

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:

- (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’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

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 ISO	
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 4135:1979, *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*.

IEC 65:1985, *Safety requirements for mains operated electronic and related apparatus for household and similar general use*.

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

IEC 801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements*.

1.3 Definitions

For the purposes of this part of ISO 10651, the definitions given in clause 2 of IEC 601-1:1988 apply except that the definition given in 2.1.5 shall be replaced by the following¹⁾.

[2.1.5] **applied part:**¹⁾ All parts of the ventilator intended to be connected to the patient or to the breathing system.

For the purposes of this part of ISO 10651, the following additional definitions also apply.

1.3.1 bacterial filter: Device intended to reduce bacteria content and particulate matter content of the gas stream.

1.3.2 calibrated control: Control with numbered marks in which the numbers purport to indicate the value of the parameter being controlled, whether or not the control has been individually calibrated.

1.3.3 clearly legible: Visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions.

1.3.4 cycling pressure: Pressure in the ventilator breathing system which initiates an inspiratory or expiratory phase.

1.3.5 driving gas: Gas which powers the lung ventilator but is not necessarily delivered to the patient.

1.3.6 driving gas input port: Gas input port to which driving gas is supplied.

1.3.7 emergency air intake port: Dedicated gas intake port through which ambient air may be drawn when the supply of fresh and/or inflating gas is insufficient.

1.3.8 expired tidal volume: Volume of gas leaving the patient's lungs during an expiratory phase.

1.3.9 expiratory phase: Interval from the start of expiratory flow to the start of inspiratory flow.

1.3.10 flow-direction-sensitive component: Component through which the gas flow has to be in one direction only for its proper functioning and/or patient safety.

1.3.11 fresh gas: Gas supplied to the lung ventilator breathing system. It excludes the following:

- a) air drawn through the emergency air intake port;
- b) air drawn through leaks in the ventilator breathing system;
- c) expired gas from the patient.

1.3.12 fresh gas input port: Gas input port to which fresh gas is supplied.

NOTE 1 There may be more than one fresh gas input port.

1.3.13 fresh gas intake port: Gas intake port, other than the emergency air intake port, through which fresh gas may be drawn into the ventilator breathing system by the lung ventilator or the patient.

1.3.14 gas exhaust port: Port of the lung ventilator from which gas is discharged to the atmosphere either directly or via an anaesthetic gas scavenging system.

1.3.15 gas input port: Port to which gas is supplied under positive pressure and through which the gas is driven by this pressure.

NOTES

2 The gas may be supplied either at a controlled pressure and/or at a controlled flow.

3 c.f. gas intake port.

1.3.16 gas intake port: The port through which gas is drawn into the ventilator breathing system by the lung ventilator or the patient.

NOTES

4 Gas may be supplied to the port at or about ambient atmosphere or end-expiratory pressure, or the port may simply be left open to the atmosphere.

5 In a ventilator breathing system, energy is required to reduce the pressure below that of the atmosphere. Therefore, when gas is supplied at or about atmospheric pressure to a gas intake port, work has to be done, either by the lung ventilator (using energy from, for example, an electrical supply or a driving gas supply) or by the patient in order to lower the breathing system pressure suf-

1) See also annex L in this part of ISO 10651.

ficiently for gas to flow in through the gas intake port. In this sense, gas is "drawn" into the breathing system. A similar argument applies, even if gas is supplied to the gas intake port at a small positive pressure to compensate for the use of positive end-expiratory pressure.

1.3.17 gas output port: Port of a lung ventilator through which gas is delivered through a tube to the patient connection port.

1.3.18 gas return port: Port of the lung ventilator through which gas is returned at respiratory pressures through a tube from the patient connection port.

1.3.19 high pressure gas input port: Gas input port to which gas is supplied at a pressure greater than 100 kPa.

1.3.20 inflating gas: Fresh gas which powers the lung ventilator and is supplied to the patient.

1.3.21 inflating gas input port: Gas input port to which inflating gas is supplied.

1.3.22 inspiratory phase: Interval from the start of inspiratory flow to the start of expiratory flow.

1.3.23 low pressure gas input port: Gas input port to which gas is supplied at a pressure not exceeding 100 kPa.

1.3.24 lung ventilator: Any device which is intended to augment automatically or provide ventilation of the patient's lungs when connected to the patient's airway, referred to as a ventilator throughout this document.

1.3.25 manual ventilation port: Port of the ventilator to which a device may be connected for manual inflation of the lungs.

1.3.26 maximum limited pressure, $P_{lim,max}$: Highest pressure measured at the patient connection port which can be attained in the ventilation breathing system during malfunction of the ventilator but with a functioning safety mechanism.

NOTE 6 Components of a ventilator are operating normally when individually they operate as the manufacturer intended, even though particular combinations of settings of controls and of the compliance and resistance of the patient's respiratory tract may lead to an inappropriate pattern of ventilation.

1.3.27 maximum working pressure, $P_{w,max}$: Highest pressure which can be attained at the patient connection port during the inspiratory phase, irrespective of the setting of controls other than any control intended to adjust this pressure, with the ventilator working normally.

NOTE 7 Even if not adjustable, this maximum may be less than the maximum limited pressure.

1.3.28 minimum limited pressure, $P_{lim,min}$: Lowest (most negative) pressure measured at the patient connection port, which can be attained in the ventilator breathing system during malfunction of the ventilator but with a functioning safety mechanism.

NOTE 8 See note 6.

1.3.29 minimum working pressure, $P_{w,min}$: Lowest (most negative) pressure which can be attained at the patient connection port during the expiratory phase, irrespective of the setting of controls other than any control intended to adjust this pressure, with the ventilator working normally.

1.3.30 operator's position: Intended orientation of the operator with respect to the equipment for normal use according to the instructions for use.

1.3.31 patient connection port (of the ventilator breathing system): Port of the ventilator breathing system to which the patient may be connected.

1.3.32 triggering: Initiation of the inspiratory phase of the lung ventilator by the inspiratory effort of the patient.

1.3.33 ventilation, $\dot{V}$: Volume of gas per minute entering or leaving the patient's lungs.

1.3.34 ventilator breathing system (VBS): Breathing system bounded by the low pressure gas input port(s), the gas intake port(s) and the patient connection port together with the fresh gas inlet and exhaust port(s), if these are provided.

NOTES

9 Attention is drawn to the definition of a breathing system in ISO 4135.

10 Gas supplied to the ventilator at any gas input port may enter the ventilator breathing system at any point.

11 Valves may be placed anywhere in relation to ports and, indeed, anywhere in the ventilator breathing system, provided the requirements of this part of ISO 10651 are met.

1.4 General requirements

The general requirements given in clause 3 of IEC 601-1:1988 apply with the following addition:

3.6j) Applicable single fault conditions are short- and open-circuits of components of wiring which can

— cause sparks to occur, or

- increase the energy of sparks, or
- increase temperatures.

A single fault condition shall not cause a monitoring and/or alarm device as in 8.2 and 11.1, and the corresponding ventilation control function shall not fail in such a way that the monitoring function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored ventilator function.

Test for compliance by simulation of a single fault condition or by visual inspection.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply.

1.6 Classification

The classification given in clause 5 of IEC 601-1:1988 applies.

NOTE 12 A ventilator may have applied parts of different types.

1.7 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply except for the following additions and modifications.

a) Amend 6.1 e) as follows:

The address of the manufacturer and/or authorized representative, as applicable, shall also be marked.

b) Amend 6.1 j) as follows:

The power input marking shall be given in amperes for the ventilator and for the sum of the current ratings for the ventilator and auxiliary mains socket outlets.

c) Amend 6.1 k) as follows:

The requirement for marking of auxiliary mains socket outlets shall apply to each auxiliary mains socket outlet and the maximum allowed output shall be marked in amperes.

d) In 6.1, add the following items:

aa) All operator-accessible flow-direction-sensitive components, unless non-interchangeable, shall be permanently marked with a clearly legible arrow indicating the direction of flow.

ab) Any high pressure gas input port shall be marked in accordance with ISO 5359.

ac) If parts are marked, the following terms shall be used at least in the national language or English. Alternatively, symbols may be used and explained in the instructions for use:

- 1 Driving gas input port: "driving gas input"
- 2 Inflating gas input port: "inflating gas input" or "driving and fresh gas input", as appropriate
- 3 Fresh gas input port: "fresh gas"
- 4 Fresh gas intake port: "fresh gas intake"
- 5 Emergency air intake port: "WARNING: emergency air intake — do not obstruct"
- 6 Manual ventilation port: "bag"
- 7 Gas output port: "gas output"
- 8 Gas return port: "gas return"
- 9 Gas exhaust port: "exhaust". If the volume of gas discharged from the exhaust port is either more or less than the expired volume, additionally: "not for spirometer"

ad) A checklist indicating the procedures to be carried out by the user immediately before use shall be permanently attached to the ventilator. The use of electronic displays, e.g. a CRT, is permitted.

ae) If auxiliary mains socket outlet(s) can accept a mains plug, the auxiliary mains socket outlet(s) shall be marked with symbol 14 given in table D1 in Appendix D of IEC 601-1:1988.

af) If gas-specific colour coding of flow controls and flexible hoses is provided, it shall be in accordance with ISO 32.

ag) Packages containing breathing attachments intended for single use shall be clearly marked with the following:

- a) a description of the contents;
- b) the words "single patient use";

NOTE 13 Symbol No. 1051 given in ISO 7000 may additionally be used.

- c) the words "sterile" or "non-sterile", as applicable;