AS/NZS 3200.2.200:2005
ISO 8359:1996

AS/NZS 3200.2.200:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.200: Particular requirements for safety—Oxygen concentrators for individual patient use

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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 20 January 2005 and on behalf of the Council of Standards New Zealand on 28 January 2005.
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The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

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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 3200.2.200—1992, *Approval and test specification—Medical electrical equipment* Part 2.200: *Particular requirements for safety—Oxygen concentrators for individual patient use.*

This Particular Standard has been reproduced from, and is identical to, ISO 8359:1996, *Oxygen concentrators for medical use—Safety requirements,* and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard* and is hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

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.

(b) The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

(c) The substitution of a full point (.) for a comma (,) when it appears as a decimal marker.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex or appendix to which they apply. A ‘normative’ annex or appendix is an integral part of a Standard, whereas an ‘informative’ one is for information and guidance.

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

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
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
60601-1-2	Part 1-2: General requirements for safety, Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety, Collateral Standard: Electromagnetic compatibility—Requirements and tests
IEC		AS	
60651	Sound level meters	1259 1259.1	Acoustics—Sound level meters Part 1: Non-integrating

ISO		
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—
9703	Anaesthesia and respiratory care alarm signals	—
9703-1	Part 1: Visual alarm signals	—
9703-2	Part 2: Auditory alarm signals	—

CONTENTS

INTRODUCTION

Oxygen concentrators provide a safe source of oxygen-enriched air for patients in need. These devices raise the level of inspired oxygen by separating nitrogen or oxygen from ambient air.

Oxygen concentrators fall into two main classes according to the means whereby gas separation is effected, namely:

a) oxygen concentrators in which oxygen selectively permeates or transports through a membrane or lattice,

b) pressure swing absorbers (PSA) in which air is exposed at a certain pressure to molecular sieve material which selectively retains nitrogen and other components until they are subsequently released when the pressure is reduced.

Details of the arrangement of test apparatus for carrying out a number of the tests to check compliance with certain requirements are given in annex N.

A rationale for the most important requirements is given in annex P. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revision.

Test methods other than those specified in this International Standard, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this International Standard are to be used as the reference methods.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.200:
Particular requirements for safety—Oxygen concentrators for individual patient use

Section 1: General

1.1 Scope

NOTE 1 See the rationale in annex P.

ISO 8359 is one of a series of International Standards based on IEC 601-1. In IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in **1.3** of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply, except that **1.1** shall be replaced by the following:

> This International Standard specifies safety requirements for continuous-flow oxygen concentrators, as defined in 1.3.8 (in this International Standard). This International Standard does not apply to oxygen concentrators intended to supply gas to several patients via a piped medical gas installation or to those intended for use in the presence of flammable anaesthetic and/or cleaning agents.

The scope of this International Standard is not restricted to membrane oxygen concentrators and pressure swing absorbers (see Introduction), as alternative methods of concentrating oxygen may become available and it is not intended that this International Standard should restrict future developments.

1.2 Normative references

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

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility requirements and tests.*