

# INTERNATIONAL STANDARD

**IEC**  
**61223-2-10**

First edition  
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**Evaluation and routine testing in  
medical imaging departments –**

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

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

*Partie 2-10:  
Essais de constance –  
Equipements de mammographie*



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For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

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

\* See web site address on title page.

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

## 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 61223-2-10 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/372/FDIS | 62B/384/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.

Annexes A and F form an integral part of this standard.

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

This standard forms part 2-10 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.

## INTRODUCTION

Some provisions or statements in the body of this part of IEC 61223 require additional information. Such information is presented in annex D, Rationale. 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 2-10: Constancy tests – X-ray equipment for mammography

## 1 Scope and object

### 1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which

- generate, influence the propagation of and detect X-RADIATION;
- process, record and present radiographic information in RADIOLOGICAL INSTALLATIONS with mammographic X-RAY EQUIPMENT using INTENSIFYING SCREENS with RADIOGRAPHIC FILM.

Special accessories of mammographic X-RAY EQUIPMENT such as biopsy plates and stereotactic devices are not within the scope of this standard.

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

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 part of IEC 61223 is designed to be applicable to X-ray equipment for mammography without digital imaging devices.

### 1.2 Object

This standard defines

- the essential parameters which describe or affect the performance of the above components of X-RAY EQUIPMENT;
- methods of checking that variations in measured quantities related to those parameters are within acceptable limits, in order to maintain adequate standards of imaging whilst reducing unnecessary IRRADIATION of the PATIENT.

The methods are based upon assessments of RADIOGRAMS of appropriate TEST DEVICES.

The purpose of the methods is

- to establish a reference level of performance when equipment is accepted;
- to detect and verify any significant variation in performance which may require corrective action.

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 does not deal with

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

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 61223-2-5:1994, *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

#### FILM BASE PLUS FOG DENSITY

for CONSTANCY TESTS in X-RAY EQUIPMENT, the optical density in an area of the RADIOGRAM, on the processed control film, that has not been exposed to light from a sensitometer. (This definition has been taken from IEC 61223-2-1.)

### 3.3.2

#### NET OPTICAL DENSITY

density above FILM BASE PLUS FOG DENSITY

## 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.

Careful consideration shall be given to the operating and test conditions, under which the equipment is checked, including the influences of environmental changes.

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 subsequent CONSTANCY TESTS.

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 in 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. However, it is important

- to perform CONSTANCY TESTS with LOADING FACTORS which are the same as those used most frequently in clinical practice;
- to reproduce and record 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, if evaluating images from IMAGE DISPLAY DEVICE, 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;
- to check the performance of the test instrumentation regularly, particularly when any significant variation in the X-RAY EQUIPMENT is suspected.

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

Before the CONSTANCY TESTS are started, the constancy of the radiographic film, the film processing and the film viewing conditions have to be checked.

#### **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 VALUES for the parameters tested.

#### **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 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**

All X-RAY EQUIPMENT under test or used for testing shall be unequivocally identified.

Interchangeable components of X-RAY EQUIPMENT such as

- ADDED FILTERS;
- ANODE material;
- BEAM LIMITING DEVICES;
- compression plates, PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;
- ANTI-SCATTER GRID;
- RADIOGRAPHIC FILM type and emulsion number;
- FILM PROCESSOR;

together with items of test instrumentation such as:

- combination of a RADIOGRAPHIC CASSETTE and INTENSIFYING SCREENS;
- TEST DEVICES;
- sensitometer;
- densitometer;
- force balance;

and settings of variables such as

- FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
- AUTOMATIC CONTROL SYSTEM density control and sensor position;
- LOADING FACTORS;
- magnification position;
- nominal FOCAL SPOT size, if applicable;

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

NOTE 1 – Most of the tests should be performed with the particular RADIOGRAPHIC CASSETTE used for the initial CONSTANCY TEST. This cassette, hereafter referred to as the "test cassette", may be kept exclusively for test procedures or identified among those used regularly in clinical work. Whereas the first is more likely to provide a stable tool for revealing changes in the equipment, the second approach will be more representative of changes of the whole system, including those due to the ageing of the cassette itself.

NOTE 2 – It is essential that any RADIOGRAPHIC FILM used in the test is of the same type as the film used in clinical practice for mammography.

RADIOGRAMS of a TEST DEVICE shall be taken with the test cassette, with the same INTENSIFYING SCREENS and film type. The RADIOGRAPHIC FILM shall be processed under known comparable conditions, and appropriate allowance shall be made for any changes in film batch according to the method specified in IEC 61223-2-1. If the film type and/or associated processing conditions are changed, a new initial CONSTANCY TEST shall be carried out.

TEST DEVICES are described for each of the performance tests described in clause 5 of this standard. In practice, some tests, for example those described in 5.1 through 5.4, may be performed simultaneously by using a composite TEST DEVICE which combines the properties of a number of individual TEST DEVICES. TEST DEVICES are discussed in detail in annex F.

## 5 Performance tests

### 5.1 X-RAY EQUIPMENT – Imaging performance

#### \*5.1.1 Image density

##### 5.1.1.1 Summary

A standard TEST DEVICE is exposed under standard conditions and the NET OPTICAL DENSITY of the image is measured at a specific position in the RADIOGRAM. RADIOGRAMS are made under both manual and AUTOMATIC EXPOSURE CONTROL. Evaluation may reveal changes in the performance under AUTOMATIC EXPOSURE CONTROL as well as changes in the RADIATION output, RADIATION QUALITY, ATTENUATION in the RADIATION BEAM and sensitivity of the imaging system.

##### 5.1.1.2 Test equipment

The test cassette shall be used for this test.

An optical densitometer shall be used which reads consistently within  $\pm 0,02$  over the range from 0 to 3,5.

The reference thickness of the ATTENUATION PHANTOM (40 mm) is used to simulate a PATIENT during the test under manual control. Three different thicknesses (preferably 20 mm, 40 mm, 60 mm) of the ATTENUATION PHANTOM shall be used for the test under AUTOMATIC EXPOSURE CONTROL.