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Standard



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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.

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STANDARD**

**ANSI/ISO
10651-4**

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Lung ventilators —

Part 4:

**Particular requirements for operator-powered
resuscitators**

Ventilateurs pulmonaires —

Partie 4 : Exigences relatives aux ressuscitateurs à puissance motrice manuelle

ANSI/ISO 10651-4

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Foreword

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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.

ANSI/ISO 10651-4

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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.

Approved as an American National Standard with deviations by ASTM International

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