AS ISO 10651.3—2004
ISO 10651-3:1997

Australian Standard™

Lung ventilators for medical use

Part 3: Particular requirements for emergency and transport ventilators

STANDARDS AUSTRALIA

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.

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Australian Chamber of Commerce and Industry

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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 10651-3:1997, *Lung ventilators for medical use,* Part 3: *Particular requirements for emergency and transport ventilators*.

The objective of this Standard is to specify requirements for portable lung ventilators designed for use in emergency situations and transport (e.g. by ambulance or rescue personnel). It is also applicable to devices permanently mounted in ambulances or aircraft.

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:

Reference to International or European Standard		*Australian or Australian/New Zealand Standard*	
ISO		AS ISO	
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
9703-2	Part 2: Auditory alarm signals	9703.2	Part 2: Auditory alarm signals
IEC		AS	
60068	Environmental testing	60068	Environmental testing
60068-2-6	Part 2: Tests—Test Fc: Vibration (sinusoidal)	60068.2.6	Part 2: Tests—Test Fc: Vibration (sinusoidal)
60068-2-29	Part 2: Tests—Test Eb and guidance: Bump	60068.2.29	Part 2: Tests—Test Eb and guidance: Bump
60068-2-32	Part 2: Tests—Test Ed: Free fall	60068.2.32	Part 2: Tests—Test Ed: Free fall
		AS/NZS	
60079	Electrical apparatus for explosive gas atmospheres	60079	Electrical apparatus for explosive gas atmospheres
60079-4	Part 4: Method of test for ignition temperature	60079.4	Part 4: Method of test for ignition temperatures
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

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.

INTRODUCTION

This part of ISO 10651 specifies requirements for portable lung ventilators designed for use in emergency situations and transport. These devices must meet the definition of a lung ventilator (to automatically augment or provide ventilation of the patient's lungs), but will frequently be used outside the hospital or home by persons with different levels of training.

A rationale for the most important requirements is given in annex M.

AUSTRALIAN STANDARD

Lung ventilators for medical use —

Part 3:
Particular requirements for emergency and transport ventilators

Section 1: General

1.1 Scope

NOTE — See the rationale in annex M.

This part of ISO 10651 is one of a series of International Standards based on 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 part of ISO 10651 take precedence over those of IEC 601-1:1988. Where this part of ISO 10651 specifies that a clause of IEC 601-1 applies, it means that the clause applies only if the requirement is relevant to the ventilator under consideration.

This part of ISO 10651 has common requirements with IEC 601-2-12. It also includes requirements from ISO 10651-1:1993.

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 part of ISO 10651 specifies requirements for portable lung ventilators designed for use in emergency situations and transport. Emergency and transport ventilators, called hereafter "ventilator", are often installed in ambulances or other types of rescue vehicles, but are often used outside this environment, where they have to be carried by the operator or other persons. These devices will frequently be used outside the hospital or home by personnel with different levels of training. This part of ISO 10651 is also applicable to devices permanently mounted in ambulances or aircraft.
>
> This part of ISO 10651 does not cover operator-powered ventilators (i.e. manual resuscitators).

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.*

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