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Resuscitators intended for use with humans

Ressuscitateurs destinés aux êtres humains

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Contents

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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.

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.

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 4135[2], 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 second[3] [cmH_2O/(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, $\mathring{V}$: 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 "mmH_2O" (and hence also "cmH_2O") 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 resuscitation 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 cmH_2O). [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 cmH_2O) 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 cmH_2O) 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 cmH_2O) 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 f ± 10 %	Tidal volume V_T 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 ($\approx$ 60 cmH_2O). An override mechanism shall be provided to enable the operator to select a higher pressure. However, automatic, pressure-cycled, gas-powered resuscitatcrs 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 ($\approx$ 60 cmH_2O) 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 $\pm$ 10 % inspiratory flow against a back pressure of 2 kPa ($\approx$ 20 cmH_2O) 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 ($\approx$ 20 cmH_2O to $\approx$ 30 cmH_2O) 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 ($\approx$ 2 cmH_2O).

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 ($\approx$ 8 cmH_2O).

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 ($\approx$ 2 cmH_2O),

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 ($\approx$ 20 cmH_2O) and at 4 kPa ($\approx$ 40 cmH_2O) 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.