

Australian Standard™

Lung ventilators for medical use

Part 1: Requirements

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
Australian and New Zealand Intensive Care Society
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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 10651-1:1993, *Lung ventilators for medical use, Part 1: Requirements*.

The objective of this Standard is to specify requirements for lung ventilators intended for medical use.

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:

- Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- In the source text ‘this part of ISO 10651’ should read ‘this Australian Standard’.
- A full point substitutes for a comma when referring to a decimal number.

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

<i>Reference to International Standard</i>		<i>Australian Standard</i>	
ISO		AS/NZS	
8185	Humidifiers for medical use—Safety requirements	8185	Humidifiers for medical use—General requirements for humidification systems
9360	Anaesthetic and respiratory equipment—Heat and moisture exchangers for use in 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	3200.1.0	Part 1.0: General requirements for safety—Parent Standard

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

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AUSTRALIAN STANDARD

Lung ventilators for medical use —**Part 1:
Requirements****Section 1: General****1.1 Scope**

ISO 10651 is one of a series of International Standards based on IEC 601-1:1988. In IEC 601-1:1988 (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 601-1:1988.

This International Standard is a revision and amplification of IEC 601-2-12:1988, *Medical electrical equipment — Part 2: Particular requirements for the safety of lung ventilators for medical use*. It includes requirements from ISO 5369:1988 and replaces both documents.

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

This part of ISO 10651 specifies requirements for lung ventilators intended for medical use, excluding ventilators primarily intended for anaesthesia, home care, transport, and other devices such as jet and high-frequency ventilators.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10651. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10651 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 32:1977, *Gas cylinders for medical use — Marking for identification of content*.

ISO 1150:1979, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*.

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems*.

ISO 5362:1986, *Anaesthetic reservoir bags*.

ISO 5367:1991, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*.

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements*.

ISO 8185:1988, *Humidifiers for medical use — Safety requirements*.

ISO 9360:1992, *Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans*.

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