AS ISO 10651.2—2004
ISO 10651-2:1996

Australian Standard™

Lung ventilators for medical use

Part 2: Particular requirements for home care ventilators

currently in preview, click buy full version

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.

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

College of Biomedical Engineering Institution of Engineers Australia

Commonwealth Department of Health and Ageing

Department of Human Services (South Australia)

Health Department of Western Australia

Medical Industry Association of Australia Inc

NSW Health Department

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Web Shop at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

Australian Standards™ and other products and services developed by Standards Australia are published and distributed under contract by SAI Global, which operates the Standards Web Shop.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

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

currently in preview, click buy full version

Australian Standard™

Lung ventilators for medical use

Part 2: Particular requirements for home care ventilators

First published as AS ISO 10651.2—2004.

COPYRIGHT

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5880 0

currently in preview, click buy full version

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'.

(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 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

currently in preview, click buy full version

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.

urrently in preview, click buy full versi

INTRODUCTION

This part of ISO 10651 specifies 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. 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 in the home or elsewhere by persons with different levels of training. Devices intended solely to augment the ventilation of spontaneously breathing patients are excluded from the scope of this part of ISO 10651.

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

urrently in preview, click buy full versi

AUSTRALIAN STANDARD

Lung ventilators for medical use —

Part 2:
Particular requirements for home care 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 requirements are relevant to the ventilator under consideration.

This part of ISO 10651 has common requirements with IEC 601-2-12 (see annex P). It also includes requirements from ISO 10651-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply with the following addition:

> This part of ISO 10651 specifies 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.
>
> Devices intended solely to augment the ventilation of spontaneously breathing patients are excluded from this part of ISO 10651, as are cuirass ventilators which apply negative pressure to the chest wall.
>
> NOTE — Requirements for ventilators intended for anaesthetic application are given in ISO 8835-1.

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 listed 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 5356-1:—[1], *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.*

1) To be published. (Revision of ISO 5356-1:1987)

Currently in preview, click buy full version

© Standards Australia