

AS/NZS 4184.3.2:1998

Australian/New Zealand Standard[®]

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

**Part 3.2: Acceptance tests—
Imaging performance of
mammographic X-ray equipment**

[Based on and including the full text of IEC 1223-3-2:1996, Evaluation and routine testing in medical imaging departments, Part 3-2: Acceptance tests—Imaging performance of mamographic X-ray equipment]

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The following interests are represented on Committee HE/3:

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 Australia & New Zealand Society of Nuclear Medicine
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE/3, Medical Electrical Equipment, as a Joint Standard.

This Standard is based on but not equivalent to and has been reproduced from IEC 1223-3-2:1996, *Evaluation and routine testing in medical imaging departments*, Part 3.2: *Acceptance tests—Imaging performance of mammographic X-ray equipment*.

An Appendix ZZ has been added to this Standard, specifying additional Australian and New Zealand requirements. The ZZ Appendix relates to Subclause 5.5.1 which has been identified by a marginal bar.

In the text of this Standard, the following print types are used:

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

The even numbered pages of the original publication are in French and are omitted from this edition. Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

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

- (i) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (ii) The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (iii) A full point substitutes for a comma when referring to a decimal marker.

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

Reference to International Standard or other Publication		Australian/New Zealand Standard	
IEC		AS/NZS	
336	X-ray tube assemblies for medical diagnosis—Characteristics of focal spots	4274	X-ray tube assemblies for medical diagnosis—Characteristics of focal spots
417N	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets—Thirteenth supplement	—	
		AS	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
601-1	Part 1: General requirements for safety	3200.1.0	Part 1: General requirements for safety—Parent Standard

iii

IEC		AS/NZS	
601-1-3	Part 1-3: Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3: General requirements for safety—Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
601-2-7	Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	3200.2.7	Part 2.7: Particular requirements for safety—High-voltage generators for diagnostic X-ray generators
601-2-28	Part 2-28: 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
601-2-32	Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment	3200.2.32	Part 2-32: Particular requirements for safety—Associated equipment of X-ray equipment
788	Medical radiology—Terminology	—	
878	Graphical symbols for electrical equipment in medical practice	4334	Graphic symbols for use on medical electrical equipment
1223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
1223-1	Part 1: General aspects	4184.1	Part 1: General aspects
1223-2-1	Part 2-1: Constancy tests—Film processors	4184.2.1	Part 2.1: Constancy tests—Film processors
1223-2-2	Part 2-2: Constancy tests—Radiographic cassettes and film changers—Film-screen contact and relative sensitivity of the screen-cassette assembly	4184.2.2	Part 2.2: Constancy tests—Radiographic cassettes and film changers—Film-screen contact and relative sensitivity of the screen-cassette assembly
1223-2-3	Part 2-3: Constancy tests—Darkroom safelight conditions	4184.2.3	Part 2.3: Constancy tests—Darkroom safelight conditions
ISO			
2092	Light metals and their alloys—Code of designation based on chemical symbols	—	

The term 'normative' has been used in this Standard to define the application of the appendix and annex to this Standard. 'Normative' appendices and annexes form an integral part of the Standard.

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CONTENTS

	<i>Page</i>
INTRODUCTION	v
 Clause	
1 Scope and object	1
1.1 Scope	1
1.2 Object	1
2 Normative references	1
3 Terminology	2
3.1 Degree of requirements	2
3.2 Use of terms	3
3.3 Defined terms	3
4 General aspects of ACCEPTANCE TESTS	3
4.1 General conditions to be considered in test procedures	3
4.2 Documents and data for the tests	4
4.3 Test conditions	4
4.4 Test parameters	4
4.5 Test equipment including PHANTOMS and TEST DEVICES	5
4.6 Evaluating the test results	6
5 Test methods for mammographic X-RAY EQUIPMENT	6
5.1 Visual and functional tests	6
5.2 X-RAY TUBE VOLTAGE	7
5.3 TOTAL FILTRATION	7
5.4 X-RAY TUBE FOCAL SPOT	8
5.5 LIGHT-FIELD INDICATOR, X-RAY FIELD limitation and beam alignment	8
5.6 Linearity and reproducibility of radiation output	9
5.7 AUTOMATIC EXPOSURE CONTROL (AEC)	9
5.8 ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTOR PLANE	10
5.9 Compression device	11
5.10 Structural ARTIFACTS	11
5.11 Moving ANTI-SCATTER GRID blurring	11
6 Test report and statement of compliance	12
 Figures	
1 Set-up for HALF-VALUE LAYER measurements	13
2 Set-up for ATTENUATION RATIO measurements	14
 Annex A – Terminology – Index of defined terms	15
 Appendix ZZ Supplementary requirements added to the Australian and New Zealand edition of IEC 1223-3-2	17

v

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (such as diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.

AUSTRALIAN/NEW ZEALAND STANDARD**EVALUATION AND ROUTINE TESTING
IN MEDICAL IMAGING DEPARTMENTS –****Part 3-2: Acceptance tests –
Imaging performance of mammographic X-ray equipment****1 Scope and object****1.1 Scope**

This part of IEC 1223 applies to those components of X-RAY EQUIPMENT which influence the image quality in RADIOGRAMS produced with mammographic X-RAY EQUIPMENT using INTENSIFYING SCREENS with RADIOGRAPHIC FILM for both contact and magnification modes of operation.

This standard does not apply to special ACCESSORIES of mammographic X-RAY EQUIPMENT such as biopsy plates and stereotactic devices.

1.2 Object

This part of IEC 1223 defines:

- a) the essential parameters which describe the performance of the above-mentioned components of X-RAY EQUIPMENT with regard to imaging properties;
- b) methods of testing whether measured quantities related to those parameters comply with specified tolerances.

These methods mainly rely on non-invasive measurements, using appropriate test equipment, performed during the installation or after the installation is completed. Signed statements covering steps in the installation procedure can be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications affecting the image quality, and to detect malfunctions affecting the image quality 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 the image quality.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 1223. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 1223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents listed below. Members of IEC and ISO maintain registers of currently valid International Standards.