

INTERNATIONAL STANDARD

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Evaluation and routine testing in medical imaging departments –

Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems

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

*Partie 3-1:
Essais d'acceptation –
Performance d'imagerie des appareils
à rayonnement X pour systèmes radiographiques
et radioscopiques*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**EVALUATION AND ROUTINE TESTING
IN MEDICAL IMAGING DEPARTMENTS –**

**Part 3-1: Acceptance tests –
Imaging performance of X-ray equipment
for radiographic and radiosopic systems**

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 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 61223-3-1 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/361/FDIS	62B/365/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.

Annex A forms an integral part of this standard.

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

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: smaller roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN IEC 60788, IN IEC 60601-1 OR IN THE IEC 61223 SERIES: SMALL CAPITALS (SEE ANNEX A).

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (for example diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.

Some provisions or statements in this standard require additional information. Such information is presented in annex D. 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 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopy systems

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which influence the image quality and PATIENT dose of diagnostic X-ray systems using radiographic and radioscopy imaging systems.

This standard applies to the performance of X-RAY EQUIPMENT in the ACCEPTANCE TEST on the following medical diagnostic X-RAY EQUIPMENT and ASSOCIATED EQUIPMENT:

- radiography equipment, for example:
 - stationary radiography EQUIPMENT;
 - mobile radiography EQUIPMENT;
 - skull radiography EQUIPMENT;
 - lung radiography EQUIPMENT;
 - TOMOGRAPHY EQUIPMENT – excluding COMPUTED TOMOGRAPHY;
 - radiography devices (SPOTFILM DEVICES) in RADIOSCOPY EQUIPMENT;
 - angiography EQUIPMENT (excluding DSA function);
 - CINERADIOGRAPHY equipment;
- RADIOSCOPY EQUIPMENT, including:
 - combined radiographic and radioscopy EQUIPMENT.

This standard applies to the generation of X-RADIATION and ACCESSORIES of digital systems. It does not apply to any digital image acquisition or image processing parts of the above mentioned diagnostic X-RAY EQUIPMENT.

NOTE – Since the characterization of digital detectors and image processing is still under development, this will be included in a later edition of this standard.

This standard does not apply to mammographic X-RAY EQUIPMENT, RADIOTHERAPY simulators, nor to dental X-RAY EQUIPMENT.

1.2 Object

This standard defines:

- a) the parameters which describe the performance of X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;
- b) methods of testing whether measured quantities related to those parameters comply with the specified tolerances.

These methods rely mainly on non-invasive measurements, using appropriate test equipment, performed during or after the installation is completed. Signed statements covering steps of product testing at the MANUFACTURER's site or during the installation procedure can be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications relating to the image quality and PATIENT dose, and to detect malfunctions that are not in agreement with those specifications.

This standard does not specify tolerances for the parameters under investigation. Nor does it consider:

- c) aspects of mechanical and electrical safety,
- d) aspects of mechanical, electrical and software performance unless they are essential to the performance of the tests directly affecting image quality and PATIENT dose.

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 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60417-1:1998, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60522:1976, *Inherent filtration of an X-ray tube assembly*

IEC 60580:1977, *Area exposure product meter*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

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 60601-2-7:1998, *Medical electrical equipment – Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60878:1988, *Graphical symbols for electrical equipment in medical practice*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61267:1994, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*