INTERNATIONAL STANDARD

IEC 61223-3-1

First edition
1999-03

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

Reference number
IEC 61223-3-1:1999(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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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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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE X

For price, see current catalogue

CONTENTS

Clause Page

Tables

Figures

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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

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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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 radioscopic 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 radioscopic 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 radioscopic 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*

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 as defined in IEC 60601-1, IEC 60788, IEC 61223-1 and in 3.3 of this standard (see annex A).

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.

3.3 Defined terms

3.3.1
ARTIFACT
apparent structure visible in the image which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

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 – LINE PAIR RESOLUTION is used here as a practical substitute for spatial resolution.

3.3.3
LOW CONTRAST RESOLUTION
lowest contrast detail object of a specified shape and area that can be resolved from an 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

3.3.5
TRANSMISSION KERMA (TRANSMISSION KERMA RATE)
AIR KERMA (AIR KERMA RATE) in the central X-RAY BEAM behind the specified attenuating layer

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 order contract, in the supplier's brochure or in other standards, for example in the IEC 60601 series.

Before any ACCEPTANCE TEST according to this standard is carried out, the EQUIPMENT has to be installed and put into service according to the set-up procedure as given in the MANUFACTURER's documentation.

An inventory of the EQUIPMENT under test, the ACCOMPANYING DOCUMENTS, and the test protocols shall be compiled. 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 order contract.

RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS, RADIOGRAPHIC FILMS and film processing are vital parts in the imaging chain. It is the responsibility of the USER to show that these components perform in an acceptable way, based upon information given by MANUFACTURERS of RADIOGRAPHIC FILMS and INTENSIFYING SCREENS, for example with respect to sensitivity, contrast and absence of ARTIFACTS.

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:

- statements of compliance with applicable parts of IEC 60601;
- list of EQUIPMENT or EQUIPMENT parts ordered and the actual delivery list;
- 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 X-RAY EQUIPMENT is to be used in medical practice and whether this results in a limitation of the scope of the tests or of the functionality of the EQUIPMENT. If certain functions are disabled, only those used need to be tested;
- guidance as to the extent and frequency of maintenance procedures;
- reports on previous tests where applicable;
- list of agreed technical modifications in the meantime between the order contract and the ACCEPTANCE TEST.

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 in figures 1 and 2.

Figure 1 includes the measuring arrangement for the TRANSMISSION KERMA, K_T, or the TRANSMISSION KERMA RATE, $\dot{K}_T$, and the X-RAY IMAGE RECEPTOR AIR KERMA, K_B, or the X-RAY IMAGERECEPTOR AIR KERMA RATE, $\dot{K}_B$, and the test parameters derived from them.

Figure 2 includes the measuring arrangement to test geometry and resolutions.

The arrangements in figures 1 and 2 are indicative only. The test may be carried out in the vertical or the horizontal position according to the mode of operation of the EQUIPMENT. Not every component in the figures is needed in every test.

The X-RAY FIELD size shall be the minimum size required for each measurement.

The distance between the additional attenuating layer and the detector of the KERMAMETER (KERMA RATEMETER) shall be not less than 250 mm.

NOTE – For the effects of SCATTERED RADIATION, see 4.5.4.

The tests shall yield information reasonably necessary for a demonstration of performance over the full range of OPERATOR accessible variables.

All relevant data, such as the identification of the X-RAY EQUIPMENT under test, identification of the test equipment used, geometrical set-up, operating characteristics, correction factors and test results of the ASSOCIATED EQUIPMENT (for example film, screen, processing) shall be recorded with the test results. The record shall include the identification of the location, the date and the names of the persons performing the tests.

4.4 Test parameters

The following items are subject to ACCEPTANCE TESTING:

– identification of EQUIPMENT;
– check of documents;
– visual and functional tests;
– X-RAY TUBE VOLTAGE;
– CURRENT TIME PRODUCT;
– LOADING TIME;
– limitation and indication of the extent of the X-RAY BEAM;
– FOCAL SPOT;
– TOTAL FILTRATION;
– RADIATION OUTPUT;
– TRANSMISSION KERMA (TRANSMISSION KERMA RATE);
– function of the AUTOMATIC EXPOSURE CONTROL;
– ATTENUATION RATIO;
– AIR KERMA (AIR KERMA RATE);
– AIR KERMA (AIR KERMA RATE) at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER;
– LINE PAIR RESOLUTION;
– LOW CONTRAST RESOLUTION;
– optical density (for AUTOMATIC EXPOSURE CONTROL test).

Annex B lists symbols and units for some of the above items.

4.5 Test equipment including PHANTOMS (ATTENUATION devices) and TEST DEVICES

4.5.1 General

Measuring equipment used for ACCEPTANCE TESTS shall be certified (for example calibration according to national or international regulations, if applicable).

The uncertainty of measuring instruments shall be less than one-third of the specified tolerances for the quantities being measured.

4.5.2 High-voltage measuring instrument

The high-voltage measuring instrument shall measure the value of X-RAY TUBE VOLTAGES within the specified range. Instruments based on either direct or indirect measurements may be used.

4.5.3 KERMAMETER

The KERMAMETER (KERMA RATEMETER) shall have a range sufficient to measure the AIR KERMA (AIR KERMA RATE) within the required accuracy for the system under test and shall be calibrated for the applied beam qualities.

If legal regulations require the use of other dosimetric quantities, they may be applied.

4.5.4 PHANTOMS (ATTENUATION devices) and TEST DEVICES

PHANTOMS and TEST DEVICES may consist of attenuating layers (PHANTOM part of the object) and/or structural elements (TEST DEVICE part of the object) which can be arranged in combination or separately.

The following requirements apply:

a) External dimensions

PHANTOM dimensions shall be at least large enough to intercept the entire RADIATION BEAM for all test conditions applicable; see figures 1 and 2.

b) ATTENUATION and hardening

The attenuating layers of the PHANTOMS shall be in aluminium of at least 99,5 % purity (Al 99,5 according to ISO 2092) and a material thickness of 25 mm ± 0,5 mm; see IEC 61267.

Some, but not all, tests will need an additional homogeneous attenuating layer of about 1,5 mm copper.

A PHANTOM of low atomic number material (for example TISSUE EQUIVALENT MATERIAL) is used to test the function of the AUTOMATIC EXPOSURE CONTROL, for example 10 cm, 15 cm or 20 cm of water.

For some tests lead layers (1 mm to 2 mm thick) are needed to make lead masks or for the shielding of direct and indirect RADIATION.

c) Effects of SCATTERED RADIATION with various measuring arrangements

In all tests care shall be taken to reduce SCATTERED RADIATION to a minimum. If it is likely that SCATTERED RADIATION will significantly affect the measurement, the correction factor shall be determined and used in calculating the results.

d) Beam limiting TEST DEVICE

The beam limiting TEST DEVICE shall comprise structural elements for testing the centring, limitation and indication of the extent of the X-RAY BEAM as marking elements and a matrix with intervals of 1 cm made of RADIATION absorbing material.

These structural elements should be of such material and arranged in such a way that the function of the AUTOMATIC EXPOSURE CONTROL is unaffected.

e) LINE PAIR RESOLUTION TEST DEVICE

The TEST DEVICE shall comprise line-group test patterns with a lead thickness of 0,05 mm and grid groups with local frequencies of 0,6 lp/mm to 5,0 lp/mm with a gradation of less than or equal to 20 % from group to group. The outer dimensions are for example 55 mm × 65 mm; see figure 3.

f) LOW CONTRAST RESOLUTION TEST DEVICE

There are many devices available to measure the LOW CONTRAST RESOLUTION. If this parameter is measured, the results should be recorded together with the description of the TEST DEVICE used.

The detail diameters shall be such that their resolution is neither enhanced nor degraded by the frequency response of the X-RAY IMAGE INTENSIFIER-television system (imaging system). For examples, see annex C.

4.5.5 Lens

A magnifying lens shall be available. A 2 × to 6 × magnification is usually suitable.

4.5.6 Densitometer

The densitometer shall cover the optical density range 0 to 3,5.

4.5.7 Additional inspection and TEST DEVICES for TOMOGRAPHY X-RAY EQUIPMENT

The following TEST DEVICES are required:

– TEST DEVICE to test the layer height adjustment:

Holder for metallic slab with holes drilled at constant intervals (or the TEST DEVICE described above with additional holes; see figure 4) with an inclination of the short axis of the test pattern of 20° to 45° to the plane of the PATIENT SUPPORT. The holes in each row of the test pattern shall be at such intervals as to give an interval of 1 mm in the direction of height;

– TOMOGRAPHY movement TEST DEVICE:

Pinhole DIAPHRAGM for displaying the tomographic movement;

– TOMOGRAPHY LINE PAIR RESOLUTION TEST DEVICE:

A line-group test pattern with a lead thickness of between 0,05 mm and 0,10 mm and grid groups with local frequencies of 0,5 lp/mm to 4 lp/mm with a gradation of less than or equal to 40 % from group to group. The outer dimensions are for example 42 mm × 110 mm; see figure 4.

4.6 Evaluating the test results

Whenever specified limiting values or tolerances are not met, verify the results by making at least two additional measurements.

In the evaluation of the results concerning limit values (upper or lower), the uncertainty in the measurement shall be taken into consideration.