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Evaluation and routine testing in medical imaging departments –

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

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

Partie 2-11: Essais de constance – Appareils de radiographie générale directe

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

FOREWORD

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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 reports or guides and they are accepted by the National Committees in that sense.
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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 61223-2-11 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/373/FDIS	62B/385/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 D form an integral part of this standard.

Annexes B and C are for information only.

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This standard forms part 2-11 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 2006. 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 2-11: Constancy tests – Equipment for general direct radiography

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; and

– process, present and store radiographic information in RADIOLOGICAL INSTALLATIONS with diagnostic X-ray systems using RADIOGRAPHIC FILM in DIRECT RADIOGRAPHY.

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 does not apply to equipment for special applications such as mammographic X-RAY EQUIPMENT or dental X-RAY EQUIPMENT; see complete list of all parts 2 of IEC 61223 in the foreword.

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 equipment for general direct radiography 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 such 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.

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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 International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

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*

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