INTERNATIONAL STANDARD

IEC 61223-3-4

First edition
2000-03

Evaluation and routine testing in medical imaging departments –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

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

Partie 3-4:
Essais d'acceptation –
Performance d'imagerie des appareils de radiographie dentaire

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Terminology, graphical and letter symbols

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 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

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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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.
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International Standard IEC 61223-3-4 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/393/FDIS	62B/402/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.

Annex A forms an integral part of this standard.

Annexes B and C 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 type;

– *test specifications: italic type;*

– TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN IEC 61223-1 OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX A: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, 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

This part of IEC 61223 is part of a series of International Standards which gives methods of acceptance testing and constancy testing for subsystems and systems (for example, diagnostic X-RAY EQUIPMENT) including film processing.

Some provisions or statements in this standard require additional information. Such information is presented in annex B. 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 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

1 Scope and object

1.1 Scope

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

This standard applies to the performance of the ACCEPTANCE TEST on dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR and dental X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR (for example, dental panoramic X-RAY EQUIPMENT or cephalometric X-RAY).

This standard applies to dental film and digital image acquisition and processing.

1.2 Object

This standard defines

a) the essential parameters which describe the performance of the above-mentioned dental X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;

b) methods of testing and 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 in the installation procedure may be used as part of the acceptance testing.

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

This standard does not in itself specify tolerances for the parameters under investigation. Neither is it intended to 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 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 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 60417-2:1998, *Graphical symbols for use on equipment – Part 2: Symbol originals*

IEC 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

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

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2-28: 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*

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 purposes, 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 in accordance with their definitions in IEC 60601-1, in IEC 60788, in IEC 61223-1, or in this standard.

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.

An index of defined terms used in this standard is given in annex A.

3.3 Defined terms

For the purpose of this part of IEC 61223, the following additional definitions apply.

3.3.1
ARTEFACT
apparent structure visible in the image which does not represent a structure within the object.

3.3.2
LINE PAIR RESOLUTION
highest spatial frequency of the specified line-group test pattern imaged under specified conditions which is distinguishable in the image. The unit is lp/mm.

NOTE Another term for LINE PAIR RESOLUTION used in literature is spatial resolution.

3.3.3
LOW CONTRAST RESOLUTION
the lowest contrast detail object of a specified object that can be resolved from a uniform background.

3.3.4
RADIATION OUTPUT
AIR KERMA per CURRENT TIME PRODUCT (mGy/mAs) at a given distance from the FOCAL SPOT in the primary X-RAY BEAM.

4 General aspects of ACCEPTANCE TESTS

4.1 General conditions to be considered in test procedures

The aim of an ACCEPTANCE TEST is to demonstrate that the specified characteristics of the EQUIPMENT lie within the specified tolerances. Some requirements are enforced by legislation. Other requirements and specifications may be in the purchase contract, in the supplier's brochure or in other standards, for example in the IEC 60601 series.

An inventory of the EQUIPMENT under test, the ACCOMPANYING DOCUMENTS, and the test protocols, shall be compiled before any ACCEPTANCE TESTS are carried out. Each item shall be identified by its MODEL OR TYPE REFERENCE (type number) and SERIAL NUMBER, and the entire inventory shall be compared with the purchase contract.

The response of non-screen dental X-ray film (NON-SCREEN FILM, rm-32-35) to a visible-light sensitometer does not match its response to X-RADIATION. It is therefore most practicable to assess the performance of a dedicated dental film processing system when EQUIPMENT is available for testing the X-RAY EQUIPMENT. A suitable test procedure is given in annex C.

RADIOGRAPHIC FILMS and film processing are vital parts in the imaging chain. It is the responsibility of the USER to ensure that these components perform in an acceptable way, for example with respect to sensitivity, contrast and absence of ARTEFACTS. A test of the performance of these components shall precede any ACCEPTANCE TEST measurements involving the IRRADIATION of RADIOGRAPHIC FILMS using the dental X-RAY EQUIPMENT.

The performance of the IMAGE DISPLAY DEVICE will affect the measured performance of a digital dental imaging system. Before any ACCEPTANCE TESTS are carried out on the X-RAY EQUIPMENT, the IMAGE DISPLAY DEVICE shall be set up, by following the MANUFACTURER'S instructions and using the MANUFACTURER'S electronic test image, to deliver its specified performance.

Non-invasive measurements are preferred for ACCEPTANCE TESTS. Whenever invasive tests are part of the programme it shall be shown that the EQUIPMENT has been restored to its pre-test condition after the test.

4.2 Documents and data for the tests

The following documentation is required:

– statement of compliance with applicable parts of IEC 60601;
– list of EQUIPMENT or EQUIPMENT parts ordered and the actual delivery list (IEC 60601-1);
– performance specification as agreed upon between the purchaser and the supplier;
– results from tests performed at the MANUFACTURER's site or during installation covering items of importance to quality, such as NOMINAL FOCAL SPOT VALUE;
– INSTRUCTIONS FOR USE, including guidance for the operation of the EQUIPMENT;
– details of the actual operating conditions under which the dental X-RAY EQUIPMENT is to be used;
– guidance as to the extent and frequency of maintenance procedures;
– reports on previous tests where applicable;
– data on technical changes.

4.3 Test conditions

Different categories of tests can be identified:

– visual inspection;
– functional tests;
– system performance;
– check of the uncertainty in the values of variables.

The measuring arrangements which may be used for performing tests are illustrated,

a) for intra-oral application (see figures 1 and 2);
b) for panoramic application (see figures 3 and 4);
c) for cephalometric application (see figure 5).

The arrangement in figure 1 is indicative only. Not every component is needed in every test.