AS ISO 10651.2—2004 ISO 10651-2:1996

Australian Standard<sup>™</sup>

Lung ventilators for medical use

Part 2: Particular requirements for home care ventilators



This Australian Standard was prepared by Committee HE-019, Anaesthetic and Breathing Equipment. It was approved on behalf of the Council of Standards Australia on 18 March 2004 and published on 3 May 2004.

The following are represented on Committee HE-019:

Australasian Society of Anaesthesia Paramedical Officers

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Industry Group

Australian Society of Anaesthetists

Australian and New Zealand College of Anaesthetists

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This Standard was issued in draft form for comment as DR 03504.

AS ISO 10651.2-2004

## Australian Standard<sup>™</sup>

### Lung ventilators for medical use

# Part 2: Particular requirements for home care ventilators

First published as AS ISO 10651.2-2004.

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Published by Standards Australia International Ltd GPO Box 5420, Sydney, NSW 2001, Australia ISBN 0 7337 5880 0 ii

### PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-019, Anaesthetic and Breathing Equipment. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 10651-2:1996, Lung ventilators for medical use, Part 2: Particular requirements for home care ventilators.

The objective of this Standard is to specify requirements for lung ventilators intended mainly for home care use but which could be used elsewhere (in hospitals) for appropriate patients in locations where the use of a ventilator complying with ISO 10651-1 is not required.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

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Reference to International or European Standard		Australian Standard		
ISO		AS ISO		
8185	Humidifiers for medical use—General requirements for humidification systems	8185	Humidifiers for medical use—General requirements for humidification systems	
9360	Anaesthetic and respiratory equipment—Heat and moisture exchangers for humidifying respired gases in humans	9360	Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans	
		9360.1	Part 1: HMEs for use with minimum tidal volumes of 250 ml	
		9360.2	Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml	
9703	Anaesthesia and respiratory care alarm signals	9703	Anaesthesia and respiratory care alarm signals	
9703-1	Part 1: Visual alarm signals	9703.1	Part 1: Visual alarm signals	
IEC		AS/NZS		
60601 60601-1	Medical electrical equipment Part 1: General requirements for safety	3200 3200.1	Medical electrical equipment 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	

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556	Sterilization of medical devices— Requirements for terminally sterilized medical devices to be labelled 'STERILE'	556 556.1	Sterilization of medical devices— Requirements for medical devices to be designated 'STERILE' Part 1: Requirements for terminally sterilized medical devices

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