INTERNATIONAL STANDARD

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

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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

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.

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

3.4
compressible unit
that part of an operator-powered resuscitator e.g. a bag or bellows that, when compressed by the operator, delivers a volume of gas

3.5
delivered oxygen concentration
average concentration of oxygen in the gas delivered from the resuscitator

3.6
delivered volume, V_{del}
volume of gas, expressed in millilitres, leaving the resuscitator through the patient connection port during the inspiratory phase

3.7
forward leakage
volume of gas produced by the resuscitator during the inspiratory phase which does not pass through the patient port to the patient but passes to the atmosphere

3.8
minute volume, $\dot{V}$
volume of gas per minute entering or leaving the patient's lungs

3.9
operator-powered resuscitator
resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device

NOTE Hereinafter called "resuscitator".

3.10
patient connection port
that opening through which gas flows to and from the patient

3.11
patient connection port connector
connector at the patient connection port which connects directly to a face mask or an appropriate mating airway device

3.12
patient valve
valve in the breathing system that directs gas into the lungs for the inspiratory phase and into the atmosphere during the expiratory phase

3.13
pressure limiting system
means for limiting the maximum delivery pressure

3.14
resuscitator deadspace, $V_{D,app}$
that volume of previously exhaled gas which is delivered from the resuscitator in the succeeding inspiratory phase

3.15
tidal volume, V_T
volume of gas, expressed in millilitres, entering or leaving the patient or the lung model during the inspiratory or expiratory phase

3.16
ventilatory cycle
ventilation cycle comprising the inspiratory phase plus the expiratory phase of breathing

4 Connectors

4.1 Patient connection port connector

The patient connection port connector of the resuscitator shall be a 15 mm female and 22 mm male coaxial connector complying with EN 1281-1.

4.2 *R*) Expiratory port connector for breathing gases

If an expiratory port connector is provided, it shall be one of the following :

a) a 30 mm male conical connector complying with EN 1281-1 or ;

b) a permanent connection or propriatory connector incompatible with EN 1281-1 and EN 737-1 ;

and with a means to prevent connection with internal lumen to any breathing attachment.

4.3 Face mask connectors

If provided with the resuscitator, face masks shall have either a 22 mm female connector or a 15 mm male connector which shall mate with the corresponding connectors specified in EN 1281-1.

4.4 *R*) Bag refill valve connectors

If a conical connector is provided for attachment of a bag refill valve, it shall be a unique 32 mm female design. The dimensions of this connector, when submitted to the test gauge given in Figure A.1, shall fit within the tolerance steps.

4.5 Bag inlet valve connectors

Bag inlet valve connectors shall not be compatible with connectors dimensioned in accordance with EN 1281-1. The bag inlet valve should be designed to minimize the risk of unintentional connection of breathing attachments which might block the valve

4.6 Threaded gas filter connectors

If the resuscitator is fitted with a threaded gas filter connection, it shall comply with EN 148-1.

4.7 Oxygen tube connector and pressure gauge connector

The oxygen tube connector, if provided, shall comply with prEN 13544-2:2000. The pressure gauge connector (if provided) shall not be compatible with tubing fitting the oxygen tube connector.

5 Operational requirements

5.1 General

All test performance requirements in this European Standard shall be satisfied when the resuscitator is operated by one person.

5.2 *R*) Dismantling and reassembly

A resuscitator intended to be dismantled by the user, e.g. for cleaning, etc. should be designed so as to minimize the risk of incorrect reassembly when all parts are mated.

The manufacturer shall recommend a functional test of operation to be carried out after reassembly (see 10.2d)).

5.3 *R*) Patient valve function after contamination with vomitus

After the resuscitator has been tested in accordance with the test described in A.4.3, it shall meet the requirements specified in 6.2, 6.4, 6.7.1 and 6.7.2.

NOTE It is preferable that the valve housing be constructed so that operation of the mechanism can be observed by the operator, e.g. through a transparent housing. Observation of the functioning mechanism of the patient valve can assist the operator in detecting abnormal operation.

5.4 Mechanical shock

5.4.1 *R*) Drop test

The resuscitator shall meet, at room temperature, the requirements specified in 6.2, 6.4 and 6.7.1, following the drop test described in A.4.4.

5.5 Immersion in water

After immersion in water by the method described in A.4.5, the resuscitator shall comply with the requirements specified in 6.2, 6.4, 6.7.1 and 6.7.2.

5.6 *R*) Bag refill valves

Bag refill valves for use with resuscitators shall not have provision for manual operation.

5.7 Materials of construction

All gas conducting parts shall be from materials selected to take into account the chemical and physical properties of any substances that the manufacturer declares can be administered by the resuscitator

6 Ventilatory requirements

6.1 *R*) Supplementary oxygen and delivered oxygen concentration

When tested by the method described in A.4.6 in accordance with the requirements of its classification (see 6.7.1) a resuscitator shall provide a minimum delivered oxygen concentration of at least 35 % (*V/V*) when connected to an oxygen source supplying not more than 15 l/min and, in addition, shall be capable of providing an oxygen concentration of at least 85 % (*V/V*) (see note). The manufacturer shall state the range of delivered oxygen concentrations at representative flows, i.e. 2 l/min, 4 l/min, 6 l/min, 8 l/min, etc.

NOTE The 85 % (*V/V*) requirement can be accomplished with the use of an attachment.

6.2 *R*) Expiratory resistance

In the absence of positive end-expiratory pressure devices, and when tested by the method described in A.4.7, the pressure generated at the patient connection port shall not exceed 0,5 kPa (≈ 5 cmH_20). (See also 10.2 c) 8)).

6.3 *R*) Inspiratory resistance

When tested by the method described in A.4.8, the pressure at the patient connection port shall not exceed 0,5 kPa (≈ 5 cmH_20) below atmospheric pressure. (See also 10.2 c) 8)).

6.4 *R*) Patient valve malfunction

When tested by the method described in A.4.9, an inadvertent positive expiratory pressure greater than 0,6 kPa (≈ 6 cmH_2O) shall not be created at an added input flow of up to 30 l/min when this flow is added in accordance with the manufacturer's instructions.

6.5 *R*) Patient valve leakage - Forward leakage

If forward leakage is a design feature, it shall be so stated in the instruction manual.

6.6 *R*) Resuscitator deadspace and rebreathing

When tested by the method described in A.4.10, the resuscitator deadspace shall not exceed 5 ml + 10 % of the minimal delivered volume specified for the classification of the resuscitator (see 6.7.1).

Excessive rebreathing should not occur during spontaneous breathing.

6.7 *R*) Ventilation performance

6.7.1 *R*) Minimum delivered volume (V_{del})

When tested as described in A.4.11 using the compliance, resistance, frequency and I:E ratio given in Table 1, the minimum delivered volume shall be as given in Table 1.

6.7.2 *R*) Pressure limitation

6.7.2.1 For resuscitators designated for use with a body mass less than 10 kg, a pressure-limiting system shall be provided so that the airway pressure does not exceed 4,5 kPa (≈ 45 cmH_20) under the test conditions described in A.4.12. However, it shall be possible to generate an airway pressure of at least 3 kPa (≈ 30 cm H_2O).

NOTE An override mechanism can be provided.

6.7.2.2 If a pressure-limiting system is provided for a resuscitator designated for use with patients of over 10 kg body mass, the pressure at which it operates shall be stated in the instruction manual [see 10.2 c)9)]. Any pressure-limiting device provided that limits pressure to below 6 kPa (≈ 60 cmH_20) shall be equipped with an override mechanism. If provided with a locking mechanism, pressure override mechanisms shall be so designed that the operating mode, i.e. on or off, is readily apparent to the user by obvious control position, flag, etc.

Compliance is tested by visual inspection.

Table 1 — Test conditions for ventilatory performance

Patient Body mass B[a]	Compliance	Resistance	Inspiration: Expiration ratio	Frequency f Breaths/min	Minimum delivered volume V_{Del}
Kg	l/kPa	kPa/(l/s)	± 20 %	± 10 %	ml
B ≤ 5	0,01	40	1:1	60	20
5 < B ≤ 10	0,1	2	1:2	25	150
10 < B ≤ 40	0,2	2	1:2	20	15 × B[1)]
B > 40	0,2	2	1:2	20	600

[a] B = Body mass, in kilograms, designated by the manufacturer in the manual.

7 Storage and operating conditions

7.1 Storage

The resuscitator and the resuscitator kit (if provided) shall, after storage at temperatures of - 40 °C and + 60 °C and at any relative humidity between 40 % r.h. and 95 % r.h., comply with clause 6 except 6.6 (deadspace).

7.2 *R*) Operating conditions

When tested by the method described in A.4.13, the resuscitator shall comply with clause 6 throughout the range of relative humidity from 15 % r.h. to 95 % r.h either :

— throughout the temperature range from - 18 °C to + 50 °C ; or

— if a specific operating range is given (see 9.2 and 10) throughout the temperature range declared by the manufacturer.

8 Requirements for resuscitator, or parts, supplied sterile

8.1 Sterility assurance

Resuscitators or parts supplied and marked as “STERILE” shall satisfy requirement 4.1 of EN 556:1994+A1:1998 for the assurance of sterility needed to make the claim of being sterile.

8.2 Packaging for resuscitators or parts supplied sterile

The packaging shall serve as an effective barrier to the penetration of micro-organisms and particulate material in accordance with EN 868-1.

The packaging shall not be capable of reclosure without clearly revealing that it has been opened.

9 Marking

9.1 General

Marking of resuscitators, or parts if applicable, packages, inserts and information to be supplied by the manufacturer shall comply with EN 1041.

NOTE Some requirements of 9 can be met by the use of appropriate symbols as given in EN 980.