

Australian/New Zealand Standard™

**Medical electrical equipment  
Part 2.201: Particular requirements for  
safety—Dento-maxillofacial X-ray  
equipment**

## **AS/NZS 3200.2.201:2000**

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 14 August 2000 and on behalf of the Council of Standards New Zealand on 23 August 2000. It was published on 11 September 2000.

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The following are represented on Committee HE-003:

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Australasian Society for Ultrasound in Medicine  
Australian Dental Association  
Australian Institute of Radiography  
Australian Radiation Laboratory  
Australian Society of Anaesthetists  
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AS/NZS 3200.2.201:2000  
(Incorporating Amendment No. 1)

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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment to supersede AS/NZS 3200.2.201:1996.

*This Standard incorporates Amendment No. 1 (July 2002). The changes required by the Amendment(s) are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure, or part thereof affected.*

This Standard is one of a series issued by Standards Australia and Standards New Zealand for the safe design and manufacture of various categories of medical equipment. It is supplementary to AS/NZS 3200.1.0:1998, *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*. The clauses in this Standard are numbered to correspond with the clauses that they supplement or modify in AS/NZS 3200.1.0, hereinafter referred to as the General Standard, and take priority over those clauses of the General Standard.

Australian or Joint Australian/New Zealand Standards referenced in this publication are detailed in Appendix LL.

In this revised version of the 1996 edition, Clause 29 has been substantially rewritten.

The term 'normative' has been used in this Standard to define the application of the Appendix to which it applies. A 'normative' Appendix is an integral part of a Standard.

## CONTENTS

		<i>Page</i>
<b>SECTION 1 GENERAL</b>		
1	SCOPE AND OBJECT.....	5
1.1	Scope.....	5
1.2	Object.....	5
1.3	Particular Standards.....	5
1.4	Environmental conditions.....	5
1.101	Application.....	5
1.101.1	Compliance with AS/NZS 3100 and AS/NZS 3200.1.0.....	5
1.101.2	Special requirements.....	5
2	TERMINOLOGY AND DEFINITIONS.....	6
2.101.1	Coefficient of variation (C).....	6
2.101.2	Collimators.....	6
2.101.3	Documents.....	6
2.101.4	Filtration.....	7
2.101.5	Radiation.....	7
2.101.6	Shall and should.....	8
2.101.7	Protective shielding.....	8
2.101.8	X-ray equipment.....	8
3	GENERAL REQUIREMENTS.....	9
4	GENERAL REQUIREMENTS FOR TESTS.....	9
5	CLASSIFICATION.....	9
6	IDENTIFICATION, MARKING AND DOCUMENTS.....	9
6.101.1	Documentation, markings and signage on equipment.....	9
6.101.2	Marking.....	9
6.102	Protective devices.....	9
6.103	X-ray tube assemblies.....	10
6.104	Light beam collimator.....	10
7	POWER INPUT.....	10
7.101	Compliance testing.....	10
<b>SECTION 2 ENVIRONMENTAL CONDITIONS.....</b>		<b>11</b>
<b>SECTION 3 PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS.....</b>		<b>12</b>
13.101	High Voltage Equipment.....	12
13.101.1	High voltage supply.....	12
13.101.2	Termination of high voltage conductors.....	12
13.101.3	High voltage isolation.....	12
13.101.4	Circuit protection.....	12
13.101.5	Undue stress on circuits or insulation.....	12
13.101.6	Supply switch.....	13
13.101.7	Transformers.....	13
<b>SECTION 4 PROTECTION AGAINST MECHANICAL HAZARDS.....</b>		<b>14</b>
28.101	Suspended masses.....	14
28.101.1	Inspection ports.....	14
28.101.2	Locking devices.....	14
28.101.3	Protection of patient from moving parts.....	15

	<i>Page</i>
SECTION 5 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION .....	16
29.101 Indication of exposure factors for radiography .....	16
29.102 Timers .....	17
29.103 Accuracy of the X-ray tube voltage .....	18
29.104 Reproducibility and output linearity .....	18
29.105 Radiation protection .....	18
29.106 Beam quality .....	19
29.107 X-ray tube voltage and field limitations.....	20
SECTION 6 PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES.....	23
SECTION 7 PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS .....	23
SECTION 8 ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT .....	23
SECTION 9 ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS .....	23
SECTION 10 CONSTRUCTIONAL REQUIREMENTS .....	24
59.101 Design and construction .....	24
59.102 Mechanical stability (other than fixed equipment).....	25
APPENDICES	
AA TEST TO BE APPLIED FOR TYPE APPROVAL.....	26
LL AUSTRALIAN/NEW ZEALAND DOCUMENTS REFERENCED IN THIS STANDARD.....	27

## STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

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**Australian/New Zealand Standard**  
**Medical electrical equipment**

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X-ray equipment**

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## SECTION 1 GENERAL

**1 SCOPE AND OBJECT**

This Clause of the General Standard applies with the following additions:

**1.1 Scope****Addition:**

This specification sets out the particular safety requirements for dento-maxillofacial X-ray equipment.

The specification applies to X-ray equipment intended for—

- (a) use with intra-oral image receptors;
- (b) use with panoramic tomography; and
- (c) use with dedicated cephalometric radiography.

**1.2 Object**

This subclause of the General Standard applies.

**1.3 Particular Standards**

This subclause of the General Standard applies.

**1.4 Environmental conditions**

This subclause of the General Standard applies.

**Additional subclause:****1.101 Application****1.101.1 Compliance with AS/NZS 3100 and AS/NZS 3200.1.0**

This specification shall be read in conjunction with AS/NZS 3100 and the appropriate provisions of these Standards shall apply to the construction of dento-maxillofacial diagnostic X-ray equipment and to the installation and safeguarding of parts which normally carry current.

**1.101.2 Special requirements****1.101.2.1 *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.