AS ISO 10651.2—2004
ISO 10651-2:1996

Australian Standard™

Lung ventilators for medical use

Part 2: Particular requirements for home care ventilators

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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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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.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this part of ISO 10651' should read 'this Australian Standard'.

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References to International Standards and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

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	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1	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

EN		AS EN	
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled ‘STERILE’	556	Sterilization of medical devices—Requirements for medical devices to be designated ‘STERILE’
		556.1	Part 1: Requirements for terminally sterilized medical devices

Only international or European referenced documents that have been adopted as Australian or Australian/New Zealand Standards have been listed.