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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FOREWORD

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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.
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 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• withdrawn;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.
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.
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.


**3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment**

IEC 60788:1984, *Medical radiology – Terminology*


IEC 61223-2-1:1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*
