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AS/NZS 4184.3.3

Australian/New Zealand Standard™

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

**Part 3.3: Acceptance tests—
Imaging performance of X-ray
equipment for digital subtraction
angiography (DSA)**

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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 identical with and has been reproduced from IEC 61223-3-3:1996, *Evaluation and routine testing in medical imaging departments*, Part 3-3: *Acceptance tests—Imaging performance of X-ray equipment used for digital subtraction angiography (DSA)*.

All IEC Standards have been renumbered as the IEC 60xxx series, therefore references in the source text should be modified by adding 60 to the number as a prefix.

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) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.
- (iii) A full point substitutes for a comma when referring to a decimal marker.
- (iv) The term 'normative' and 'informative' has 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 only for information and guidance.

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

<i>Reference to International Standard or other Publication</i>	<i>Australian/New Zealand Standard</i>
IEC	AS/NZS
60417N Graphical symbols for use on equipment—Index, survey and compilation of the single sheets—Thirteenth supplement	—
60601 Medical electrical equipment	3200 Approval and test specification—Medical electrical equipment

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IEC		AS/NZS	
60601-1	Part 1: General requirements for safety Amendment 1 (1991) Amendment 2 (1995)	3200.1.0	Part 1.0: General requirements for safety—Parent Standard Amendment 1 (1991) Amendment 2 (1995)
60601-1-3	Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3 Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
60601-2-7	Part 2: 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 of diagnostic X-ray 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 department
61223-1	Part 1: General aspects	4184.1	Part 1: General aspects
61223-2-4	Part 2-4: Constancy tests—Hard copy cameras	4181.2.4	Part 2.4: Constancy tests—Hard copy cameras
61223-2-5	Part 2-5: Constancy tests—Image display devices	4181.2.5	Part 2.5: Constancy tests—Image display devices
ISO			
2092	Light metals and their alloys—Code of designation based on chemical symbols		

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INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (e.g. 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 3-3: Acceptance tests –
Imaging performance of X-ray equipment
for digital subtraction angiography (DSA)****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 of EQUIPMENT for digital subtraction angiography (DSA) with an imaging system consisting of an X-ray generation subsystem, a detection device comprising an X-RAY IMAGE INTENSIFIER television chain, means of digitization and digital image processing, image storage and image manipulation including subtraction, and facilities for image display.

This standard does not apply to general equipment of digital imaging. If such an equipment includes a DSA function, it is restricted to the DSA function.

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 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.