

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: <https://standards.iteh.ai/standards/iec/61223-2-7:1999>

Essais de constance –

*Appareils de radiographie dentaire intra-orale à l'exclusion
des appareils dentaires panoramiques*



Reference number
IEC 61223-2-7:1999(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

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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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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE

S

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

**Part 2-7: Constasy 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.
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- 6) Attention is drawn to the possibility that some of the elements of this International standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-2-7 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.

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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

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*

<https://standards.iteh.ai/> 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.