

Australian/New Zealand Standard™

**Medical electrical equipment—
Dose area product meters**



Standards Australia



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Paerewa Aotearoa

AS/NZS 4957:2002

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 18 March 2002 and on behalf of the Council of Standards New Zealand on 21 March 2002. It was published on 15 May 2002.

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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 60580:2000, *Medical electrical equipment—Dose area product meters*.

Those terms listed in the Index of Defined Terms appear in SMALL CAPITALS.

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

- (a) Its number does not appear on each page and its identity is shown on the cover and title page.
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Some pages of the original IEC Standard which relate to IEC administrative matters, do not appear in this version.

References to international Standards should be replaced by references to equivalent Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard or other publication</i> *	<i>Australian or Australian/New Zealand Standard</i>
ISO/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 safety—Parent Standard
60601-1-1 – Collateral standard: Safety requirements for medical electrical systems	3200.1.1 Part 1:1: General requirements for safety. Collateral Standard: Safety requirements for medical electrical systems
60601-1-2 – Collateral standard: Electromagnetic compatibility – Requirements and tests	3200.1.2 Part 1.2: General requirements for safety. Collateral Standard: Electromagnetic compatibility – Requirements and tests
60731 Medical electrical equipment—Dosimeters with ionization chambers as used in radiotherapy	4537 Medical electrical equipment—Dosimeters with ionization chambers as used in radiotherapy
60950 Safety of information technology equipment	3260 Safety of information technology equipment including electrical business equipment (incorporating Amendments 1, 2, 3 & 4)
61000 Electromagnetic compatibility (EMC)	61000 Electromagnetic compatibility (EMC)
61000-4-3 Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test	61000.4.3 Part 4.3: Testing and measurement techniques— Radiated radio-frequency electromagnetic field immunity test

* Any international Standards not listed do not have an Australian/New Zealand equivalent.

ISO	AS	
International vocabulary of basic and general terms in metrology	3807	Vocabulary of basic and general terms in metrology
Guide to the expression of uncertainty in measurement	2833	Metrology – Symbols for expressing uncertainty of measurements

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INTRODUCTION

Diagnostic radiology is the largest contributor to man-made ionizing radiation to which the public is exposed. The reduction in the exposure received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS or procedures has therefore become a central issue in recent years. The purpose of routine measurement of DOSE AREA PRODUCT is to help in achieving an overall reduction in the radiation received by PATIENTS undergoing MEDICAL RADIOLOGICAL EXAMINATIONS. Provided adequate records are kept, it is possible to determine patient doses, to compare different examination techniques, to establish a technique giving minimum radiation to a PATIENT, and to ensure a maintenance of that technique; in this respect, such measurements have a place of particular importance in training establishments. Examination of records may also indicate a deterioration in the efficiency of the image-production system. DOSE AREA PRODUCT METERS must be of satisfactory quality and must therefore fulfil the special requirements laid down in this International Standard.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment—Dose area product meters**1 Scope and object**

This International Standard specifies the performance and testing of DOSE AREA PRODUCT METERS with IONIZATION CHAMBERS intended to measure DOSE AREA PRODUCT and/or DOSE AREA PRODUCT RATE to which the PATIENT is exposed during MEDICAL RADIOLOGICAL EXAMINATIONS.

The object of this International Standard is

- 1) to establish requirements for a satisfactory level of performance for DOSE AREA PRODUCT METERS, and
- 2) to standardize the methods for the determination of compliance with this level of performance.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 60417 (all parts), *Graphical symbols for use on equipment*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60731:1997, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60950:1999, *Safety of information technology equipment*

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test¹⁾*

¹⁾ There exists a consolidated edition 1.1 (1998) that includes IEC 61000-4-3 (1995) and its amendment 1 (1998).