INTERNATIONAL STANDARD

IEC 61223-2-7

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

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

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

Partie 2-7: Essais de constance – Appareils de radiographie dentaire intra-orale à l'exclusion des appareils dentaires panoramiques

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-7: Constancy tests – Equipment for intra-oral dental radiography excluding dental panoramic 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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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-2-7 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/370/FDIS	62B/382/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, C and D are for information only.

This standard forms part 2-7 of IEC 61223, which will include the following parts:

Part 1: General aspects

Part 2-1: Constancy tests – Film processors

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

Part 2-3: Constancy tests – Darkroom safelight conditions

Part 2-4: Constancy tests – Hard copy cameras

Part 2-5: Constancy tests – Image display devices

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

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

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

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

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

The committee has decided that this publication remains valid until 2003.

At this date, in accordance with the committee's decision, the publication will be

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

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

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to RADIOLOGICAL INSTALLATIONS with diagnostic X-ray systems designed to expose intra-orally placed radiographic films or electronic equipment (sensors), but excluding dental panoramic equipment.

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

This part of IEC 61223 is designed to be applicable to equipment for intra-oral dental radiography without digital imaging devices.

1.2 Object

This standard describes a method to check, in terms of functional parameters, that the constancy of the quality of images produced by intra-oral dental X-RAY EQUIPMENT is maintained after installation, calibration and adjustment have been carried out.

This standard defines

– the functional parameters, which describe the performance of X-RAY EQUIPMENT for intra-oral dental radiographic examination;

– methods of checking, whether variations in measured functional parameters meet ESTABLISHED CRITERIA, in order to ensure that the conditions for adequate imaging performance are maintained, while unnecessary IRRADIATION of the PATIENT is avoided.

The methods are based upon assessment of radiographic information using an appropriate TEST DEVICE.

The purpose of the methods is

– to establish a reference level of performance following an ACCEPTANCE TEST and an initial CONSTANCY TEST;

– to detect and verify any significant variation in functional parameters which may then require corrective actions.

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

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

This standard is not intended to deal with:

– aspects of mechanical or electrical safety;
– checks of the effectiveness of the direct means of protection against X-RADIATION;
– optimization of imaging performance.

In general, the use of a densitometer to check the optical densities is recommended. However, for simplicity, in this standard only the use of a simple TEST DEVICE and the visual comparison of a UNIFORM CONSTANCY TEST FILM with a reference INITIAL CONSTANCY TEST FILM is regarded as sufficient.

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

2 Normative references

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

IEC 60788:1984, *Medical radiology – Terminology*

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

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

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

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

IEC 61223-2-4:1994, *Evaluation and routine testing in medical imaging departments – Part 2-4: Constancy tests – Hard copy cameras*

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

3 Terminology

3.1 Degree of requirements

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

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

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

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

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

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

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788 or other IEC publications or in 3.3 of this standard; see annex A. Where a defined term is used as a qualifier in another defined or undefined term it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a derived term without definition. Test specifications are in italics.

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

3.3 Definitions

3.3.1
INITIAL CONSTANCY TEST FILM
film containing the RADIOGRAM of the step wedge part of the TEST DEVICE

3.3.2
UNIFORM CONSTANCY TEST FILM
film containing the RADIOGRAM of the homogeneous FILTER part of the TEST DEVICE

3.3.3
INITIAL REFERENCE FILM
film with an optical density resulting from processing a non-irradiated film under specific conditions prepared during the initial CONSTANCY TEST

3.3.4
NON-IRRADIATED CONSTANCY TEST FILM
film with an optical density resulting from processing a non-irradiated film under specific conditions

4 General aspects of CONSTANCY TESTS

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

In particular, attention shall be paid to darkroom safelight conditions, according to IEC 61223-2-3, and proper film processing, according to IEC 61223-2-1 (see clause 2). When using FILM ILLUMINATORS special attention should also be paid to lighting conditions. This clause does not apply for systems with sensors to digital imaging.

Careful consideration shall be given to the operating and test conditions, under which the equipment is checked, taking into account the recommended environmental conditions of operation.

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

The TEST DEVICE is described in 5.1.2.

In CONSTANCY TESTS of X-RAY EQUIPMENT for intra-oral dental RADIOGRAPHY, TEST DEVICES are used

– to simulate ATTENUATION and FILTRATION of the X-RAY BEAM;
– to provide structures, which are needed to permit evaluation of measured functional parameters;
– to position these materials or objects in the X-RAY BEAM in a reproducible fashion.

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

4.1 General conditions affecting test procedures

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

– to record and reproduce all significant settings of the X-RAY EQUIPMENT and ACCESSORIES each time a test is undertaken and to check that the same equipment, components and ACCESSORIES are being used;
– to consider the influence of environmental changes on the results. Variations in mains voltage and, when IMAGE DISPLAY DEVICE images are evaluated, room lighting conditions are of special importance;
– to use RADIOGRAPHIC FILM which is handled, processed and viewed in accordance with the standards and technical reports referenced in clause 2 or by using a system for digital imaging to follow the MANUFACTURER'S instructions;
– to check the performance of the test instrumentation regularly, particularly when any significant variation in the X-RAY EQUIPMENT is suspected.

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

4.2 Establishment of BASELINE VALUES

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

A new BASELINE VALUE shall be established when any change occurs in any component which may cause a significant variation in the result of the CONSTANCY TEST. If the change involves a component of the X-RAY EQUIPMENT or ACCESSORIES, the new CONSTANCY TEST shall be carried out after an ACCEPTANCE TEST has indicated that the performance is satisfactory. For the initial CONSTANCY TEST, see 5.3.2.1.

4.3 Frequency of CONSTANCY TESTS

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

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

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

4.4 Identification of equipment, instrumentation and test conditions

The following conditions shall be specified in connection with the use of TEST DEVICES:

Interchangeable components of X-RAY EQUIPMENT such as

– ADDED FILTER(S);
– BEAM LIMITING DEVICE (cone);
– RADIOGRAPHIC FILM type and emulsion number or the specification of the used sensor system;
– FILM PROCESSOR, if required;
– HARD COPY CAMERA, if required;

together with items of test instrumentation, and settings of all selectable values of functional parameters used in the test such as

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
– peak value of the X-RAY TUBE VOLTAGE;
– mean value of the X-RAY TUBE CURRENT;
– IRRADIATION TIME;

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

NOTE – It is essential that any RADIOGRAPHIC FILM used in the test is of the same type as the film used for the CONSTANCY TEST for the FILM PROCESSOR. When using sensor systems, it is essential to use the same sensor for the tests.

4.5 Measured functional parameters

In order to detect significant changes in equipment performance, the optical density is measured.

Careful consideration shall be given to the appropriate choice of standard test conditions, under which the equipment is checked, including environmental parameters.

5 Performance tests

5.1 Test equipment

5.1.1 Test film/sensor system

Each type of X-RAY EQUIPMENT used in dental practice shall be tested with the type of RADIOGRAPHIC FILM, SCREEN-FILM system(s) and the sensor system, as appropriate, as used in dental practice.

5.1.2 TEST DEVICE

Tests are carried out with a TEST DEVICE (see figure 1) that contains:

– a holder for the film with a step wedge for producing the INITIAL CONSTANCY TEST FILM, or a holder for fixing the sensor;

– a holder for the film with a homogeneous FILTER for producing the UNIFORM CONSTANCY TEST FILM or a uniform image produced by the sensor system;

– an open slot to enable the density of both films to be compared.

If digital imaging is applied, the equipment shall be capable of displaying two images adjacent to each other.

NOTE – If digital imaging is applied means should be provided for digital read-out of the grey values of the displayed image(s) at arbitrary positions.

5.1.2.1 Step wedge

NOTE – The step wedge part of the TEST DEVICE is used to produce a film containing the RADIOGRAM with density steps. This film containing the RADIOGRAM, further named INITIAL CONSTANCY TEST FILM, is produced once during the initial CONSTANCY TEST. The purpose is to give a reference scale for the determination of the optical densities of the films containing the RADIOGRAMS produced during the following CONSTANCY TESTS.

The step wedge part of the TEST DEVICE shall be made of an absorbing material, for example aluminium, so that a reasonable range of optical densities of the INITIAL CONSTANCY TEST FILM is produced. The film is exposed using the same X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME as used for a typical PATIENT investigation. The difference in optical densities between adjacent steps shall be between 0,10 and 0,20 on the INITIAL CONSTANCY TEST FILM.

NOTE – The following table provides guidance for the possible thickness of aluminium of a purity better than 99 % and the approximate optical densities on the INITIAL CONSTANCY TEST FILM. Values may differ depending on the LOADING FACTORS actually used.

Aluminium thickness mm	Optical density
2,5	1,50
3,5	1,30
4,75	1,10
7,0	0,90
9,0	0,70

5.1.2.2 FILTER

The TEST DEVICE shall also have a homogeneous FILTER of the same thickness and material as the middle step of the step wedge, for example 4,75 mm of aluminium. This FILTER is used to expose the UNIFORM CONSTANCY TEST FILM for CONSTANCY TESTS and should be approximately 4 cm × 5 cm in size.

The TEST DEVICE shall be provided with an alignment aid to ensure that the current BEAM APPLICATOR types and X-RAY SOURCE ASSEMBLY can be positioned reproducibly with respect to the TEST DEVICE. Imprinted circles or rectangles as well as a centre marking shall be provided to facilitate correct positioning of the BEAM APPLICATOR applied.

5.1.3 INITIAL REFERENCE FILM

NOTE – The INITIAL REFERENCE FILM is a fresh non-irradiated film processed under specific conditions. Thus the FILM BASE PLUS FOG DENSITY is at the minimum obtainable. Comparison of the optical density of a current non-irradiated film processed under the current film processing conditions with those of this INITIAL REFERENCE FILM gives information about the status of film storage and film processing.

INITIAL REFERENCE FILMS are not used for digital imaging systems with a sensor.

If INITIAL REFERENCE FILMS are not available from the film MANUFACTURER then it will be necessary for the USER to produce one. The INITIAL REFERENCE FILM is a fresh non-irradiated film of the same type used in clinical practice which is processed in developer not older than two days in a FILM PROCESSOR; see IEC 61223-2-1.

NOTE – The optical density of this INITIAL REFERENCE FILM should be not more than 0,25. This value represents the current state of the art. In the case of major improvement of films or film processing, a smaller value may be considered.

5.2 Test procedures

5.2.1 Check of film processing

NOTE – This subclause is not applicable if using sensor-supported digital imaging systems.

Before starting the CONSTANCY TESTS the proper working of the film processing equipment should be verified according to IEC 61223-2-1.

NOTE 1 – Performing the test described in 5.3.1 may serve as a quick check of the FILM PROCESSOR performance.

NOTE 2 – The developer deteriorates with time due to oxidation of the developer solution. In order to avoid working with developer solution with decreased activity, the use of a developer not older than eight days is recommended.

5.2.2 Check of RADIATION FIELD size

For checking the RADIATION FIELD size, the INITIAL CONSTANCY TEST FILM shall be produced with the RADIATION BEAM AXIS perpendicular to the ENTRANCE SURFACE of the TEST DEVICE. The tip of the BEAM APPLICATOR shall touch the TEST DEVICE.

For the measuring arrangement, see figure 1.

5.3 Data evaluation

5.3.1 FILM BASE PLUS FOG DENSITY

The NON-IRRADIATED CONSTANCY TEST FILM is placed in the upper portion of the open area of the TEST DEVICE, and the INITIAL REFERENCE FILM is placed in the lower portion, so that both films are adjacent to, and in contact with (but not overlapping), each other.

FILM BASE PLUS FOG DENSITY is established by visual comparison of the NON-IRRADIATED TEST FILM with the INITIAL REFERENCE FILM.

5.3.2 Optical density

5.3.2.1 Initial CONSTANCY TEST

An INITIAL CONSTANCY TEST FILM is obtained using the step wedge portion of the TEST DEVICE. A film is exposed using the same X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME as used for a typical PATIENT investigation.

This INITIAL CONSTANCY TEST FILM is processed at conditions (for example time, temperature) specified by the MANUFACTURER and in a developer not older than eight days.

Using a sensor-supported digital imaging system, steps similar to those mentioned above shall be applied on the images of the sensor.

5.3.2.2 CONSTANCY TEST

For CONSTANCY TESTS, a UNIFORM CONSTANCY TEST FILM is produced by applying the homogeneous FILTER part of the TEST DEVICE (see 5.1.2.2) under the same conditions as used to produce the INITIAL CONSTANCY TEST FILM.

This UNIFORM CONSTANCY TEST FILM is processed using the same processing conditions (for example time and temperature) as used to produce the INITIAL CONSTANCY TEST FILM.

The UNIFORM CONSTANCY TEST FILM is placed in the upper portion of the open area of the TEST DEVICE, and the INITIAL CONSTANCY TEST FILM is placed in the lower portion, so that both films are adjacent to, and in contact with (but not overlapping) each other. The number of the step, which matches the density of the UNIFORM CONSTANCY TEST FILM is recorded.

Using a digital imaging system the same procedure applies as in the initial CONSTANCY TEST. The processing and viewing conditions shall not be changed.

5.4 Criteria to be applied

5.4.1 FILM BASE PLUS FOG DENSITY

The optical density of the NON-IRRADIATED CONSTANCY TEST FILM shall not visibly deviate from the optical density of the INITIAL REFERENCE FILM.

NOTE – If a densitometer is used, the deviation in optical density should not be more than 0,02.

5.4.2 Optical density

The optical density of the UNIFORM CONSTANCY TEST FILM, obtained during constancy testing, shall not deviate by more than one step from the centre step of the INITIAL CONSTANCY TEST FILM.

5.5 Action to be taken

If the equipment fails to meet the ESTABLISHED CRITERIA the first step should be to determine the possible faults and corrective actions (see annex D). More general hints are given in annex C.

Graphical records of test results according to annex B may show any trend with time in the values of the functional parameters and will indicate when any of these values is tending to exceed the ESTABLISHED CRITERIA as given in 5.4.

If such a trend occurs or the value of any functional parameter fails to meet the ESTABLISHED CRITERIA as given in 5.4, checks should be carried out as described in annex C of this standard.

6 Statement of compliance

The test report shall be headed:

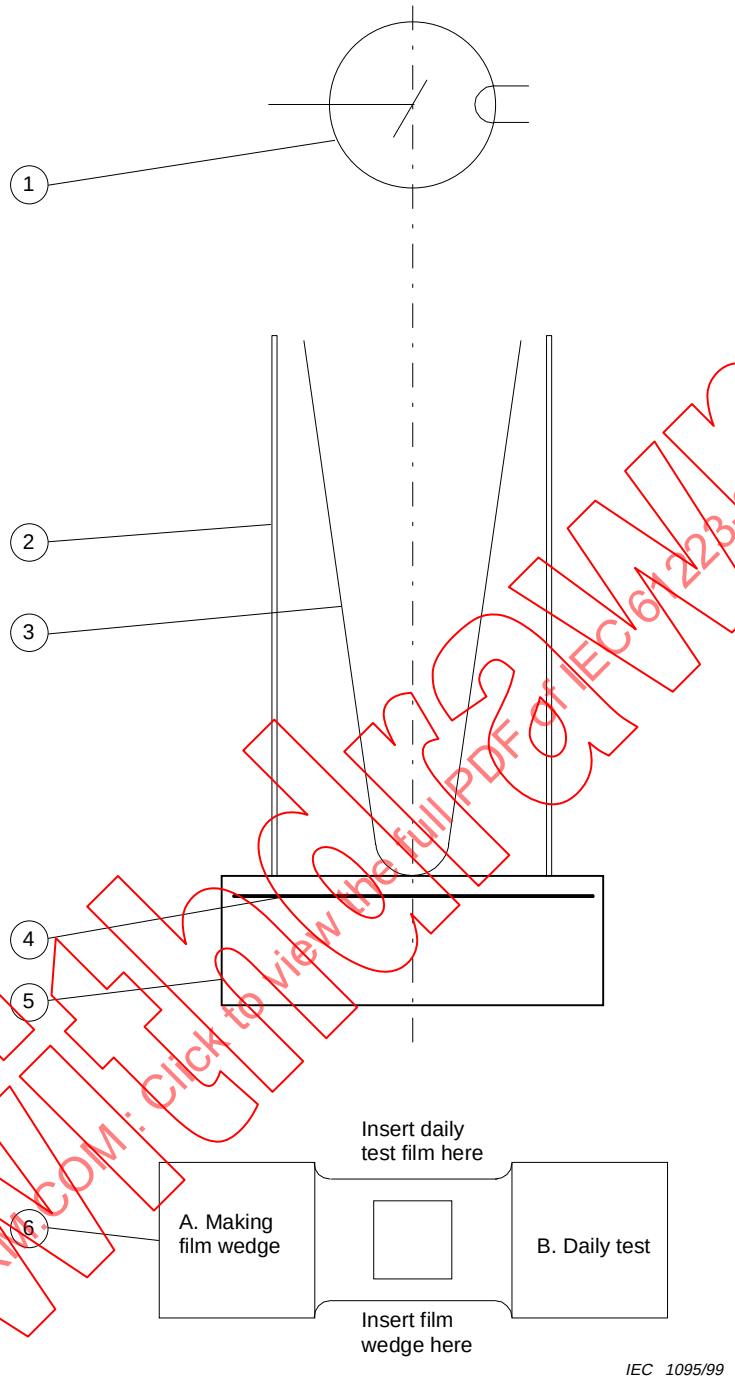
Test report
on constancy tests of equipment for intra-oral dental radiography
excluding dental panoramic equipment
according to IEC 61223-2-7:1999

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

The equipment for intra-oral dental radiography,.... *), complies with IEC 61223-2-7:1999).

———————

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



Key

1 X-RAY TUBE
2 Circular cone
3 Tip cone
4 Filter (4,75 mm aluminium)
5 Housing to fix part A or B of the TEST DEVICE
6 TEST DEVICE

Figure 1 – Measuring arrangement for intra-oral dental RADIOGRAPHY

Annex A
(normative)

Terminology – Index of defined terms

Annex B
(informative)

Example of a form for the standardized test report

Test report
on constancy tests of equipment for intra-oral dental radiography
excluding dental panoramic equipment
according to IEC 61223-2-7:1999)

Identifications

Person performing test	Identification:
X-RAY EQUIPMENT	Identification:
– X-RAY SOURCE ASSEMBLY	Identification:
– time switch	Identification:
– BEAM APPLICATOR	Identification:
– sensor-supported digital imaging system	Identification:
Non-X-RAY EQUIPMENT	
– darkroom used	Identification:
	yes ☐ no ☐
– film processing equipment	Identification:
– developer:	
• type	Identification:
• date of preparation	Date:
• temperature	Value:
• time of processing	Time:
– RADIOGRAPHIC FILM:	
• supplier	Identification:
• type	Identification:
• emulsion number	Number:
• date of first use	Date:
– SCREEN-FILM combination	Identification:
– sensor, if used	Identification:
– densitometer, if used	Identification:
TEST DEVICE used	Identification:

History of tests

– most recent test on darkroom safelight conditions (not applicable using digital imaging equipment)	Date:
– most recent test on film processing equipment (not applicable using digital imaging equipment)	Date:
– most recent initial CONSTANCY TEST	Date:
– previous CONSTANCY TEST	Date: