

Australian Standard<sup>®</sup>

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**APPROVAL AND TEST  
SPECIFICATION—**

**DENTAL AND MOBILE  
DIAGNOSTIC X-RAY EQUIPMENT**

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X-RAY APPARATUS, DENTAL AND MOBILE MEDICAL  
(APPROVAL AND TEST SPECIFICATION)]

This Australian standard was prepared by Committee EL/18/8, Mobile and Dental X-ray Machines. It was approved on behalf of the Council of The Standards Association of Australia on 22 March 1985 and published on 7 June 1985.

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The following interests are represented on Committee EL/18/8:

- Australasian College of Physical Scientists in Medicine
- Australian Dental Association Incorporated
- Australian Institute of Radiography
- Australian Medical Devices and Diagnostic Association
- Confederation of Australian Industry
- Department of Defence
- Department of Health
- Department of Health, Queensland
- Department of Public Works, New South Wales
- Department of Veterans Affairs
- Diagnostic Imaging and Medical Electronics Association of Australia
- Health Department of Western Australia
- Royal Australasian College of Radiologists
- Statutory Electricity Authorities
- United Dental Hospital of Sydney
- University of Sydney

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*This standard was issued in draft form for comment as DR 83210.*

First published (as AS 3201, Part 5) . . . . .	1977
AS 3205 first published . . . . .	1985

## PREFACE

This standard was prepared by the Association's Committee on Dental and Mobile X-ray Machines. It supersedes AS 3201, Part 5—1977, Dental and Mobile Medical X-ray Machines. This standard incorporates requirements for the safety of dental and mobile diagnostic X-ray equipment and is one of a series of approval and test specifications issued by the Association. These approval and test specifications for individual items of electromedical equipment are supplementary to the parent approval and test specification for all electromedical equipment, i.e. AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements.

The purpose of the series is to specify requirements with which compliance may be necessary to gain approval for the sale and use of electromedical equipment in Australia. Only safety matters and conditions closely allied thereto are covered. In some instances, however, these are more stringent than for most electrical appliances because of the exacting additional requirements necessary to ensure the safety of the patient, and because of the environmental conditions, e.g. high humidity, hazardous location, in which X-ray equipment is liable to be used.

The clauses of this particular standard supplement or modify the corresponding clauses in AS 3200. As stated in Clause 1.2, the requirements of a particular standard take priority, where appropriate, over those of AS 3200. Where the reference in the text of this standard indicates an 'addition' or 'replacement' of the relevant requirements, tests or explanation notes of AS 3200, these changes are made to the relevant text which then becomes part of the standard. Where no changes are necessary the words 'this Section of AS 3200 applies' are used.

The revision of AS 3201, Part 5 was primarily undertaken to accommodate new and modified requirements applicable to dental and mobile diagnostic X-ray equipment and to align the content with the following standards:

AS 2398 Fixed Diagnostic X-ray Equipment—Design Construction and Installation—Safety Requirements

AS XXXX Diagnostic X-ray Facilities—Safe Practices\*

Significant changes from AS 3201, Part 5 include the following:

- (a) The application of the new edition to—
  - (i) dental panoramic X-ray equipment having an intra-oral X-ray source;
  - (ii) dental panoramic X-ray equipment for tomography; and
  - (iii) cephalometric X-ray equipment.
- (b) New requirements for battery-powered mobile X-ray equipment.
- (c) Additional safety requirements for capacitor-discharge X-ray equipment.
- (d) Expanded requirements for protection against the hazards of radiation.

During the preparation of this standard reference was made to documentation published by the following organizations:

International Electrotechnical Commission (IEC)

International Commission on Radiological Protection (ICRP)

National Health and Medical Research Council (NHMRC)

Acknowledgement is made of the assistance received from these sources.

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\* In course of preparation

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## STANDARDS ASSOCIATION OF AUSTRALIA

## Australian Standard

APPROVAL AND TEST SPECIFICATION—  
DENTAL AND MOBILE DIAGNOSTIC X-RAY EQUIPMENTSECTION 1. SCOPE, APPLICATION AND REFERENCED  
DOCUMENTS

This Section of AS 3200 is applicable, except as follows:

**ADDITION**

**1.1 SCOPE.** Add the following:

This specification sets out the particular safety requirements for dental and mobile diagnostic X-ray equipment as defined in Clause 2.2.

The specification also applies to—

- (a) X-ray equipment for dental panoramic radiography with an intra-oral X-ray source;
- (b) X-ray equipment for dental panoramic tomography; and
- (c) cephalometric X-ray equipment.

It also specifies the measures to be taken for the provision of protection additional to that incorporated in the X-ray equipment against the hazards of ionizing radiation.

**ADDITION**

**1.2 APPLICATION.** Add the following:

**1.2.1 Compliance with AS 3100, and AS 3200.** This specification shall be read in conjunction with AS 3100 and AS 3200, and the appropriate provisions of these standards shall apply to the construction of dental and mobile diagnostic X-ray equipment and to the installation and safeguarding of parts which normally carry current.

**1.2.2 Special requirements.**

**1.2.2.1 Special requirements of this standard.** X-ray equipment covered by this specification shall be deemed to comply with this specification only if it complies with all the requirements of this specification and passes the tests specified herein.

**1.2.2.2 Requirements of other standards.** Electrical accessories and components incorporated in dental and mobile diagnostic X-ray equipment which are depended upon for safety shall also comply with the relevant requirements of individual Approval and Test Specifications unless these requirements are varied herein.

**1.2.2.3 Protection against radiation.** Where other Australian standards are issued, which deal with specific requirements for the safety of radiological staff, the patient, and the public, these standards shall supersede the protection requirements of this standard where the requirements are more stringent.

**1.2.2.4 Requirements for hazardous locations.** X-ray equipment suitable for use in areas where flammable medical agents are used including hospitals, medical rooms in industrial premises, dental surgeries, and the like, shall comply with the relevant requirements of AS 1169.

**ADDITION**

**1.3 REFERENCED DOCUMENTS.** The following documents are referred to in this standard:

**1.3.1 Standards**

- |         |   |
|---------|---|
| AS 1169 | Minimizing of Combustion Hazards Arising from the Medical Use of Flammable Anaesthetic Agents |
| AS 1656 | Steel Wire Ropes (Other than for Mining Purposes)   |
| AS 2398 | Fixed Diagnostic X-ray Equipment—Design, Construction and Installation—Safety Requirements    |
| AS MB1  | SAA Steel Wire Rope Manual  |
| AS XXXX | Diagnostic X-ray Facilities—Safe Practices*   |

**1.3.2 Approval and Test Specifications:**

- |         |   |
|---------|---|
| AS 3100 | Definitions and General Requirements for Electrical Materials and Equipment |
| AS 3126 | Extra-low Voltage Transformers  |
| AS 3193 | Transformer-type Battery Chargers   |
| AS 3200 | Electromedical Equipment—General Requirements                               |
| AS 3208 | Transformers in Electromedical Equipment                                    |

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\* In course of preparation.