

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

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For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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CONTENTS

	Page
FOREWORD	3
Clause	
1 Scope and object	5
1.1 Scope	5
1.2 Object.....	5
2 Normative references.....	6
3 Terminology.....	7
3.1 Degree of requirements	7
3.2 Use of terms	7
3.3 Definitions	7
4 General aspects of CONSTANCY TESTS.....	8
4.1 General conditions affecting test procedures	8
4.2 Establishment of BASELINE VALUES.....	9
4.3 Frequency of CONSTANCY TESTS.....	9
4.4 Identification of equipment, instrumentation and test conditions	9
4.5 Measured functional parameters	10
5 Performance tests.....	10
5.1 Test equipment.....	10
5.2 Test procedures.....	11
5.3 Data evaluation.....	11
5.4 Criteria to be applied	12
5.5 Action to be taken.....	12
6 Statement of compliance.....	13
Annex A (normative) Terminology – Index of defined terms.....	15
Annex B (informative) Example of a form for the standardized test report.....	17
Annex C (informative) Guidance on action to be taken	19
Annex D (informative) Possible faults and corrective actions	20
Figure 1 – Measuring arrangement for intra-oral dental RADIOGRAPHY	14

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.
- 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 specifications, 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.
- 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).

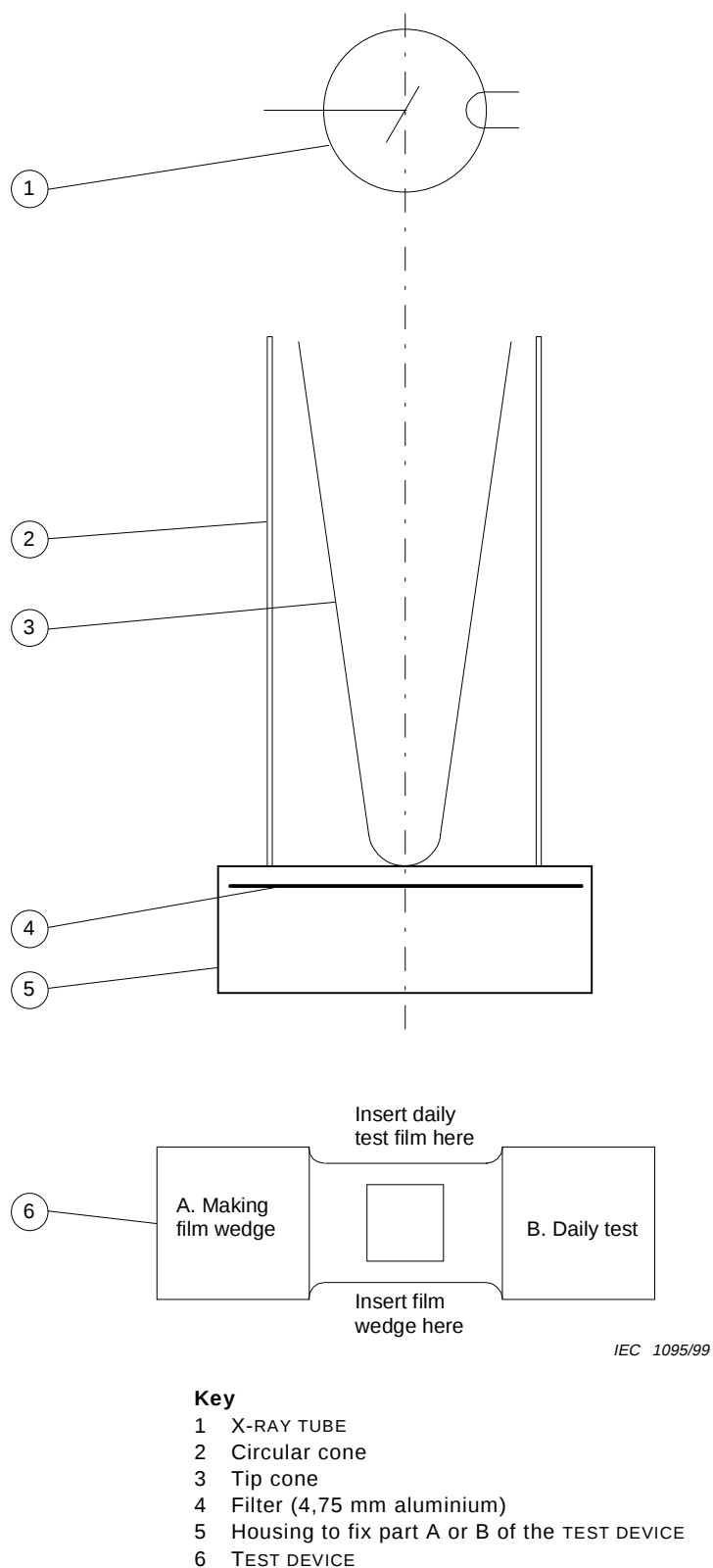


Figure 1 – Measuring arrangement for intra-oral dental RADIOGRAPHY

Annex A (normative)

Terminology – Index of defined terms

IEC 60788	rm-..-
Name of unit in the International System SI	rm-..-.*
Derived term without definition	rm-..-..+
Term without definition	rm-..-..-
Name of earlier unit	rm-..-..
Shortened term	rm-..-..s
Clause 3 of IEC 61223-1	AG-3...
Clause 3 of IEC 61223-2-XY	XY-3...
ACCEPTANCE TEST	AG-3.2.4
ACCESSORY	rm-83-06
ACCOMPANYING DOCUMENTS	rm-82-01
ADDED FILTER	rm-35-02
ATTENUATION	rm-12-08
BASELINE VALUE	AG-3.2.7
BEAM APPLICATOR	rm-37-30
BEAM LIMITING DEVICE	rm-37-28
CONSTANCY TEST	AG-3.2.6
ENTRANCE SURFACE	rm-37-17
ESTABLISHED CRITERIA	AG-3.2.8
FILM BASE PLUS FOG DENSITY	1-3.2.2
FILM ILLUMINATOR	2-3.2.1
FILM PROCESSOR	1-3.2.1
FILTER	rm-35-01
FILTRATION	rm-12-11
FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	rm-37-13
HARD COPY CAMERA	4-3.3.1
HIGH-VOLTAGE GENERATOR	rm-21-01
IMAGE DISPLAY DEVICE	5-3.3.1
INITIAL CONSTANCY TEST FILM	7-3.3.1
INITIAL REFERENCE FILM	7-3.3.3
INSTRUCTIONS FOR USE	rm-82-02
IONIZING RADIATION	rm-11-02
IRRADIATION	rm-12-09

LOADING FACTOR	rm-36-01
MANUFACTURER.....	rm-85-03-
NON-IRRADIATED CONSTANCY TEST FILM.....	7-3.3.4
PATIENT	rm-62-03
QUALITY ASSURANCE PROGRAMME	AG-3.2.2
RADIATION BEAM AXIS	rm-37-06
RADIATION FIELD	rm-37-07
RADIOGRAM	rm-32-02
RADIOGRAPHIC FILM	rm-32-32
RADIOGRAPHY	rm-41-06
RADIOLOGICAL INSTALLATION	rm-20-24
SCREEN FILM	rm-32-36
Specific	rm-74-01
Specified	rm-74-02
SPEED INDEX	1-3.2.3
STATUS TEST	AG-3.2.5
TEST DEVICE.....	rm-71-04
UNIFORM CONSTANCY TEST FILM.....	7-3.3.2
USER	rm-85-01
X-RADIATION.....	rm-11-01-
X-RAY BEAM.....	rm-37-05+
X-RAY EQUIPMENT	rm-20-20
X-RAY SOURCE ASSEMBLY	rm-20-05+
X-RAY TUBE	rm-22-03
X-RAY TUBE CURRENT	rm-36-07
X-RAY TUBE VOLTAGE	rm-36-02

Annex B (informative)

Example of a form for the standardized test report

Test report on constancy 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
- time switch
- BEAM APPLICATOR
- sensor-supported digital imaging system

Identification:

Identification:

Identification:

Identification:

Non-X-RAY EQUIPMENT

- darkroom used
- film processing equipment
- developer:
 - type
 - date of preparation
 - temperature
 - time of processing
- RADIOGRAPHIC FILM:
 - supplier
 - type
 - emulsion number
 - date of first use
- SCREEN-FILM combination
- sensor, if used
- densitometer, if used

Identification:

yes ☐ no ☐

Identification:

Identification:

Date:

Value:

Time:

Identification:

Identification:

Number:

Date:

Identification:

Identification:

Identification:

TEST DEVICE used

Identification:

History of tests

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

Date:

Date:

Date:

Date:

Operating parameters

- X-RAY TUBE VOLTAGE
- X-RAY TUBE CURRENT
- IRRADIATION TIME

or

- automatic key position
- correction key position

Value [kV_p]:

Value [mA]:

Value [ms]:

Test results

Functional parameter	Result of initial CONSTANCY TEST	Result of present CONSTANCY TEST
FILM BASE PLUS FOG DENSITY (not applicable when using digital imaging equipment)		
Optical density		

Annex C

(informative)

Guidance on action to be taken

C.1 If the test result indicates that the equipment does not perform according to specified requirements or to ESTABLISHED CRITERIA, the performance of the test equipment should be verified, and the result confirmed by repeating the test, before any further action is initiated.

C.2 If the result of the repeated test confirms that the equipment fails to perform according to the specified requirements or to ESTABLISHED CRITERIA, one or more of the following actions may be taken:

- a) action is initiated as specified in the QUALITY ASSURANCE PROGRAMME for the equipment tested;
- b) the person responsible for the management of the QUALITY ASSURANCE PROGRAMME is informed;
- c) the person responsible for the daily management of the equipment tested is informed.

C.3 If the result of a test indicates that the equipment fails marginally to perform according to specified requirements or to ESTABLISHED CRITERIA, i.e. the equipment can still be used in clinical practice for the investigations made with this equipment

- a) the result of the next CONSTANCY TEST should be awaited but meanwhile the quality of the clinical images produced should be closely monitored;
- b) the frequency of the CONSTANCY TEST should be increased;
- c) the failure of the CONSTANCY TEST should be recorded as an item requiring attention when the next routine servicing is carried out.

C.4 If equipment has a history of failing to perform according to ESTABLISHED CRITERIA of a CONSTANCY TEST, the personnel described in items b) and c) of C.2 should consider

- a) carrying out a STATUS TEST; together with
- b) a relaxation in the criteria to be applied; together with
- c) a restriction on the use of the equipment tested with respect to the category of radiological application; together with
- d) thorough non-routine service and overhaul of equipment by authorized service personnel; together with
- e) placing the equipment on the list of equipment requiring replacement.

C.5 If the result of a test substantially fails to perform according to specified requirements or to ESTABLISHED CRITERIA

- a) a STATUS TEST is carried out and its result is referred to the personnel described in items b) and c) of C.2;
- b) an examination is made to determine whether servicing of the equipment:
 - is appropriate; and
 - should be immediate; and
- c) a decision is made whether
 - further clinical use of the equipment is suspended; or
 - action according to C.4 is taken.

C.6 Other action to be decided upon by the USER.

Annex D (informative)

Possible faults and corrective actions

D.1 General considerations

Most faults occurring in intra-oral dental RADIOGRAPHY are caused by the film processing. The next probable causes for faults are fluctuations in mains voltage and in the timer, especially those working mechanically. HIGH-VOLTAGE GENERATORS and X-RAY TUBES are very seldom the reason for poor results in intra-oral dental RADIOGRAPHY.

Development time should be selected based on developer temperature and should closely follow the recommendations of the film and chemistry MANUFACTURER.

Fluctuations in mains voltage may be a possible source of deviation in results, especially in buildings with insufficient mains power. When several items of equipment are switched on simultaneously, a voltage drop may occur, which may influence the constancy of the X-RAY TUBE VOLTAGE.

It is important that after change in the components of the equipment a new initial CONSTANCY TEST should be carried out. The same applies if during service or repair of equipment, an equipment parameter (for example temperature of developer, SPEED INDEX of the film-developer combination or correction of the timer) is changed.

D.2 Procedures

The following faults are listed with regard to their possible origin and corrective actions to be taken.

D.2.1 RADIOGRAM too dark (optical film density too high)

Description of possible reason	Description of corrective actions
Developer over-replenished	Prepare new developer.
Developer temperature too high	Observe the time necessary for temperature stabilization. If time is found to be correct, the temperature has to be measured and, if necessary, the temperature control has to be adjusted or repaired.
Processing time too long (see NOTE below)	Measure the processing SPEED INDEX and compare this with the prescribed value. If there is a deviation, check the adjustment or have the processor serviced.
Speed of film too high	When another type of film is used, make a correlation between both film types. For such a connection, use the new film and the old film in parallel for three successive CONSTANCY TESTS. Carry out a new initial CONSTANCY TEST. One should be aware that between different batches of film of the same type differences in sensitivity may occur. Should that be the case establish a new BASELINE VALUE.
Pre-IRRADIATION by light or X-RADIATION	Check the darkroom for extraneous or non-correct light sources as well as for the influence of IONIZING RADIATION. Look also into the storage conditions for the film material.
Application of film with undefined characteristic	Follow the INSTRUCTIONS FOR USE with respect to the developer, for example.
Film too old or incorrectly stored	Pay attention to the expiry date of the film and the storage conditions.
Timer defect	Repair the timer.
X-RAY TUBE VOLTAGE or X-RAY TUBE CURRENT too high or IRRADIATION TIME too long	Reduce the IRRADIATION TIME and/or have the equipment serviced.
FILTER changed or removed	Apply recommended FILTER
NOTE – If the processing time of the FILM PROCESSOR can be adjusted, the time and temperature chosen should be those recommended by the MANUFACTURER of the film.	

D.2.2 RADIOGRAM too light (optical film density too low)

Description of possible reason	Description of corrective actions
Developer exhausted or not replenished correctly	Prepare new developer or replenish correctly.
Developer temperature too low	Adjust developer temperature.
Processing time too short (see NOTE in D.2.1)	Adjust processing time.
Film in use of insufficient sensitivity	Apply film of higher speed.
(Not applicable)	–
Application of film with undefined characteristics	Follow the INSTRUCTIONS FOR USE with respect to the developer, the temperature, the time and the storage conditions. Always use film with defined characteristics.
Film too old or incorrectly stored	Pay attention to the expiry date of the film and storage conditions.
Timer defect	Repair the timer.
X-RAY TUBE VOLTAGE or X-RAY TUBE CURRENT too low or IRRADIATION TIME too short	Check the LOADING FACTORS, especially the stud settings. If the IRRADIATION TIME needs to be significantly increased to obtain a reasonable optical density, take the equipment out of service until the fault has been traced and remedied.
FILTER changed or additional FILTER applied	Check whether an additional FILTER has been introduced. Use only the recommended FILTER.

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Q1 Please report on **ONE STANDARD** and **ONE STANDARD ONLY**. Enter the exact number of the standard: (e.g. 60601-1-1)

.....

Q2 Please tell us in what capacity(ies) you bought the standard (tick all that apply). I am the/a:

- purchasing agent ☐
librarian ☐
researcher ☐
design engineer ☐
safety engineer ☐
testing engineer ☐
marketing specialist ☐
other

Q3 I work for/in/as a:
(tick all that apply)

- manufacturing ☐
consultant ☐
government ☐
test/certification facility ☐
public utility ☐
education ☐
military ☐
other

Q4 This standard will be used for:
(tick all that apply)

- general reference ☐
product research ☐
product design/development ☐
specifications ☐
tenders ☐
quality assessment ☐
certification ☐
technical documentation ☐
thesis ☐
manufacturing ☐
other

Q5 This standard meets my needs:
(tick one)

- not at all ☐
nearly ☐
fairly well ☐
exactly ☐

Q6 If you ticked NOT AT ALL in Question 5 the reason is: (tick all that apply)

- standard is out of date ☐
standard is incomplete ☐
standard is too academic ☐
standard is too superficial ☐
title is misleading ☐
I made the wrong choice ☐
other

Q7 Please assess the standard in the following categories, using the numbers:

- (1) unacceptable,
(2) below average,
(3) average,
(4) above average,
(5) exceptional,
(6) not applicable

- timeliness
quality of writing.....
technical contents.....
logic of arrangement of contents
tables, charts, graphs, figures.....
other

Q8 I read/use the: (tick one)

- French text only ☐
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