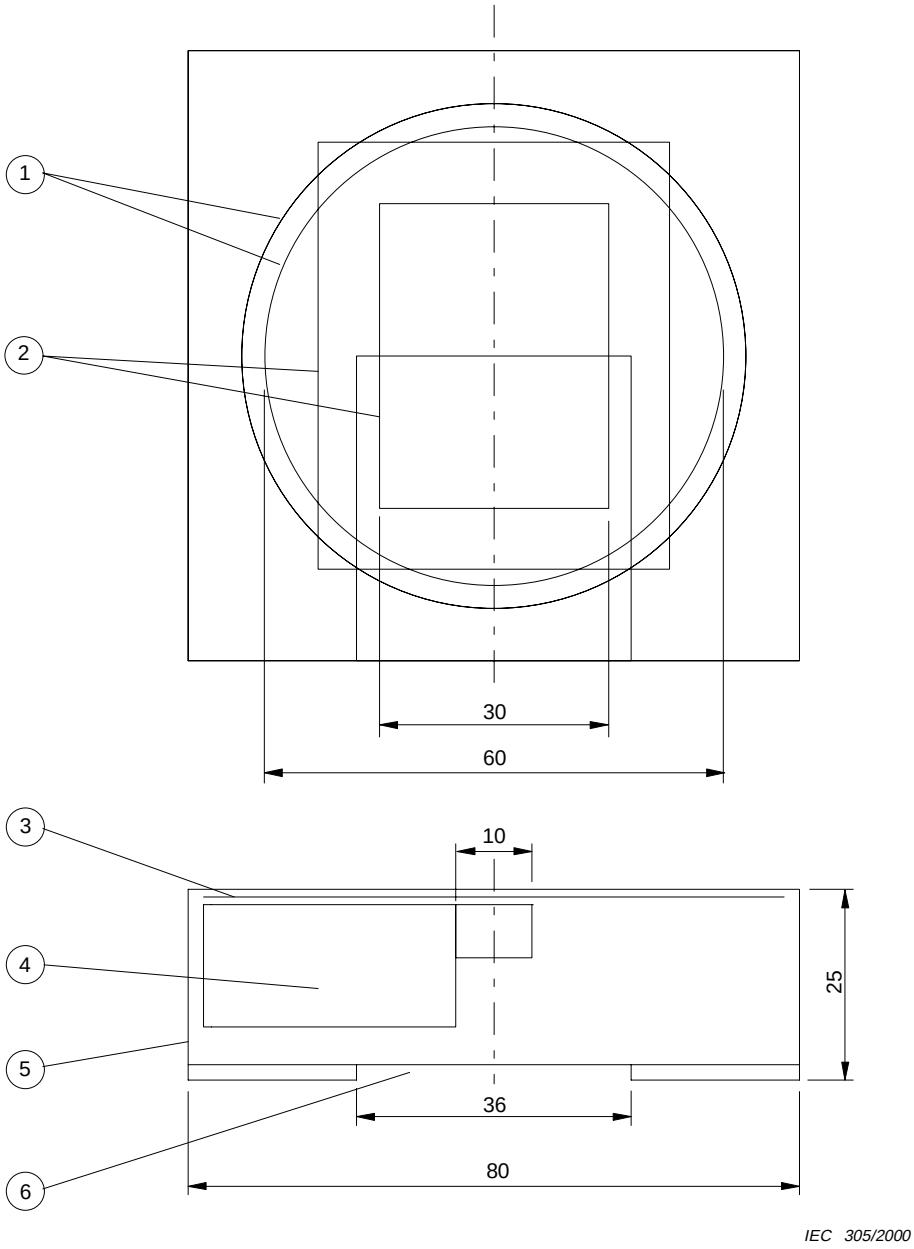
Figure 4 – Example of a dental panoramic X-RAY EQUIPMENT with extra-oral digital X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA, resolution, image homogeneity and panoramic layer



Key

1 X-RAY TUBE
2 Additional attenuating layer/PHANTOM (0,8 mm copper)
3 Dental PHANTOM (see figure 6)
4 Film-screen system, digital sensor or KERMAMETER

Figure 5 – Example of a cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

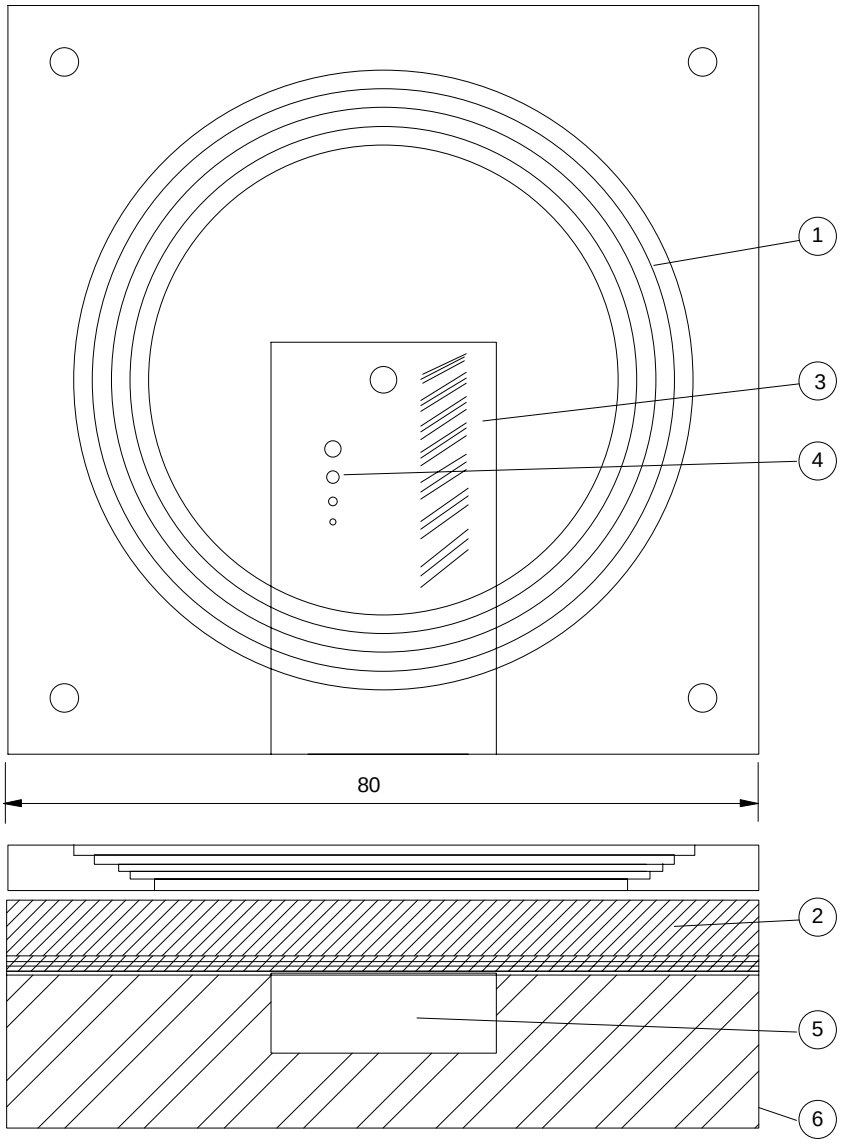


Dimensions in millimetres

Key

1 Centring mark for DENTAL BEAM APPLICATOR
2 Centring mark for DENTAL BEAM APPLICATOR
3 Copper foil 0,3 mm
4 Polytetrafluorethylen steps (first step = 8 mm, second step = 16 mm)
5 Phantom housing
6 Recess for dental film

Figure 6 – Dental PHANTOM (example)



IEC 306/2000

Dimensions in millimetres

Key

1 Centring mark for DENTAL BEAM APPLICATOR

2 Additional attenuating layer/PHANTOM (6,0 mm aluminium)

3 TEST DEVICE for LINE PAIR RESOLUTION
(4 lp/mm up to 8 lp/mm for intra-oral application)
(1,6 lp/mm up to 3 lp/mm for panoramic or cephalometric application)

4 TEST DEVICE for LOW CONTRAST RESOLUTION

5 Space for positioning of the digital sensor (dimensions in accordance to the sensor geometry)

6 Basic PHANTOM

Figure 7 – Dental PHANTOM for digital image acquisition or processing parts (example)

Annex A
(normative)

Terminology – Index of defined terms

Annex B
(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 50.103.1 of IEC 60601-2-7 Ed. 2: ±10 %.

Concerning 5.3 *TOTAL FILTRATION*

See IEC 60601-1-3:

Subclause 29.201.5: QUALITY EQUIVALENT FILTRATION — not less than 1,5 mm Al, or
Table 204 – HALF VALUE LAYERS in X-RAY EQUIPMENT — 1,8 mm Al at 60 kV.

Concerning 5.4 *FOCAL SPOT of the X-RAY TUBE*

Table B.1 – Typical values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES (see table 5 of IEC 60336)

NOMINAL FOCAL SPOT VALUE	FOCAL SPOT dimensions Permissible values mm	
F	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 5.7 *Reproducibility of RADIATION OUTPUT*

See IEC 60601-2-7 Ed.2:

Subclause 50.102.1 Reproducibility:

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS.

Reference documents

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – Section 3: Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

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

Annex C
(informative)

ACCEPTANCE TEST for processing of non-screen dental X-ray films (non-screen film)

Use the configuration of figure 2. Set a LOADING TIME that gives an IRRADIATION in the X-RAY IMAGE RECEPTOR plane which the film MANUFACTURER recommends to produce a specified optical density.

NOTE The TEST DEVICE is designed so that the setting for "adult molars" should be appropriate.

Remove the KERMAMETER detector, insert a dental X-ray film in the same position, and repeat the IRRADIATION.

Compare the optical density of the processed film with the specified value.

NOTE If a calibrated sensitometer is not available, a similar procedure may be used to test the processing of screen-type films used for panoramic dental RADIOGRAPHY. If the "intra-oral" X-RAY EQUIPMENT operates at an X-RAY TUBE VOLTAGE greater than 60 kV, it may be used to irradiate the panoramic cassette.

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[2] DIN 6868 Part 1: *Image quality assurance in X-ray departments; General;* Beuth Verlag GmbH, Burggrafenstrasse 6, 10787 Berlin, Germany

[3] DIN 6868 Part 51: *Image quality assurance in X-ray departments; Acceptance testing of dental radiographic equipment;* Beuth Verlag GmbH, Burggrafenstrasse 6, 10787 Berlin, Germany

[4] Gray, J.E., Winkler, N.T., Stears, J. and Frank, E.D.: *Quality Control in Diagnostic Imaging,* University Park Press, Baltimore, 1983

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[8] Quality Control and Radiation Protection in Diagnostic Radiology and Nuclear Medicine; Proceedings of a workshop, Grado, Italy, 1993; *Radiation Protection Dosimetry,* Vol. 57 Nos. 1, 4, 1995

[9] IEC 60601-2-32: 1994, *Medical electrical equipment – Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment*

[10] ISO 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results*

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

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