

American National Standard



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

ANSI/AAMI/ ISO 10651- 4:2002

Lung ventilators—Part 4:
Particular requirements
for operator-powered
resuscitators



This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: 703-525-4890; Fax: 703-525-1067.

Printed in the United States of America

ISBN 1-57020-539-6

INTERNATIONAL
STANDARD

AAMI

Advancing Safety in Medical Technology

**ANSI/ISO
10651-4**

First edition
2002-03-01

Lung ventilators —

Part 4:

**Particular requirements for operator-powered
resuscitators**

Ventilateurs pulmonaires —

Partie 4 : Exigences relatives aux ressuscitateurs à puissance motrice manuelle

This is a preview copy of the document. It is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

ANSI/ISO 10651-4

MOD in ANSI/ISO 10651-4 means that ASTM International has approved the standard as an American National Standard with deviations. The U.S. deviations are appended to the end of ANSI/ISO 10651-4.



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

These materials are subject to copyright claims of ASTM International. Not for resale without the prior written permission of ASTM International. No part of this publication may be reproduced in any form, including an electronic retrieval system, without the prior written permission of ASTM International.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 10651 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10651-4 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee SC 3, Lung ventilators and related equipment, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

ISO 10651 consists of the following parts, under the general title Lung ventilators:

- Part 1: Requirements
- Part 2: Particular requirements for home care ventilators
- Part 3: Particular requirements for emergency and transport ventilators
- Part 4: Particular requirements for operator-powered resuscitators

Annex A forms a normative part of this part of ISO 10651. Annex B is for information only.

For the purposes of this part of ISO 10651, the CEN annex regarding fulfilment of European Council Directives has been removed.

Contents

	Page
Foreword.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Connectors	3
5 Operational requirements	3
6 Ventilatory requirements.....	4
7 Storage and operating conditions.....	6
8 Requirements for resuscitator, or parts, supplied sterile	6
9 Marking	6
10 Information to be provided by the manufacturer in operating and maintenance instructions	7
Annex A (normative) Test methods.....	9
Annex B (informative) Rationale.....	19
Bibliography.....	22

For a complete copy of this AAMI document, contact AAMI at
+1-877-249-8226 or visit www.aami.org.

Foreword

This document (EN ISO 10651-4:2002) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Annex A is normative and form part of this European Standard.

Annex B is for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard : Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

1 Scope

This European Standard specifies requirements for operator-powered resuscitators intended for use with all age groups and which are portable and intended to provide lung ventilation to individuals whose breathing is inadequate. Operator-powered resuscitators for infants and children are designated according to body mass range and approximate age equivalent.

Electrically-and gas-powered resuscitators are not covered by this European Standard.

NOTE Annex B contains rationale statements for this Part of this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with **R** after their number.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 148-1, Respiratory protective devices - Threads for facepieces –Part 1: Standard thread connection.

EN 556: 1994+A1:1998, Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "STERILE".

EN 737-1, Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum.

EN 868-1, Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods.

EN 1041, Information supplied by the manufacturer with medical devices.

EN 1281-1, Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.

prEN 13544-2:2000, Respiratory therapy equipment – Part 2 : Specifications for tubing and connectors.

EN ISO 4135:1996, Anaesthesiology – Vocabulary (ISO 4135 :1995).

3 Terms and definitions

For the purposes of this part of EN ISO 10651, the terms and definitions given in EN ISO 4135:1996 and the following terms and definitions apply.

NOTE Some of the definitions have been taken from EN ISO 4135, but they are included in this European Standard for convenience; other definitions, which are given in EN ISO 4135, for apparatus in general, have been modified slightly for the purposes of this European Standard as they apply specifically to resuscitators.

3.1 reverse leakage

volume of expired gas which does not pass through the expiratory port but returns to the resuscitator

3.2 bag inlet valve

valve activated by the subatmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit with gas at ambient pressure

3.3 bag refill valve

valve, with no manual trigger, activated by the sub-atmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit from a pressurized gas source