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Resuscitators intended for use with humans

Ressuscitateurs destinés aux êtres humains

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8382 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

Annexes A and B form an integral part of this International Standard. Annexes C, D and E are for information only.

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Introduction

This International Standard applies to ventilatory resuscitators, i.e. small portable ventilators intended to be used in emergencies both outside and inside hospitals. These devices are intended for use by medical personnel and for emergency use by personnel with very limited training. They are intended to be used at the site of an emergency and during patient transport.

The effective and safe use of a resuscitator is determined not only by the performance of the resuscitator, but also by the skill of the operator. This International Standard does not describe the content of the training programmes to develop such skill and does not state who should or should not use a resuscitator. This will be determined by the organizations involved in teaching resuscitation.

In certain countries, resuscitators are intended for use by non-trained personnel and lower pressure limits are set. Some countries also reserve the use of automatic gas-powered resuscitators to trained individuals under medical supervision. This International Standard is not intended to conflict with these established practices.

Annex A details test methods, while annex B provides tables of resistances and compliances required to set up the test lung. Annex C gives a rationale for various clauses in this International Standard and is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been given. Annexes D and E provide advice concerning materials to be used in resuscitators and face masks.

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Resuscitators intended for use with humans

1 Scope

This International Standard specifies minimum performance and safety requirements for ventilatory resuscitators intended for use with all age groups. It specifies the performance of operator-powered and gas-powered ventilatory resuscitators which are portable and intended for use in emergency situations to provide lung ventilation to individuals whose breathing is inadequate. For gas-powered resuscitators, requirements are included for the gas supply. Resuscitators for infants and children are designated according to body mass range and approximate age equivalent.

Devices which have been designed only to deliver gases to a patient breathing adequately and devices which are intended to assist or provide for the ventilation of a patient for an extended period of time are not covered by this International Standard.

Electrically-powered resuscitators are not covered by this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 407 : 1983, *Small medical gas cylinders — Yoke-type valve connections*.

ISO 5356-1 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5359 : —¹⁾, *Low-pressure flexible connecting assemblies for use with medical gas systems*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

NOTE — Some of the definitions have been taken from ISO 4135²⁾, but they are included in this International Standard for convenience; other definitions, which are given in ISO 4135, for apparatus in general have been modified slightly for the purposes of this International Standard as they apply specifically to resuscitators.

3.1 resuscitator: Portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate.

3.2 compliance, C : Volume change of the gases in the compartment produced by a unit pressure change, expressed in litres per kilopascal (l/kPa).

3.3 resistance, R : Pressure drop per unit of flow at a specified flow, expressed in kilopascals per litre per second [kPa/(l/s)].

NOTE — According to conventional practice, this has generally been expressed in centimetres of water per litre per second³⁾ [cmH₂O/(l/s)].

3.4 ventilatory cycle: Cycle comprising the inspiratory phase plus the expiratory phase.

3.5 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 time.

NOTE — The physical conditions under which gas volumes are measured should be given.

3.6 minute volume, \dot{V} : Volume of gas, expressed in litres per minute, entering or leaving the patient or the lung model.

NOTE — The physical conditions under which measurements are made should be given.

1) To be published.

2) ISO 4135 : 1979, *Anaesthesiology — Vocabulary*.

3) For the purposes of this International Standard fluid pressure is expressed in kilopascals; however, approximate conversion values are given in parentheses in conventional centimetres of water. Although the unit "mmH₂O" (and hence also "cmH₂O") is deprecated in ISO 31-3, values are given in this unit throughout this International Standard since it is widely used in practice.

3.7 stroke volume: Volume of gas deliverable from the resuscitator to the end of the patient connector during an inspiratory phase of the ventilatory cycle.

3.8 airway: Passageway for gas into and out of the lungs.

3.9 infant: Individual weighing up to 10 kg, or being approximately one year of age.

3.10 bag inlet valve: Valve activated by the sub-atmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit with gas at ambient pressure.

3.11 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 compressed gas source.

3.12 demand [intermittent flow] apparatus: Device delivering a flow of gas, patient-triggered, during inspiration only at ambient pressure (or at respiratory pressure).

3.13 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.

3.14 patient connector: That part of the resuscitator which connects directly to a face mask or an appropriate mating airway device.

3.15 patient connection port: That opening at the patient end of an expiratory valve unit; a Y-piece fitting or a unidirectional valve to which may be connected either a tracheal tube or a face mask angle piece.

3.16 expiratory port: Opening through which gases and/or vapours pass from the patient during expiration.

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

3.18 delivered oxygen concentration: Average concentration of oxygen in the gas delivered from the resuscitator.

3.19 apparatus deadspace, $V_{D,app}$: That volume of previously exhaled gas which is delivered from the resuscitator in the succeeding inspiratory phase.

3.20 operator-powered resuscitator: Resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device.

3.21 gas-powered resuscitator: Resuscitator powered by the energy of compressed gas.

3.22 manually cycled, gas-powered resuscitator: Operator-activated resuscitator whereby the work of resusci-

tion is accomplished by the energy of compressed gas and not the operator.

3.23 automatic resuscitator: Resuscitator in which the cyclic flow of gas for inflation of the lungs is independent of any inspiratory effort of the patient or repetitive action of the operator.

NOTE — The expiratory phase may also be automatically cycled.

3.24 back leak: Volume of expired gas which does not pass through the expiratory port but returns to the resuscitator.

3.25 forward leak: 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.

3.26 maximum delivery pressure: Highest gauge pressure that can be attained at the patient connection port when the apparatus is functioning normally.

3.27 ventilatory frequency, f : Number of ventilatory cycles per minute.

NOTE — This definition differs from the one given in ISO 4135 because it refers to the number of ventilatory cycles of the resuscitator, not the patient breaths.

3.28 pressure limiting system: Mechanism for limiting the maximum delivery pressure.

4 Symbols

In addition to the symbols given in clause 3, the following symbols are used in this International Standard:

System deadspace: $V_{D,system}$

Oxygen concentration in bag: $F_{O_2,bag}$

5 Connectors

5.1 Patient connection port (see also annex C)

The patient connection port of the resuscitator shall have 15 mm female and 22 mm male coaxial connectors with dimensions in accordance with ISO 5356-1.

5.2 Expiratory port for breathing gases

(see also annex C)

If a tapered connector is provided at the expiratory port, it shall be a 30 mm male conical connector or a 19 mm male conical connector in accordance with ISO 5356-1.

The connector shall incorporate a baulk, e.g. ridges in the internal lumen of the connector, so that it cannot accept a 22 mm male conical connector as specified in ISO 5356-1.

NOTE — Such a baulk should not significantly increase the resistance to gas flow through the connector.

5.3 Face mask connectors (see also annex C)

If provided with the resuscitator, face masks shall have either a 22 mm female connector or a 15 mm male connector which will mate with the corresponding connectors specified in ISO 5356-1.

5.4 Bag refill valve connectors (see also annex C)

If a conical connector is provided at the inlet port for the attachment of a bag refill valve, it shall be a 32 mm female conical connector providing a secure fit with the gauges shown in figure A.1.

5.5 Bag inlet valve connectors

Bag inlet valve connectors shall not be compatible with connectors dimensioned in accordance with ISO 5356-1.

NOTE — For resuscitators intended for use in hazardous environments, attention is drawn to CEN 148, a draft standard on threaded gas filter connections.

6 Operational requirements

6.1 General

Ideally, patient respiration through the resuscitator, that is, through connectors, the bag for hand-powered resuscitators and any filtration apparatus should be obtained within the inspiratory and expiratory resistance requirements given in this International Standard. All performance requirements in this International Standard should be satisfied when the resuscitator is operated by one person, since frequently only one person will be available to operate the resuscitator. This should be attainable when the resuscitator is used with either a face mask or an artificial airway device.

6.2 Dismantling and reassembly (see also annex C)

The manufacturer shall recommend a functional test of operation to be carried out after reassembly [see 11.3.2d)].

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

6.3 Patient valve function after contamination with vomitus (see also annex C)

After the resuscitator has been tested in accordance with the test described in A.5.3, it shall meet the requirements specified in 8.3, 8.5, 8.8.1, 8.8.2, 8.9, 8.10.1, 8.10.2 and 8.10.3, as appropriate.

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

6.4 Mechanical shock

6.4.1 Drop test (see also annex C)

If the resuscitator is intended to be operated outside of its carrying case, plastic bag, mounting bracket, etc., it shall meet the requirements specified in 8.3, 8.5, 8.8.1, 8.9, 8.10.1, 8.10.2 and 8.10.3 as appropriate, following the drop test described in A.5.4. If the resuscitator is intended for operation only inside its carrying case, it may be so tested, but the case shall be open and in its "ready-for-use" condition.

6.4.2 Mechanical shock test for resuscitator fixtures that are mounted on castors or on wheels (see also annex C)

The resuscitator shall meet the requirements specified in 8.3, 8.5, 8.8.1, 8.8.2, 8.9, 8.10.1, 8.10.2 and 8.10.3, as appropriate, after being tipped over from its normal operating position onto a concrete floor as described in A.5.5.

6.5 Immersion in water (see also annex C)

After immersion in water by the method described in A.5.6, the resuscitator shall comply with the requirements specified in 8.3, 8.5, 8.8.1, 8.8.2, 8.9, 8.10.1, 8.10.2 and 8.10.3, as appropriate.

6.6 Bag refill valves (see also annex C)

Bag refill valves for use with operator-powered resuscitators shall not have provisions for manual operation.

7 Physical requirements

7.1 Size (see also annex C)

The resuscitator, with a container, if provided, shall pass through a rectangular opening 300 mm × 600 mm in size.

7.2 Resuscitator mass

Except for gas-powered resuscitators designed to be an integral part of a neonatal critical care system, the mass of the resuscitator container and contents (including any full gas cylinders) shall not exceed 18 kg.

8 Performance

8.1 Supplementary oxygen and delivered oxygen concentration

8.1.1 Operator-powered resuscitators (see also annex C)

When tested by the method described in A.5.7 in accordance with the requirements of its classification (see 8.8.1), an operator-powered resuscitator shall deliver a minimum oxygen concentration of at least 40 % (V/V) when connected to an oxygen source supplying not more than 15 l/min, and shall be capable of delivering at least 85 % (V/V) (see note). The manufacturer shall state the range of concentrations at representative flows, e.g. 2 l/min, 4 l/min, 6 l/min, 8 l/min,

etc. If the resuscitator is intended to be hand-operated, only one hand shall be used to compress the compressible unit, and the hand of the person carrying out the test shall not exceed the dimensions given in figure A.2.

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

8.1.2 Gas-powered resuscitators (see also annex C)

When tested by the method described in A.5.8, a gas-powered resuscitator shall deliver an oxygen concentration of at least 85 % (V/V). If the resuscitator is capable of delivering other oxygen concentrations, the manufacturer shall state the conditions under which the various concentrations may be delivered.

8.2 Resistance to inspiration and expiration

See the requirement for information to be provided by the manufacturer under 11.3.2c)10).

8.3 Expiratory resistance (see also annex C)

In the absence of positive end-expiratory devices, and when tested by the method described in A.5.9, the pressure generated at the patient connection port shall not exceed 0,5 kPa (\approx 5 cmH₂O). [See also 11.3.2c)11).]

8.4 Inspiratory resistance (see also annex C)

When tested by the method described in A.5.10, the pressure at the patient connection port shall not exceed 0,5 kPa (\approx 5 cmH₂O) below atmospheric pressure. [See also 11.3.2c)11).]

8.5 Patient valve malfunction (see also annex B)

When tested by the method described in A.5.11, the patient valve of the resuscitator shall not jam in the inspiratory position at an added input flow of up to 30 l/min when this flow is added in accordance with the manufacturer's instructions.

8.6 Patient valve leakage — Forward leakage (see also annex C)

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

8.7 Apparatus deadspace (see also annex C)

When tested by the method described in A.5.12, the apparatus deadspace shall not exceed 5 ml + 10 % of the tidal volume specified for the classification of the resuscitator (see 8.8.1).

8.8 Ventilation performance

8.8.1 Tidal volume (see also annex C)

Resuscitators intended for use with infants and children up to 40 kg body mass shall be classified according to the body mass range for which they are suitable. This body mass range shall be derived from a requirement for a tidal volume of 15 ml/kg body mass.

Resuscitators delivering a tidal volume of 600 ml and over shall be classified as adult resuscitators.

The tidal volumes specified shall be delivered under the test conditions listed in table 1 using the methods described in A.5.13, without the use of the override mechanism on any pressure-limiting system.

NOTE — Resuscitators designed to deliver a tidal volume of 20 ml to 50 ml are usually suitable for use with neonates.

8.8.2 Pressure limitation (operator-powered resuscitators) (see also annex C)

8.8.2.1 For resuscitators classified for use with neonates and infants, a pressure-limiting system shall be provided so that the airway pressure does not exceed 4,5 kPa (\approx 45 cmH₂O) under the test conditions described in A.5.15.

NOTE — An override mechanism may be provided.

8.8.2.2 If a pressure-limiting system is provided for a resuscitator classified for use with patients of over 10 kg body mass, the pressure at which it operates shall be stated in the instruction manual [see 11.3.2c)12)]. Any pressure-limiting device provided that limits pressure to below 6 kPa (\approx 60 cmH₂O) 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.

Table 1 — Test conditions

| Classification kg | Compliance l/kPa | Resistance kPa/(l/s) | Inspiration : expiration ratio ± 20 % | Frequency <i>f</i> ± 10 % | Tidal volume <i>V_T</i> ml |
|----------------------|---------------------|-------------------------|--|---------------------------------|---|
| ≤ 5 | 0,01 | 40 | 1 : 1 | 60 | 20 |
| > 5 ≤ 10 | 0,1 | 2 | 1 : 2 | 25 | 150 |
| > 10 ≤ 40 | 0,2 | 2 | 1 : 2 | 20 | 15 × B ¹⁾ |
| > 40 | 0,2 | 2 | 1 : 2 | 20 | ≥ 600 |

1) Body mass, in kilograms, stated by the manufacturer in the manual.

on or off, is readily apparent to the user by obvious control position, flag, etc.

NOTE — If the resuscitator is equipped with a pressure-limiting system, there should be an audible or visible warning to the operator when the pressure-limiting system is operating.

8.9 Gas-powered resuscitators

8.9.1 Pressure-limiting system (see also annex C)

A pressure-limiting system shall be incorporated in gas-powered resuscitators. When the resuscitator is supplied with gas at the range of pressures specified in 10.5, the airway pressure shall not exceed 6 kPa (≈ 60 cmH₂O). An override mechanism shall be provided to enable the operator to select a higher pressure. However, automatic, pressure-cycled, gas-powered resuscitators shall not be equipped with any type of 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.

NOTES

1 A setting for the pressure-limiting system higher than 6 kPa (≈ 60 cmH₂O) may be made available for certain patients, although the selection of such a setting requires medical advice.

2 There should be an audible or visible warning to the operator when the pressure-limiting system is operating.

8.9.2 Inspiratory flow

All gas-powered resuscitators shall be capable of delivering 40 l/min ± 10 % inspiratory flow against a back pressure of 2 kPa (≈ 20 cmH₂O) when tested by the method described in A.5.14.

NOTE — Devices with fixed flows should be set to this value. Devices with operator-adjustable flows should include this value in their range of adjustment.

8.9.3 Manually cycled, gas-powered resuscitators

Manually cycled gas-powered resuscitators shall meet the requirements specified in 8.1.2, 8.9.1 and 8.9.2, when tested by the methods described in A.5.8, A.5.13, A.5.14 and A.5.16.

8.9.4 Automatic pressure-cycled, gas-powered resuscitators

Automatic pressure-cycled resuscitators shall have positive cycling pressures in the range of 2 kPa to 3 kPa (≈ 20 cmH₂O to ≈ 30 cmH₂O) when tested by the method described in A.5.17. (See also 11.1.1.)

NOTE — A negative-pressure phase may cause a decrease in arterial oxygen partial pressure (p_{O_2}) or Functional Residual Capacity (FRC).

8.9.5 Automatic time-cycled, gas-powered resuscitators

Automatic time-cycled, gas-powered resuscitators shall meet the requirements specified in 8.1.2, 8.8.1, 8.9.1 and 8.9.2,

when tested by the methods described in A.5.8, A.5.13, A.5.14 and A.5.16.

8.9.6 Volume-cycled, gas-powered resuscitators

Volume-cycled, gas-powered resuscitators shall meet the requirements specified in 8.1.2, 8.8.1, 8.9.1 and 8.9.2, when tested by the methods described in A.5.8, A.5.13, A.5.14 and A.5.16.

8.10 Demand valves

NOTE — These devices are subject to the requirements of this International Standard only when included as an integral part of a resuscitator.

8.10.1 Pressure for initiation (see also annex C)

When tested by the method described in A.5.18.1, the pressure drop needed to initiate gas flow shall be no more than a negative 0,2 kPa (≈ 2 cmH₂O).

8.10.2 Peak inspiratory flow (see also annex C)

When tested by the method described in A.5.18.2, the minimum peak inspiratory flow shall be 100 l/min for at least 10 s, at an outlet pressure of no more than 0,8 kPa (≈ 8 cmH₂O).

8.10.3 Termination pressure (see also annex C)

Demand flow shall terminate either when the negative input pressure equals atmospheric pressure or at a pressure stated by the manufacturer, when tested by the method described in A.5.18.3.

9 Resistance to environment

9.1 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 % and 95 % meet the general requirements and the specific requirements for the category of resuscitator being tested, i.e. operator-powered or gas-powered, etc., specified in clause 8.

9.2 Operating conditions (see also annex C)

When tested by the method described in A.5.19, the resuscitator shall meet the general requirements and the specific requirements for the category of resuscitator being tested, specified in clause 8, throughout the temperature range from -18 °C to $+50$ °C and a humidity range from 40 % r.h. to 95 % r.h.

10 Gas supply

10.1 Gas cylinders, cylinder valves and yoke connections

If provided, gas cylinders, cylinder valves and yoke connections of the pin index type shall meet the requirements given in ISO 407.

NOTE — Small cylinders with special fittings are frequently used in special situations.

10.2 Indication of contents

Each gas supplied at cylinder pressure shall be monitored by a cylinder pressure gauge or contents indicator.

10.3 Captive valve key

If detachable, the hand wheel, key or other device shall be made captive by means of a retaining chain or similar attachment capable of withstanding a static load of not less than 200 N (20 kg) without breaking.

10.4 Connections for compressed gas (see also annex C)

Gas connections between different gas services shall be non-interchangeable and shall not allow parts of the resuscitator to be incorrectly connected. If the device has a threaded connection, it shall meet the requirements given in ISO 5359.

NOTE — If provided, a press-fit connection should give an easy and reliable connection with 6 mm inside diameter elastomeric tubing.

10.5 Supply pressures (see also annex C)

When supplied with gas at a pressure between 270 kPa and 550 kPa [see 11.3.2n)], the resuscitator shall meet the general requirements and any specific requirements for the type of resuscitator being tested, i.e. automatically or manually cycled, specified in clause 8. Testing shall be as described in A.5.20.

11 Information to be supplied by manufacturer

11.1 Marking

11.1.1 Manufacturer's warning (see also annex C)

For automatic pressure-cycled, gas-powered resuscitators, the manufacturer shall provide a warning on the resuscitator and the resuscitator case, and in the instructions for use that the unit is not designed to be used with closed-chest cardiac compression.

NOTE — Where possible, simple operating instructions should be provided on the resuscitator or the container.

11.1.2 Range of supply pressures

The range of supply pressures through which the resuscitator will operate shall be marked on the resuscitator.

11.1.3 Gas source for spontaneously breathing patients

If supplied, the gas source supplying a spontaneously breathing patient, if it is other than the reservoir, shall be indicated on the resuscitator.

11.1.4 Indication of pressure-limiting system setting

If the resuscitator is supplied with a pressure-limiting system set at one fixed pressure, the nominal pressure setting at which the system is activated shall be marked on the resuscitator.

11.2 Training

The instructions provided shall include a warning that the unit must only be used by persons who have received adequate training in resuscitation techniques.

11.3 Information to be provided by manufacturer in operating and maintenance instructions

11.3.1 General

The manufacturer shall provide instructions for use and maintenance instructions. The size and shape of this (these) manual(s) shall be such that it (they) may be enclosed within or attached to the resuscitator container. The instructions for use shall state that additional copies are available on request from the manufacturer.

11.3.2 Contents

The manual shall be divided into sections to facilitate understanding of the instructions and shall include the following information:

- a) a warning that the resuscitator must be used only by persons who have received adequate training;
- b) instructions on how to make the resuscitator operational in all intended modes of operation;
- c) a specification detailing the following information:
 - 1) the body mass range for which the resuscitator is suitable for use,
 - 2) range of ventilatory frequency,
 - 3) attainable delivery pressures,
 - 4) operating environmental limits,
 - 5) storage environmental limits,
 - 6) delivered oxygen concentrations under various test conditions,
 - 7) characteristics and/or dimensions of the gas inlet connection,

- 8) stroke-volume range for operator-powered resuscitators,
 - 9) apparatus deadspace (backward leakage and forward leakage, where appropriate),
 - 10) expiratory resistance and inspiratory resistance, and any special fittings which impose such resistance,
 - 11) the value of end-expiratory pressure generated by the resuscitator in normal use, if greater than 0,2 kPa (≈ 2 cmH₂O),
 - 12) details of the pressure-limiting system and override mechanism operation, if any,
 - 13) external dimensions of the resuscitator and, if provided, the resuscitator case,
 - 14) mass of the resuscitator and, if provided, the resuscitator case;
- d) instructions for the dismantling and reassembly of components for cleaning and sterilization (if applicable). This shall include an illustration of the parts in their correct relationship. The manufacturer shall recommend a functional test of operation to be carried out after reassembly;
 - e) recommendations for the preferred methods of cleaning and disinfection or sterilization of the resuscitator and its components;
 - f) a recommended functional test for operation to be carried out immediately prior to use;
 - g) a list of operator-replaceable parts;
 - h) recommendations for frequency of approved or factory service;

NOTE — If no service is required, this should also be stated in the manual.

- i) resuscitator flow capabilities (if gas-powered) at 2 kPa (≈ 20 cmH₂O) and at 4 kPa (≈ 40 cmH₂O) airway pressure;
- j) recommendations for use in hazardous or explosive atmospheres, including a warning that if the resuscitator will entrain or permit the patient to inhale gas from the atmosphere, its use in contaminated environments may be hazardous unless entrainment is prevented — if applicable, the manufacturer shall describe how to prevent such entrainment or inhalation, for example, by the use of a filter;
- k) warnings that in the presence of high oxygen concentrations there is danger from smoking or open flames and that oil should not be used with the resuscitator;
- l) date of publication and/or revision of the manual;
- m) the approximate duration of the gas supply, expressed as time per litre cylinder volume when charged to the maximum nationally approved filling pressure and when the resuscitator is delivering a minute volume of 10 l/min (or the nearest setting to this) of
 - at least 85 % (V/V) oxygen, and
 - the manufacturer's selected value less than 85 % (V/V) oxygen, if the resuscitator is so capable;
- n) the range of supply pressures with which the resuscitator meets the applicable requirements specified in clause 8 and details of any necessary adjustments for particular supply pressures.

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Annex A (normative)

Test methods

A.1 General test conditions

The ambient temperature for the duration of the tests shall be between 20 °C and 25 °C, except where otherwise stated. The relative humidity shall be within the range from 45 % to 75 %, except where otherwise stated.

A.2 Apparatus

Typical test apparatus is shown in figures A.1 to A.6; alternative test apparatus of equivalent or greater accuracy may be used (see A.3).

A.2.1 Test lung (see figures A.4 and A.5 for examples), with appropriate compliance and resistance characteristics (see table 1).

A.2.2 Resistors, if not provided with the test lung.

A.2.3 Pressure-, flow-, and volume-measuring and -recording apparatus, including a pneumotachograph.

A.2.4 Temperature-measurement apparatus.

A.2.5 Deadspace-measurement apparatus (see figure A.3 for typical example).

A.2.6 Negative pressure generator (see figure A.6 for typical example).

A.2.7 Graduated cylinder, of at least 200 ml capacity.

A.2.8 Oxygen analyser.

A.2.9 Water reservoir, minimum 1 m × 1 m × 1m.

A.2.10 Template, 300 mm × 400 mm.

A.2.11 Compressed air source, capable of varying over the range from 270 kPa to 550 kPa, and of producing a flow rate from 5 l/min to 60 l/min.

NOTES

1 This apparatus is only required if the resuscitator uses compressed air within the stated pressure ranges during normal operation.

2 Flow rates exceeding 60 l/min may be required, if the resuscitator is capable of flow rates exceeding 60 l/min (see A.5.16).

A.2.12 Environmental chamber, capable of maintaining temperatures from $-40\text{ °C} \pm 1\text{ °C}$ to $+60\text{ °C} \pm 1\text{ °C}$ and relative humidity from 40 % to 95 % for periods of up to seven days.

A.2.13 Oxygen supply, capable of varying over the range from 270 kPa to 550 kPa and of producing a flow rate of at least 30 l/min.

A.2.14 Vacuum source, capable of producing flow rates from 5 l/min to 50 l/min.

A.2.15 Gas source, capable of varying through the range of pressures from 270 kPa to 550 kPa.

A.3 Test apparatus tolerances

Test apparatus shall have the following minimum tolerances:

- Oxygen analyser: $\pm 1\%$ (V/V) of the concentration being measured with a response time of greater than 90 % in 10 s.
- Compliances: $\pm 5\%$ of required compliance value throughout a range of inspiratory phase times from 0,5 s to 6 s (see annex C).
- Pressure, flow and volume: $\pm 2,5\%$ of the reading plus $\pm 2,5\%$ of the full scale reading.

The reading accuracy of the associated recording device shall be maintained at a frequency of up to 10 Hz.

- Resistances: $\pm 20\%$ for linear resistances and $\pm 10\%$ for parabolic resistances within the designated flow range (see annex B).
- Temperature measurement: $\pm 0,5\text{ °C}$.

A.4 Conditioning and reference conditions

A.4.1 Conditioning of resuscitator and test apparatus

Unless otherwise specified in particular tests, place the resuscitator and test apparatus in the test location and allow sufficient time for the resuscitator and apparatus to reach equilibrium with ambient conditions.

A.4.2 Reference conditions

Correct all test readings to the reference conditions of ATPD (20 °C, 1 atm¹⁾, 0 % r.h.).

A.5 Test procedures

A.5.1 Bag refill valve connectors

Using a 32 mm gauge (see figure A.1), measure the internal and external diameters of the connector.

A.5.2 Dismantling and reassembly

Verify by inspection of the resuscitator and accompanying documents that a functional test has been provided to test operation after reassembly.

A.5.3 Valve function after contamination with vomitus

A.5.3.1 Test material

Simulated vomitus, prepared by mixing two parts of baby meal beef with vegetable meal and one part water.

A.5.3.2 Procedure

Warm the simulated vomitus to 37 °C ± 3 °C and pour 175 ml into the patient connection port while cycling the resuscitator at a rate of 30 breaths/min for resuscitators suitable for use with patients of a body mass up to 10 kg, and at a rate of 12 breaths/min for all other models. Perform this test with the resuscitator connected to the test lung (A.2.1). Continue to cycle the resuscitator for 30 s. Clear the resuscitator of the mixture according to the manufacturer's instructions and verify the resuscitator's performance.

NOTE — Some of the test solution may spill over when poured into the patient connection port.

A.5.4 Drop test

Drop the resuscitator from a height of at least 1 m onto a concrete floor in the worst case orientation. For the purposes of this test, the resuscitator shall be a complete unit, including the face mask, valve, hose, regulator and cylinder, as appropriate. If the resuscitator kit includes a cylinder, perform the test with the cylinder empty.

A.5.5 Mechanical shock test for resuscitator fixtures that are mounted on castors or on wheels

Place the resuscitator in its recommended operating position. Tip the resuscitator over in its worst case orientation. This test shall only be performed once.

A.5.6 Immersion in water

Arrange the resuscitator in its ready-for-use condition, i.e. gas on, gas off, etc. and drop it from a height of 1 m into the water reservoir (A.2.9). Take the resuscitator out after 10 s and shake out the water for not more than 20 s. Begin ventilating the test lung (A.2.1) immediately.

A.5.7 Supplementary oxygen and delivered oxygen concentration

Connect the resuscitator to the test lung (A.2.1) set at C 20 and R 20 characteristics. Connect an oxygen analyser (A.2.8) at a site in the compliance chamber as far away as possible from the patient connection port. Ventilate the test lung at a frequency of 12 breaths/min and a tidal volume of 600 ml. Introduce input oxygen flows of no more than 15 l/min. Continue this procedure until a stable value for oxygen concentration is achieved. Use only one hand to compress the compressible unit (see figure A.2 for maximum allowable hand dimensions).

A.5.8 Delivered oxygen concentration for gas-powered resuscitators

Connect the resuscitator to the test lung (A.2.1) set at C 20 and R 20 characteristics. Connect the oxygen analyser (A.2.8) at a site in the compliance chamber as far away as possible from the patient connection port. Ventilate the test lung at a frequency of 12 breaths/min and a tidal volume of 600 ml. Continue this procedure until a stable value for oxygen concentration is reached. Confirm that the resuscitator delivers an oxygen concentration of at least 85 % (V/V). If the resuscitator is capable of delivering other oxygen concentrations, arrange the resuscitator as recommended by the manufacturer and confirm that the oxygen concentration delivered to the test lung is within the range given by the manufacturer.

Repeat the whole procedure using the test lung set at C 50 and R 5 characteristics.

Both tests shall be performed at the maximum and minimum flow settings recommended for the resuscitator.

A.5.9 Expiratory resistance

For resuscitators suitable for use with patients with a body mass of up to 10 kg, connect the patient connection port to the air source and introduce air at a flow rate of 5 l/min. Record the expiratory pressure generated at the patient connection port.

For all other resuscitators, connect the patient connection port to the air source and introduce air at a flow rate of 50 l/min. Record the pressure generated at the patient connection port.

A.5.10 Inspiratory resistance

For resuscitators suitable for use with patients with a body mass of up to 10 kg, connect the patient connection port to a

1) 1 atm = 101 325 Pa = 760 mmHg

vacuum source producing an air flow rate of 5 l/min. Record the inspiratory pressure generated at the patient connection port.

For all other resuscitators, connect the patient connection port to a vacuum source producing an air flow rate of 50 l/min. Record the inspiratory pressure generated at the patient connection port.

A.5.11 Patient valve malfunction

Connect the resuscitator to the test lung (A.2.1) set at C 20 and R 20 characteristics. Ventilate the test lung at a frequency of 12 breaths/min and a tidal volume of 600 ml. Using the oxygen supply (A.2.13), pass oxygen, as recommended by the manufacturer, at a flow rate of 30 l/min. Verify that the valve does not jam in the inspiratory position.

A.5.12 Apparatus deadspace

A.5.12.1 Principle

Ventilation by the resuscitator of a "bag-in-bottle" reservoir with 100 % (V/V) oxygen as tracer gas. Calculation of the total deadspace of the resuscitator from the volume of ventilation and the oxygen concentration of the inspired gas captured inside the bag.

A.5.12.2 Preparation of apparatus prior to testing resuscitator

Set up the deadspace measurement apparatus (A.2.5; see figure A.3). Close the tap to the oxygen analyser (A.2.8). Open the ball valve. Connect the resuscitator and ventilate until the balloon fills the bottle completely and is pressed against the inner walls. Close the ball valve. Open the oxygen analyser tap. Open the flowmeter and fill the bottle with 100 % (V/V) oxygen. Close the oxygen flowmeter when the pressure gauge reads approximately 1 kPa (≈ 10 cmH₂O).

Connect the 22 mm/15 mm test connector to the 22 mm female socket and supply the appropriate flow of atmospheric air to the side nipple (see table A.1).

Open the ball valve, whereby the expiratory flowpath is flushed with 100 % (V/V) oxygen.

Ventilate the lung by covering and opening the 10 mm diameter hole with a finger. Hold the tidal volume constant by means of the respirometer (V) and pressure gauge (P). The number of ventilating cycles is given in table A.1.

Close the ball valve and open the analyser tap. Adjust the 100 % (V/V) oxygen flow to approximately 5 l/min. Record the reading for the oxygen concentration in the bag, F_{O₂, bag}, of the oxygen analyser. Close off the oxygen flow when the pressure gauge reads 1 kPa (≈ 10 cmH₂O) again.

Determine the internal deadspace of the test apparatus for every combination of test parameters used.

The apparatus is now ready for testing the resuscitator.

A.5.12.3 Procedure

Test the resuscitator using the same procedure as described for the test connector (see A.5.12.2).

A.5.12.4 Expression of results

Calculate the system deadspace (i.e. with test connection) using the following equation:

$$V_{D, \text{system}} = \frac{F_{O_2, \text{bag (test connection)}} - 21}{79} \times V_T$$

NOTE — The apparatus should be so designed that V_{D, system} = 20 ml or less. The oxygen analyser should be calibrated to read 21 % with atmospheric air and be accurate to within ± 1 % (V/V) oxygen.

Calculate the apparatus deadspace of the resuscitator being tested using the following equation:

$$V_{D, \text{app}} = \frac{F_{O_2, \text{bag}} - 21}{79} \times V_T - V_{D, \text{system}}$$

A.5.13 Tidal volumes

Connect the resuscitator to the appropriate test lung (A.2.1; see figures A.4 and A.5) having the characteristics stated in table 1. Measure the volume (A.2.3). Use only one hand to compress the compressible unit (see figure A.2 for maximum allowable hand dimensions). Perform these tests without the use of an override mechanism if one is provided.

A.5.14 Inspiratory flows

Connect a flowmeter with an upstream flow regulator to the patient connection port by means of a 22 mm hose incorporating a pressure gauge. Operate the resuscitator and adjust

Table A.1 — Test parameters

| Tidal volume V _T ml | Compliance C ml/kPa (ml/cmH ₂ O) | Expiratory resistance R _{exp} kPa/(l/s) [cmH ₂ O/(l/s)] | Test flow for internal deadspace l/min | Test cycles |
|--------------------------------------|---|---|---|-------------|
| 600 | 200 (20) | 0,5 [5] | 30 | > 15 |
| 100 | 100 (10) | 2 [20] | 5 | > 50 |

the flow regulator to give an output pressure of 2 kPa (≈ 20 cmH₂O). If appropriate, adjust the regulator flow setting to give 40 l/min ± 10 % while maintaining the output pressure at 2 kPa (≈ 20 cmH₂O). Confirm that the required flow is achieved.

A.5.15 Pressure limitation (operator-powered resuscitators)

For resuscitators classified for use with patients up to 10 kg body mass, occlude the patient connection port and, using the compressed air source (A.2.11), pass air at a flow rate of 15 l/min through the pressure-limiting system. Record the pressure at the patient connection port.

For resuscitators classified for use with patients of over 10 kg body mass and equipped with pressure-limiting systems, occlude the patient connection port and, using the compressed air source (A.2.11), pass air at a flow rate of 60 l/min through the pressure-limiting system. Record the pressure at the patient connection port.

A.5.16 Pressure-limiting system (gas-powered resuscitators)

Follow the method described in A.5.14, substituting flows of 60 l/min or the maximum flow delivered by the resuscitator, whichever is greater.

A.5.17 Pressure-cycling system (automatic, pressure-cycled, gas-powered resuscitators)

Connect the resuscitator to the appropriate test lung (A.2.1; see figures A.4 and A.5) having the characteristics stated in table 1. Operate the resuscitator and record the pressure at which the resuscitator cycles from inspiration to expiration.

A.5.18 Peak inspiratory flow and flow threshold

Connect the demand valve to be tested as shown in figure A.6 and carry out the test procedure described in A.5.18.1 to A.5.18.3.

A.5.18.1 Flow threshold

Adjust the regulator which controls the negative input pressure, $p_{\text{neg},i}$ and note the reading on the negative pressure gauge (P) at which output flow is initiated.

A.5.18.2 Peak flow

Set the negative pressure, p_{neg} , to 0,8 kPa by adjusting the regulator which controls the negative input pressure, $p_{\text{neg},i}$. Verify that the output flow, $q_{V,o}$, is 100 l/min for at least 10 s.

A.5.18.3 Flow termination

Adjust the regulator which controls the negative input pressure, $p_{\text{neg},i}$, until the output flow, $q_{V,o}$, is 5,0 l/min.

Gradually decrease the negative input pressure until flow terminates and record the reading on the negative pressure gauge (P) at which this occurs.

A.5.19 Operating conditions

A.5.19.1 General

Following completion of each phase of the test, operate the resuscitator under the conditions described in the general requirements and also under the specific conditions for the category of resuscitator being tested, i.e. gas-powered volume-cycled, hand-powered, etc., specified in clause 8.

A.5.19.2 Procedure

NOTE — In each of the operational tests given, the resuscitator should be operated continuously for a period of at least 10 min.

A.5.19.2.1 Prepare the resuscitator in accordance with the general requirements. Place the resuscitator system in the environmental chamber (A.2.12) set at 50 °C and at least 95 % r.h. Maintain these conditions for no fewer than seven days.

At the end of this period, operate and test the resuscitator.

Once testing has been completed, return the resuscitator, within 5 min, to ambient conditions of 18 °C to 22 °C and 40 % r.h. to 70 % r.h. for a period of no fewer than seven days.

At the end of this period, operate and test the resuscitator.

A.5.19.2.2 Place the resuscitator in the environmental chamber set at -40 °C for a period of at least 4 h or until the resuscitator stabilizes.

At the end of this period, return the resuscitator, within 5 min, to an ambient temperature between 18 °C and 22 °C. Allow the resuscitator to stabilize for at least 4 h.

At the end of this period, operate and test the resuscitator.

A.5.19.2.3 Place the resuscitator in the environmental chamber at $+60$ °C and at 40 % r.h. to 70 % r.h. for a period of not less than 4 h.

At the end of this period, return the resuscitator, within 5 min, to ambient conditions of 18 °C to 22 °C and 40 % r.h. to 70 % r.h. Allow the resuscitator to stabilize for 4 h.

At the end of this period, operate and test the resuscitator.

A.5.19.2.4 Place the resuscitator in the environmental chamber set at -18 °C for 4 h.

At the end of this period, operate and test the resuscitator.

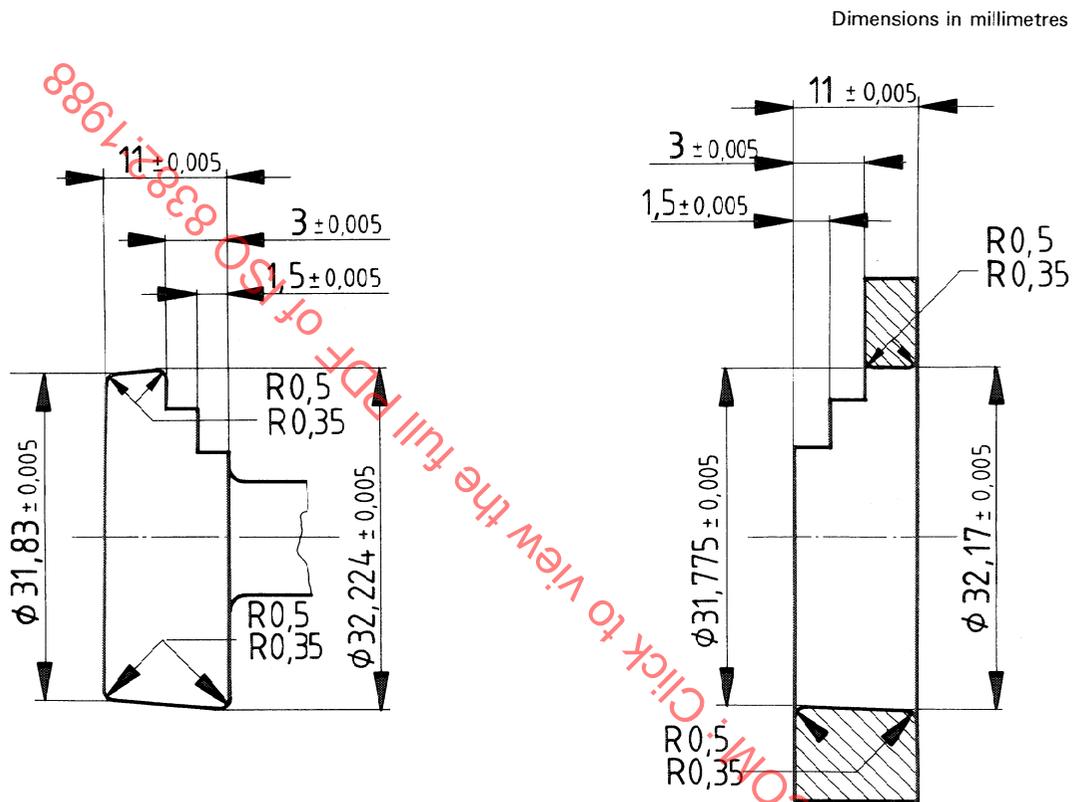
Once testing has been completed, return the resuscitator to ambient conditions of 18 °C to 22 °C.

Within 5 min, operate and test the resuscitator.

A.5.20 Supply pressures

Connect the resuscitator to the gas source (A.2.15) and test its performance at source pressures of 270 kPa and 550 kPa using

the test methods described for the general requirements and any specific requirements for the type of resuscitator being tested, i.e. automatically or manually cycled, specified in clause 8.



NOTES

- 1 Basic taper is 1 : 28 on diameter.
- 2 Engagement is 9,5 nom.

Figure A.1 — 32 mm ring and plug gauges

Dimensions in millimetres

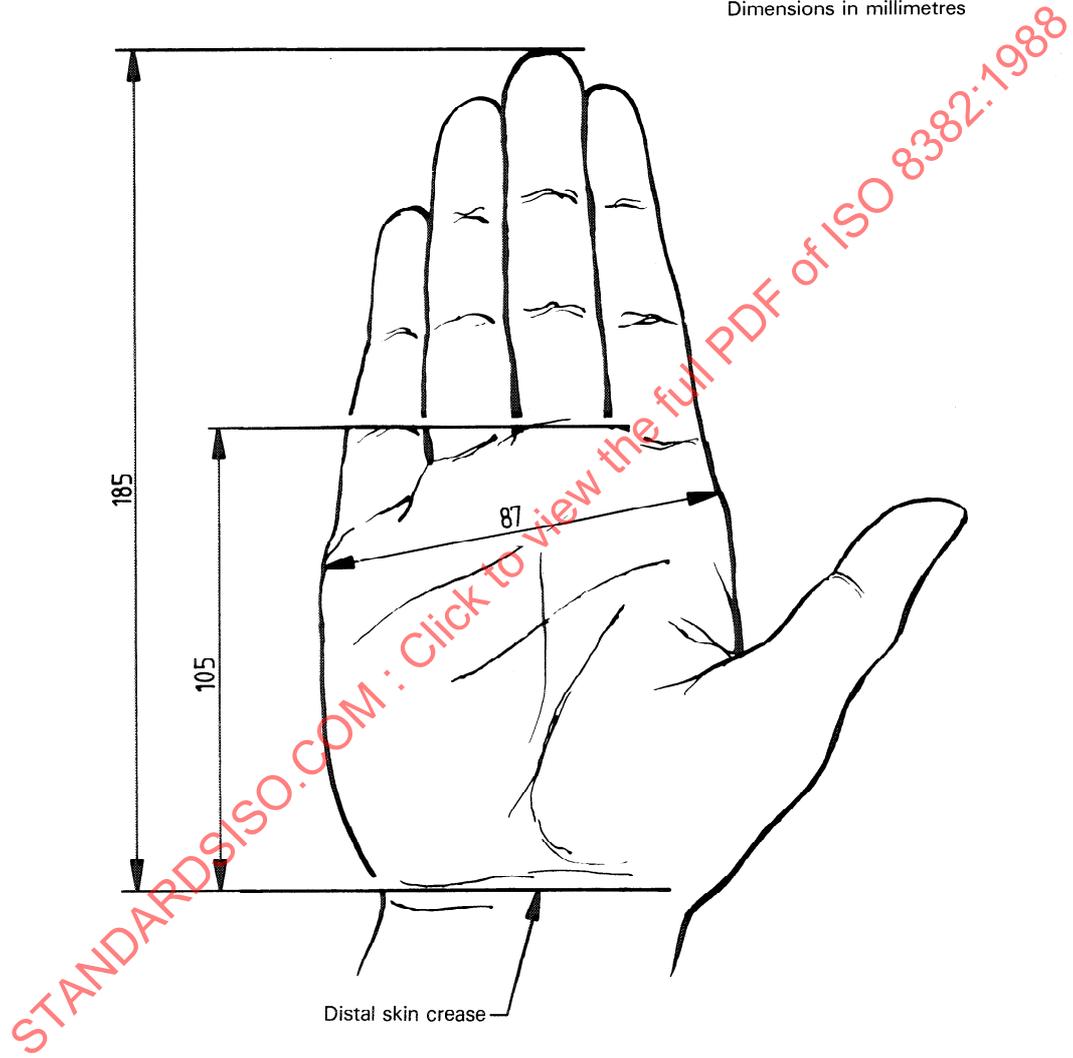


Figure A.2 – Maximum hand dimensions

Dimensions in millimetres

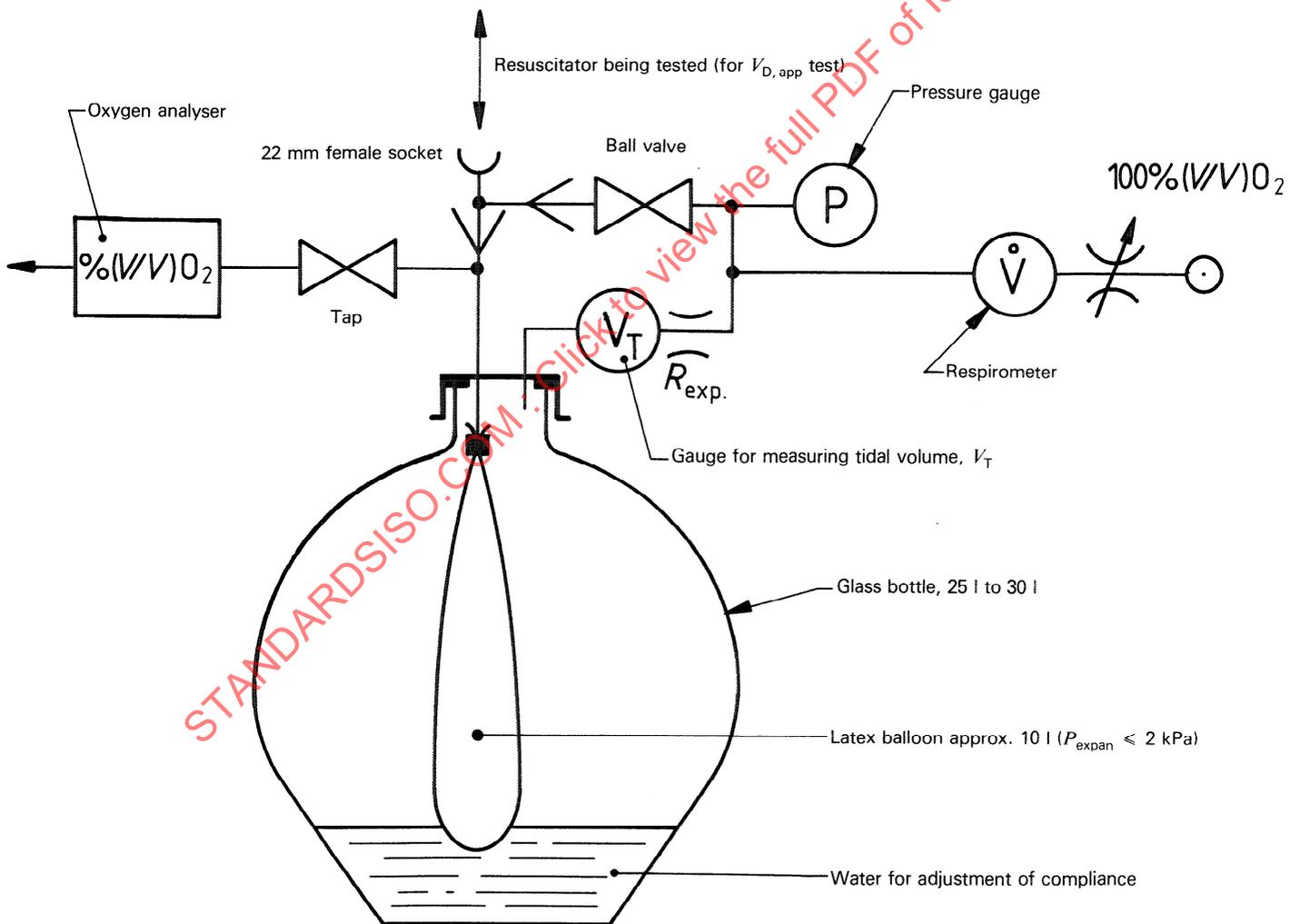
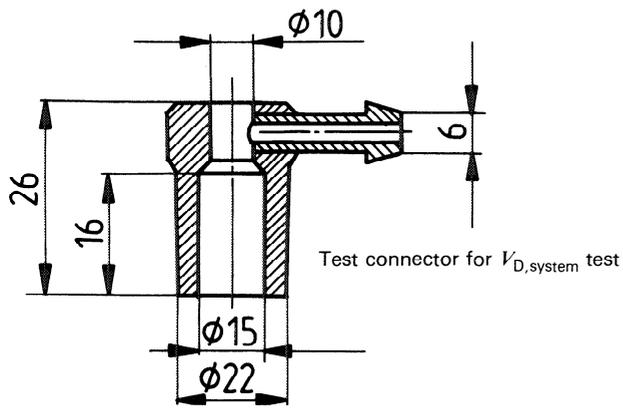


Figure A.3 — Test set-up for measuring total apparatus deadspace

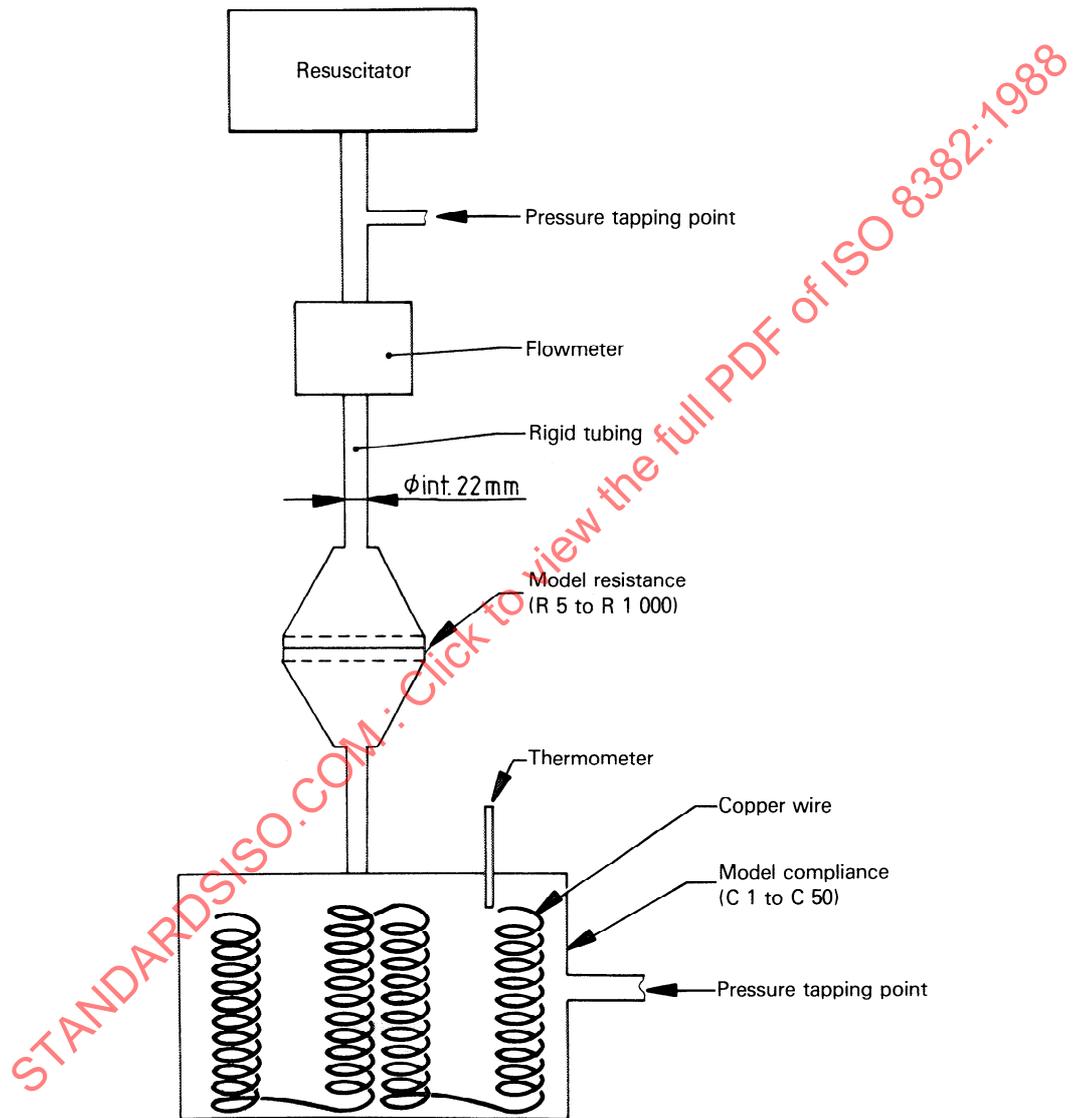


Figure A.4 – Representative passive test lung system

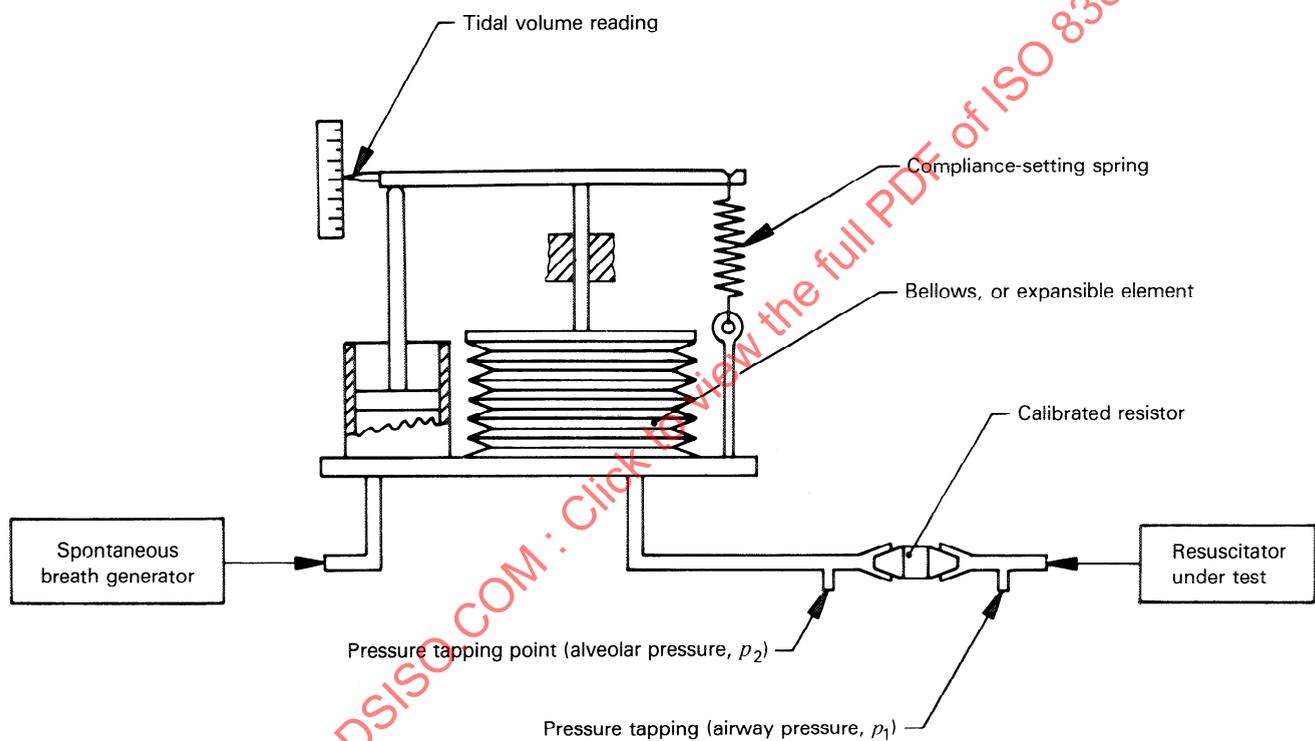


Figure A.5 — Example of active test lung system

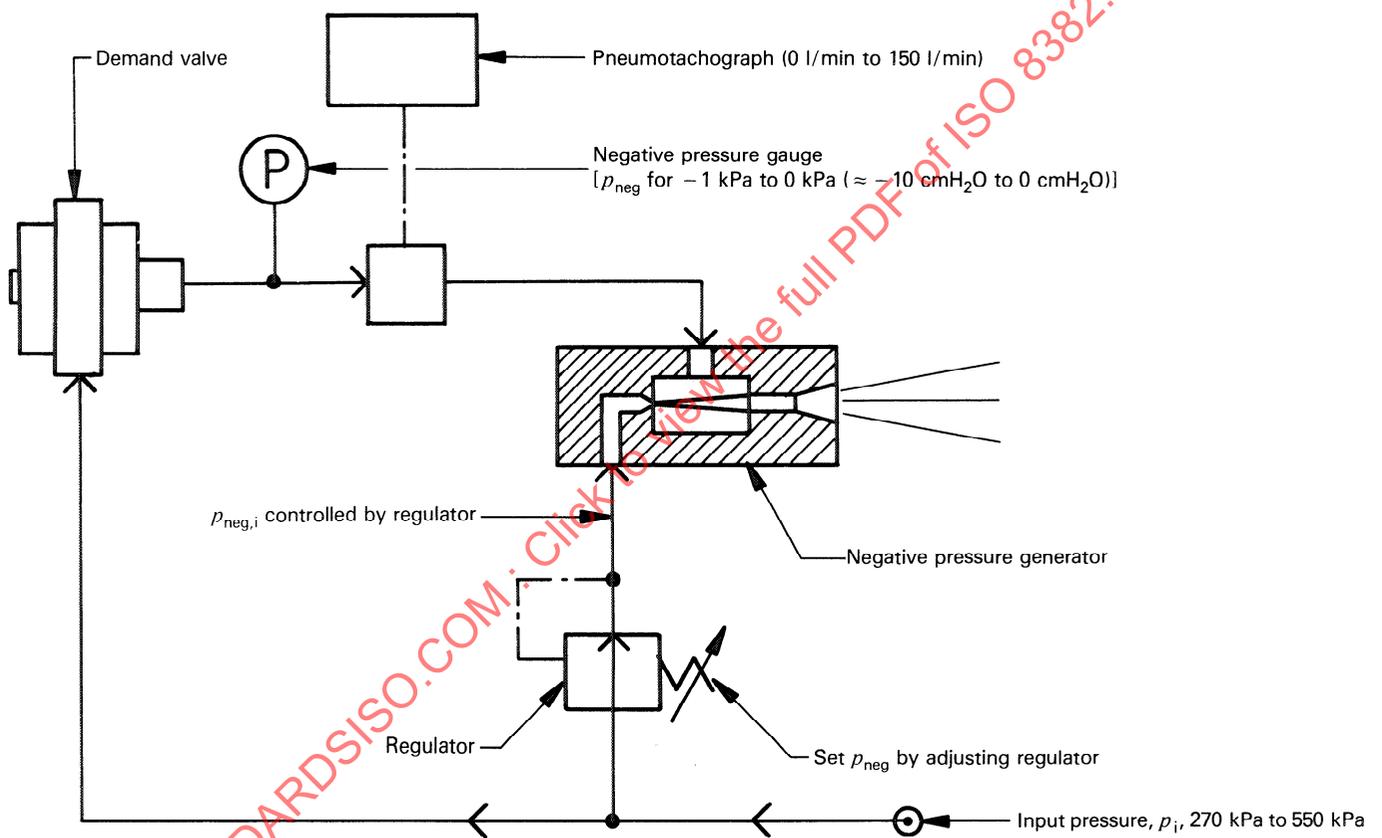


Figure A.6 — Example of test apparatus for testing demand valves (threshold and peak flows)

Annex B (normative)

Compliances and resistances required to set up test lung

Table B.1 – Required compliances

| Classification ¹⁾ | Compliance <i>C</i> | |
|------------------------------|------------------------|-----------------------|
| | ml/kPa | ml/cmH ₂ O |
| C 50 ²⁾ | 500 | (50) |
| C 20 | 200 | (20) |
| C 10 | 100 | (10) |
| C 1 | 10 | (1) |

1) The classification was originally based on conventional centimetres of water.
2) Not used in test procedure.

Table B.2 – Required resistances

| Classification ¹⁾ | Resistance | | | | Range of air flow ³⁾ (for linear or parabolic resistances) l/s |
|------------------------------|--------------------|----------------------------|---|----------------------------|---|
| | linear <i>R</i> | | parabolic ²⁾ <i>R_p</i> | | |
| | kPa/(l/s) | [cmH ₂ O/(l/s)] | kPa/(l/s) | [cmH ₂ O/(l/s)] | |
| R 5 | 0,5 | [5] | 0,77 | [7,7] | 0 to 2 |
| R 20 | 2 | [20] | 0,56 | [5,6] | 0,5 to 1 |
| R 50 ⁴⁾ | 5 | [50] | 0,39 | [3,9] | 0,25 to 0,5 |
| R 400 | 40 | [400] | 0,14 | [1,4] | 0,05 to 0,075 |

1) The classification was originally based on conventional centimetres of water.
2) The values for parabolic resistances refer to the nominal inside diameter in millimetres of thin plate, sharp-cornered orifices needed to achieve these resistance values. Other geometric shapes may be used, e.g. thicker orifices with rounded corners, but nominal diameters would be different.
3) The tolerances for the flow range values are ± 20 % for linear resistances and ± 10 % for parabolic resistances.
4) Not used in test procedure.