

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:

Australasian College of Physical Scientists and Engineers in Medicine
Australian and New Zealand Society of Nuclear Medicine
Australian Dental Association Inc.
Australian Dental Industry Association
Australian Institute of Radiography
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.