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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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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.
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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 61223-2-10 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 2005. 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.

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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*