AS ISO 10651.4—2004
ISO 10651-4:2002



Australian Standard™

# Lung ventilators for medical use

## Part 4: Particular requirements for operator-powered resuscitators

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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# 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 10651-4:2002, *Lung ventilators,* Part 4: *Particular requirements for operator-powered resuscitators.* ISO 10651-4 was prepared by the European Committee for Standardization (CEN) Technical Committee TC 215, Respiratory and anaesthetic equipment, in collaboration with ISO Technical Committee TC 121, Anaesthetic and respiratory equipment, in accordance with the Vienna Agreement on technical cooperation between ISO and CEN.

The objective of this Standard is to specify 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.

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from a European 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.

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References to International Standards and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

| *Reference to European Standard* | | *Australian Standard* | |
|---|---|---|---|
| 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 Standards have been listed.

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NOTES

# Lung ventilators

## Part 4: Particular requirements for operator-powered resuscitators

### 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

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