

Australian/New Zealand Standard™

**Evaluation and routine testing in
medical imaging departments**

**Part 3.4: Acceptance tests—Imaging
performance of dental X-ray equipment**



AS/NZS 4184.3.4:2002

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-008, Diagnostic Ionizing Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 12 August 2002 and on behalf of the Council of Standards New Zealand on 20 August 2002. It was published on 27 September 2002.

The following are represented on Committee HE-008:

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Australian and New Zealand Society of Nuclear Medicine
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Australian Radiation Protection and Nuclear Safety Agency
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-008, Diagnostic Ionizing Imaging Equipment.

This Standard is identical with, and has been reproduced from, IEC 61223-3-4:2000, *Evaluation and routine testing in medical imaging departments—Part 3-4: Acceptance tests—Imaging performance of dental X-ray equipment*.

In the text of this Standard, the following fonts are used:

- (a) Requirements, compliance with which can be tested, and definitions
.....in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions, references
..... in smaller roman type
- (c) Headings, of sub-clauses and test specifications *in italic type*
- (d) Terms used throughout the Standard, which have been
defined in Annex A IN SMALL CAPITALS

As this publication has been reproduced from an International Standard, the following modifications apply:

- (i) Its number does not appear on each page and its identity is shown on the cover and title page.
- (ii) The words: 'this Australian/New Zealand Standard' should replace the words 'this part of IEC 61223' wherever they appear.
- (iii) A full point (.) substitutes for a comma (,) where it appears as a decimal marker.
- (iv) In the second paragraph of Clause 1.1, the words 'cephalometric X-RAY EQUIPMENT' should replace the words 'cephalometric X-RAY'.
- (v) In the third paragraph of Clause 1.1, the word 'dental' should be deleted.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex to which they apply. A 'normative' annex is an integral part of a Standard, whereas an 'informative' annex is for information or guidance only.

Some pages of the original, which relate to IEC administrative matters, do not appear in this version.

The references to International Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>
IEC		AS/NZS
60336	X-ray tube assemblies for medical diagnosis—Characteristics of focal spots	—
60417	Graphical symbols for use on equipment	—
60417-1	Part 1: Overview and application	—
60417-2	Part 2: Symbol originals	—
60522	Determination of the permanent filtration of X-ray tube assemblies	—

IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for rd safety—Parent Standard
60601-2-28	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	3200.2.28	Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators
60788	Medical radiology—Terminology	—	
60878	Graphical symbols for electrical equipment in medical practice	4334	Graphic symbols for use on medical electrical equipment
61223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
61223-1	Part 1: General aspects	4184.1	Part 1: General aspects
61267	Medical diagnostic X-ray equipment—Radiation conditions for use in the determination of characteristics	4358	Medical diagnostic X-ray equipment—Radiation conditions for use in the determination of characteristics
ISO			
2092	Light metals and their alloys—Code of designation based on chemical symbols	—	

AUSTRALIAN/NEW ZEALAND STANDARD

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.

4.5.3 KERMAMETER

Dental radiography uses X-RAY BEAMS with smaller dimensions, lower energy and lower AIR KERMA RATES than general medical radiography. It shall be ensured that the KERMAMETER used for these tests is suitable for the purpose and calibrated for the energy and KERMARATE in use and that the detector is smaller than the nominated beam dimensions.

4.5.4 PHANTOMS and TEST DEVICES

These TEST DEVICES may consist of structural elements which can be arranged in combination or separately.

The test device shall contain a grid group with a spatial frequency equal to, or higher than, the spatial frequency to be resolved. The following requirements apply:

a) External dimensions

The dimensions of these PHANTOMS shall be at least large enough to intercept the entire RADIATION BEAM for all test conditions applicable:

- 1) for intra-oral application (see figures 6 and 7);
- 2) for panoramic application;
- 3) for cephalometric application.

b) ATTENUATION and hardening

The aluminium PHANTOMS shall be of at least 99,5 % purity (Al 99,5 % according to ISO 2092) and a material thickness of 6 mm $\pm$ 0,1 mm (see IEC 61267).

c) TEST DEVICE for LINE PAIR RESOLUTION for digital imaging

Suitable TEST DEVICES may comprise line-group test patterns with a lead thickness of 0,05 mm and grid groups with local frequencies

- 1) for intra-oral application of 4,0 lp/mm to 8,0 lp/mm
 - 2) for panoramic application of 1,6 lp/mm to 3,0 lp/mm
 - 3) for cephalometric application of 1,6 lp/mm to 3,0 lp/mm
- with a gradation of ≤ 20 % from group to group.

d) TEST DEVICE for LOW CONTRAST RESOLUTION for digital imaging

The TEST DEVICE shall contain one minimal contrast object with a contrast lower or equal to the contrast to be detected. A suitable TEST DEVICE is one with holes in a 0,5 mm Al foil (see figure 7):

- 1) for intra-oral application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter;
- 2) for panoramic application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter;
- 3) for cephalometric application, 1 mm, 1,5 mm, 2 mm, 2,5 mm diameter.

4.5.5 Lens

A magnifying lens shall be available. A 2,5 $\times$ magnification is usually suitable.

4.5.6 Densitometer

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

4.6 Evaluating the test results

Whenever specified limiting values or tolerances are exceeded, 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.

5 Test methods for dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR

5.1 Visual and functional tests

5.1.1 Requirements

The operation and functioning of the dental X-RAY EQUIPMENT shall comply with what is specified.

All OPERATOR accessible controls shall be labelled with a graphical symbol, for example according to IEC 60417 or IEC 60878, and/or in plain language. The colour of indicator lamps shall comply with applicable standards, for example IEC 60601-1. The marking on the X-RAY TUBE ASSEMBLY shall comply with IEC 60601-2-28.

The INSTRUCTIONS FOR USE shall describe comprehensively how the dental X-RAY EQUIPMENT under test is to be operated. The function of each OPERATOR accessible control, indicator and DISPLAY shall be described and all symbols shall be illustrated with their significance. Reproductions in the INSTRUCTIONS FOR USE shall be in agreement with the actual dental X-RAY EQUIPMENT, with respect to position, labels and symbols. The INSTRUCTIONS FOR USE shall be in the language that is required locally.

5.1.2 Test methods

The tests are performed by visual inspection and functional check. They comprise

- *inventory of EQUIPMENT under test;*
- *check on the presence of all documents according to 4.2;*
- *functional test of the mechanical and electrical adjustment devices;*
- *functional test and identification of the control elements;*
- *visual inspection of the labelling of control elements;*
- *visual inspection of the markings on the X-RAY TUBE ASSEMBLY;*
- *visual inspection of the INSTRUCTIONS FOR USE (according to IEC 60601-1).*

5.2 *X-RAY TUBE VOLTAGE

5.2.1 Requirement

The MEASURED VALUES for the X-RAY TUBE VOLTAGE shall comply with the INDICATED VALUES within the specified tolerances.

5.2.2 Test methods

The measurements shall be carried out with the arrangement in figure 1. The tests are preferably performed using a non-invasive method.