

Evaluation and routine testing in medical imaging departments —

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

The European Standard EN 61223-3-4:2000 has the status of a British Standard

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National foreword

This British Standard is the official English language version of EN 61223-3-4:2000. It is identical with IEC 61223-3-4:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/73, X-ray equipment components, protection and utilization, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
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Foreword

The text of document 62B/393/FDIS, future edition 1 of IEC 61223-3-4, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61223-3-4 on 2000-06-01.

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with the EN have to be withdrawn (dow) 2003-06-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes A and ZA are normative and annexes B and C are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-3-4:2000 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standards indicated:

IEC 60601-2-32 NOTE: Harmonized as EN 60601-2-32:1994 (not modified).

CONTENTS

	Page
INTRODUCTION	6
Clause	
1 Scope and object	6
1.1 Scope	6
1.2 Object	6
2 Normative references	7
3 Terminology	7
3.1 Degree of requirements	7
3.2 Use of terms	8
3.3 Defined terms	8
4 General aspects of ACCEPTANCE TESTS	8
4.1 General conditions to be considered in test procedures	8
4.2 Documents and data for the tests	9
4.3 Test conditions	9
4.4 Scope of tests	10
4.5 Test equipment including PHANTOMS and TEST DEVICES	10
4.6 Evaluating the test results	12
5 Test methods for dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR	12
5.1 Visual and functional tests	12
5.2 *X-RAY TUBE VOLTAGE	12
5.3 *TOTAL FILTRATION	13
5.4 *FOCAL SPOT of the X-RAY TUBE	13
5.5 Limitation and alignment of the X-RAY BEAM	14
5.6 FOCAL SPOT TO SKIN DISTANCE	14
5.7 *Reproducibility of RADIATION OUTPUT	15
5.8 LINE PAIR RESOLUTION	15
5.9 LOW CONTRAST RESOLUTION	15
6 Test methods for dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR	16
6.1 Visual and functional tests	16
6.2 X-RAY TUBE VOLTAGE	16
6.3 TOTAL FILTRATION	16
6.4 FOCAL SPOT of the X-RAY TUBE	16
6.5 Limitation and alignment of the X-RAY BEAM	16
6.6 FOCAL SPOT TO SKIN DISTANCE	17
6.7 Reproducibility of RADIATION OUTPUT	17
6.8 LINE PAIR RESOLUTION	18
6.9 LOW CONTRAST RESOLUTION	18
6.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS	18
6.11 Image homogeneity	18
6.12 Indicators for patients' positioning	19
6.13 Panoramic layer	19

Clause	Page
7 Test methods for dental cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR	19
7.1 Visual and functional tests	19
7.2 X-RAY TUBE VOLTAGE	19
7.3 TOTAL FILTRATION	19
7.4 FOCAL SPOT of the X-RAY TUBE	19
7.5 Limitation and alignment of the X-RAY BEAM	19
7.6 FOCAL SPOT TO SKIN DISTANCE	20
7.7 Reproducibility of RADIATION OUTPUT	20
7.8 LINE PAIR RESOLUTION	20
7.9 LOW CONTRAST RESOLUTION	20
7.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS	20
8 Test report and statement of compliance	20
Annex A (normative) Terminology – Index of defined terms	29
Annex B (informative) Examples of requirements (accuracy, tolerances, discrepancies) according to actual IEC standards or state of the art	31
Annex C (informative) ACCEPTANCE TEST for processing of non-screen dental X-ray films (non-screen film)	33
Bibliography	34
Annex ZA (normative) Normative references to international publications with their corresponding European publications	35
Figure 1 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution	22
Figure 2 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution	23
Figure 3 – Dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution	24
Figure 4 – Example of a dental panoramic X-RAY EQUIPMENT with extra-oral digital X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA, resolution, image homogeneity and panoramic layer	25
Figure 5 – Example of a cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution	26
Figure 6 – Dental PHANTOM (example)	27
Figure 7 – Dental PHANTOM for digital image acquisition or processing parts (example)	28
Table B.1 – Typical values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES	32

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.

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 dental X-RAY EQUIPMENT tested, identification of the test equipment used, geometrical set-up, operating characteristics, correction factors and test results of the ASSOCIATED EQUIPMENT (RADIOGRAPHIC FILM, 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 Scope of tests

The following are subject to ACCEPTANCE TESTING:

- identification of dental X-RAY EQUIPMENT;
- check of documents;
- visual and functional tests;
- X-RAY TUBE VOLTAGE;
- TOTAL FILTRATION;
- FOCAL SPOT;
- limitation and alignment of the X-RAY BEAM;
- LINE PAIR RESOLUTION;
- LOW CONTRAST RESOLUTION;
- RADIATION OUTPUT;
- optical density.

4.5 Test equipment including PHANTOMS and TEST DEVICES

4.5.1 General

Measuring equipment used for ACCEPTANCE TESTS shall be certified as calibrated against a national standard or an International Standard where such a standard exists.

The uncertainty of measuring instruments shall be less than the tolerance stated for the MEASURED VALUES.

4.5.2 High-voltage measuring instrument

Wherever practicable, the X-RAY TUBE VOLTAGE should be measured by a radiographic penetrameter.

NOTE If it is necessary to use an electronic high-voltage measuring instrument, the USER should evaluate the significance of any deviation between the INDICATED VALUES and MEASURED VALUES.

In some types of dental X-RAY EQUIPMENT, there is a variation of X-RAY TUBE VOLTAGE at the beginning of the LOADING TIME, which is of no clinical consequence.

Some panoramic equipment is designed so that the X-RAY TUBE VOLTAGE is deliberately varied during the LOADING TIME.

No general guidance can be given as different types of "digital kV meter" respond to different aspects of the voltage/time characteristic.