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# Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans[1]

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*This standard has been approved for use by agencies of the Department of Defense.*

## INTRODUCTION

In January of 1989, ASTM Subcommittee F29.03.03 met in Boston with representatives of the American Heart Association and the U.S. Department of Defense to discuss the revision of this specification. It was unanimously determined that until a revised version of this specification that would be consistent with the American Heart Association's revised Standards and Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care was available, ISO 8382-1988, should be used as the specific reference for manually-triggered gas-powered resuscitators. Shortly thereafter, the Subcommittee Chairman published a letter to this effect in the *Journal of the American Medical Association*.[2] The Subcommittee reaffirmed this stance at a subsequent meeting in March of 1990. This specification is therefore similar in content to ISO 8382.

## 1. Scope

1.1 This specification covers ventilatory resuscitators, that is, 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 varying degrees of training. They are intended to be used at the site of an emergency and during patient transport. Resuscitators intended for use on all age groups are included within the scope of this specification.

1.1.1 This specification does not intend to discourage or impede future innovation or development of resuscitators.

1.2 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 specification does not describe the content of the training programs 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.

1.2.1 In certain countries, resuscitators are intended for use by nontrained 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 specification is not intended to conflict with these established practices.

1.3 Annex A1 details test methods, while Annex A2 provides tables of resistances and compliances required to set up the test lung. Annex A3 gives a rationale for various clauses in this specification and is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been given. Annex A4 and Annex A5 provide advice concerning materials to be used in resuscitators and face masks.

1.4 The values stated in SI units are to be regarded as the standard.

1.5 *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

2.1 The following standards contain provisions that, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.14 on Ventilators.

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[2] American Heart Association, "Standards and Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardia Care (ECC)," *Journal of the American Medical Association*, Vol 255, No. 21, June 6, 1986, pp. 2905-2984.

2.2 *ASTM Standards:*
F 1054 Specification for Conical Fittings of 15 mm and 22 mm Sizes[3]
F 1243 Specification for Tracheal Tube Connectors[3]
2.3 *ANSI Standard:*
ANSI/CAA V-1 Compressed Gas Cylinder Valve Outlet and Inlet Connections[4]
2.4 *ISO Standards:*
ISO 407 Small Medical Gas Cylinders—Yoke-Type Valve Connections[4]
ISO 4135 Anaesthesiology—Vocabulary[4]
ISO 5356-1 Anaesthetic and Respiratory Equipment—Conical Connectors—Part 1: Cones and Sockets[4]
ISO 5359 Low-Pressure Flexible Connecting Assemblies (Hose Assemblies) for Use with Medical Gas Systems[4]
ISO 7228 Tracheal Tube Connectors[4]
ISO 8382 Resuscitators Intended for Use with Humans[4]

## 3. Terminology

3.1 *Definitions*—Some of these definitions have been taken from ISO 4135, but are included in this specification for convenience. Other definitions, that are given in ISO 4135, for apparatus in general, have been modified slightly for the purposes of this specification as they apply specifically to resuscitators:

3.1.1 *airway*—the passageway for gas into and out of the lungs.

3.1.2 *apparatus deadspace* $V_{D,app}$— that volume of previously exhaled gas that is delivered from the resuscitator in the succeeding inspiratory phase.

3.1.3 *automatic resuscitator*—a resuscitator in which the cyclic flow of gas for inflation of the lungs is independent of any inspiratory effect of the patient or repetitive action of the operator.

3.1.3.1 *Discussion*—The expiratory phase may also be automatically cycled.

3.1.4 *back leak*—the volume of expired gas which does not pass through the expiratory port but returns to the resuscitator.

3.1.5 *bag inlet valve*—a valve activated by the subatmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit from a compressed gas source.

3.1.6 *bag refill valve*—a valve, with no manual trigger, activated by the subatmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit from a compressed gas source.

3.1.7 *compliance, C*—volume change of the gases in the compartment produced by a unit pressure change, expressed in litres per kilopascal (L/kPa).

3.1.8 *compressible unit*—that part of an operator-powered resuscitator that, when compressed by the operator, delivers a volume of gas, for example, a bag or bellows.

3.1.9 *delivered oxygen concentration*—the average concentration of oxygen in the gas delivered from the resuscitator.

3.1.10 *demand (intermittent flow) apparatus*—a device delivering a flow of gas, patient-triggered, during inspiration only at ambient pressure (or at respiratory pressure).

3.1.11 *expiratory port*—an opening through which gases or vapors, or both, pass from the patient during expiration.

3.1.12 *forward leak*—the volume of gas produced by the resuscitator during the inspiratory phase that does not pass through the patient port to the patient but passes to the atmosphere.

3.1.13 *gas-powered resuscitator*—a resuscitator powered by the energy of compressed gas.

3.1.14 *infant*—an individual weighing up to 10 kg, or being approximately one year of age.

3.1.15 *manually cycled, gas-powered resuscitator*— an operator-activated resuscitator whereby the work of resuscitation is accomplished by the energy of compressed gas and not the operator.

3.1.16 *maximum delivery pressure*—the highest gage pressure that can be attained at the patient connection port when the apparatus is functioning normally.

3.1.17 *minute volume,* $\dot{V}$—the volume of gas, expressed in litres per minute, entering or leaving the patient or the lung model.

3.1.18 *Discussion*—The physical conditions under which measurements are made should be given.

3.1.19 *operator-powered resuscitator*—a resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device.

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

3.1.21 *patient connector*—that part of the resuscitator that connects directly to a face mask or an appropriate mating airway device.

3.1.22 *patient valve*—a valve in the breathing system that directs gas into the lungs for the inspiratory phase and into the atmosphere during the expiratory phase.

3.1.23 *pressure limiting system*—a mechanism for limiting the maximum delivery pressure.

3.1.24 *resistance, R*—pressure drop per unit of flow at a specified flow, expressed in kilopascals per litre per second [kPa/(L/s)].

3.1.24.1 *Discussion*—According to conventional practice, this has generally been expressed in centimetres of water per litre per second [$cmH_2O$/(L/s)].

3.1.25 *resuscitator*—a portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate.

3.1.26 *stroke volume*—the volume of gas deliverable from the resuscitator to the end of the patient connector during an inspiratory phase of the ventilatory cycle.

3.1.27 *tidal volume,* $V_T$—the volume of gas, expressed in millilitres, entering or leaving the patient or the lung model during the inspiratory or expiratory phase time.

3.1.27.1 *Discussion*—The physical conditions under which gas volumes are measured should be given.

[3] *Annual Book of ASTM Standards*, Vol 13.01.
[4] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.1.28 *ventilatory cycle*—the cycle comprising the inspiratory phase plus the expiratory phase.

3.1.29 *ventilatory frequency, f*—the number of ventilatory cycles per minute.

3.1.29.1 *Discussion*—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.

3.2 *Symbols:* In addition to the symbols given in clause 3, the following symbols are used in this specification:

3.2.1 $V_{D,system}$—system deadspace.

3.2.2 $F_{O_2,bag}$— oxygen concentration in bag.

## 4. Connectors

4.1 *Patient Connection Port (See also* Annex A3*)*—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 and Specification F 1054.

4.2 *Expiratory Port for Breathing Gases (See also* Annex A3*)*—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 and Specification F 1054.

4.2.1 The connector shall incorporate a baulk, for example, 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 and Specification F 1054.

NOTE 1—Such a baulk should not significantly increase the resistance to gas flow through the connector.

4.3 *Face Mask Connectors (See also* Annex A3*)*—If provided with the resuscitator, face masks shall have either a 22 mm female connector or a 15 mm male connector that will mate with the corresponding connectors specified in ISO 5356-1 and Specification F 1054.

4.4 *Bag Refill Valve Connectors (See also* Annex A3*)*—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 gages shown in Fig. A1.1.

4.5 *Bag Inlet Valve Connectors*—Bag inlet valve connectors shall not be compatible with connectors dimensioned in accordance with ISO 5356-1 and Specification F 1054.

NOTE 2—For resuscitators intended for use in hazardous environments, attention is drawn to CEN 148, a draft standard on threaded gas filter connections.

## 5. Operational Requirements

5.1 *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 specification. All performance requirements in this specification 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.

5.2 *Dismantling and Reassembly (See also* Annex A3*)*—The manufacturer shall recommend a functional test of operation to be carried out after reassembly (see 10.3.2.3(*d*)).

NOTE 3—A resuscitator intended to be dismantled by the user, for example, for cleaning, etc., should be designed so as to suppress the risk of incorrect reassembly when all parts are mated.

5.3 *Patient Valve Function After Contamination with Vomitus (See also* Annex A3*)*— After the resuscitator has been tested in accordance with the test described in A1.5.3, it shall meet the requirements specified in 7.3, 7.5, 7.8.1, 7.8.2, 7.9, 7.10.1, 7.10.2, and 7.10.3, as appropriate.

NOTE 4—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.

5.4 *Mechanical Shock*:

5.4.1 *Drop Test (See also* Annex A3*)*—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 7.3, 7.5, 7.8.1, 7.9, 7.10.1, 7.10.2, and 7.10.3 as appropriate, following the drop test described in A1.5.4. 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.

5.4.2 *Mechanical Shock Test for Resuscitator Fixtures that are Mounted on Castors or on Wheels (See also* Annex A3*)*—The resuscitator shall meet the requirements specified in 7.3, 7.5, 7.8.1, 7.8.2, 7.9, 7.10.1, 7.10.2, and 7.10.3, as appropriate, after being tipped over from its normal operating position onto a concrete floor as described in A1.5.5.

5.5 *Immersion in Water (See also* Annex A3*)*—After immersion in water by the method described in A1.5.6, the resuscitator shall comply with the requirements specified in 7.3, 7.5, 7.8.1, 7.8.2, 7.9, 7.10.1, 7.10.2, and 7.10.3, as appropriate.

5.6 *Bag Refill Valves (See also* Annex A3*)*—Bag refill valves for use with operator-powered resuscitators shall not have provisions for manual operation.

## 6. Physical Properties

6.1 *Size (See also* Annex A3*)*—The resuscitator, with a container, if provided, shall pass through a rectangular opening 300 by 600 mm in size, in at least one position.

6.2 *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.

## 7. Performance Requirements

7.1 *Supplementary Oxygen and Delivered Oxygen Concentration*:

7.1.1 *Operator-Powered Resuscitators (See also* Annex A3*)*—When tested by the method described in A1.5.7 in accordance with the requirements of this classification (see 7.8.1), 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 5). The manufacturer shall state the range of concentrations at representative flows, for example, 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 Fig. A1.2.

NOTE 5—The 85 % (V/V) requirement may be accomplished with the use of an attachment.

7.1.2 *Gas-Powered Resuscitators (See also* Annex A3*)*—When tested by the method described in A1.5.8, 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.

7.2 *Resistance to Inspiration and Expiration*—See the requirement for information to be provided by the manufacturer under 10.3.2.3(*c*).

7.3 *Expiratory Resistance (See also* Annex A3*)*—In the absence of positive end-expiratory devices, and when tested by the method described in A1.5.9, the pressure generated at the patient connection port shall not exceed 0,5 kPa (≃5 $cmH_2O$). (See also 10.3.2.3( *c*).)

7.4 *Inspiratory Resistance (See also* Annex A3*)*—When tested by the method described in A1.5.10, the pressure at the patient connection port shall not exceed 0,5 kPa (≃5 $cmH_2O$) below atmospheric pressure. (See also 10.3.2.3(*c*).)

7.5 *Patient Valve Malfunction (See also* Annex A2*)*—When tested by the method described in A1.5.11, 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.

7.6 *Patient Valve Leakage—Forward Leakage (See also* Annex A3*)*—Where forward leakage is a design feature, it shall be so stated in the instruction manual.

7.7 *Apparatus Deadspace (See also* Annex A3*)*—When tested by the method described in A1.5.12, the apparatus deadspace shall not exceed 5.0 to 5.5 % of the tidal volume specified for the classification of the resuscitator (see 7.8.1).

7.8 *Ventilation Performance*:

7.8.1 *Tidal Volume (See also* Annex A3*)*—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.

7.8.1.1 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 A1.5.13, without the use of the override mechanism on any pressure-limiting system.

NOTE 6—Resuscitators designed to deliver a tidal volume of 20 to 50 mL are usually suitable for use with neonates.

7.8.2 *Pressure Limitation (Operator-Powered Resuscitators) (See also* Annex A3*)*:

7.8.2.1 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 (≃45 $cmH_2O$) under the test conditions described in A1.5.15.

NOTE 7—An override mechanism may be provided.

7.8.2.2 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 10.3.2.3(*c*)). Any pressure limiting device provided that it limits pressure to below 6 kPa (≃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, that is, on or off, is readily apparent to the user by obvious control position, flag, etc.

NOTE 8—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.

7.9 *Gas-Powered Resuscitators*:

7.9.1 *Pressure-Limiting System (See also* Annex A3*)*—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 $cmH_2O$). 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, that is, on or off, is readily apparent to the user by obvious control position, flag, etc.

NOTE 9—A setting for the pressure-limiting system higher than 6 kPa (≃60 $cmH_2O$) may be made available for certain patients, although the selection of such a setting requires medical advice.

NOTE 10—There should be an audible or visible warning to the operator when the pressure-limiting system is operating.

7.9.2 *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 $cmH_2O$) when tested by the method described in A1.5.14.

NOTE 11—Devices with fixed flows should be set to this value. Devices

**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[A] |
| >40 | 0,2 | 2 | 1:2 | 20 | >600 |

[A]Body mass, in kilograms, stated by the manufacturer in the manual.

with operator-adjustable flows should include this value in their range of adjustment.

7.9.3 *Manually Cycled, Gas-Powered Resuscitators*—Manually cycled gas-powered resuscitators shall meet the requirements specified in 7.1.2, 7.9.1, and 7.9.2 when tested by the methods described A1.5.8, A1.5.13, A1.5.14, and A1.5.16.

7.9.4 *Automatic Pressure-Cycled, Gas-Powered Resuscitators*—Automatic pressure-cycled resuscitators shall have positive cycling pressures in the range of 2 to 3 kPa (≃20 to ≃30 cmH $_2$O) when tested by the method described in A1.5.17 (see also 10.1.1).

NOTE 12—A negative-pressure phase may cause a decrease in arterial oxygen partial pressure ($pO_2$) or functional residual capacity (FRC).

7.9.5 *Automatic Time-Cycled, Gas-Powered Resuscitators*—Automatic time-cycled, gas-powered resuscitators shall meet the requirements specified in 7.1.2, 7.8.1, 7.9.1, and 7.9.2, when tested by the methods described in A1.5.8, A1.5.13, A1.5.14, and A1.5.16.

7.9.6 *Volume-Cycled, Gas-Powered Resuscitators*—Volume-cycled, gas-powered resuscitators shall meet the requirements specified in 7.1.2, 7.8.1, 7.9.1, and 7.9.2, when tested by the methods described in A1.5.8, A1.5.13, A1.5.14, and A1.5.16.

7.10 *Demand Valves*:

NOTE 13—These devices are subject to the requirements of this specification only when included as an integral part of a resuscitator.

7.10.1 *Pressure for Initiation (See also* Annex A3*)*—When tested by the method described in A1.5.18, the pressure drop needed to initiate gas flow shall be no more than a negative 0.2 kPa (≃2 $cmH_2O$).

7.10.2 *Peak Inspiratory Flow (See also* Annex A3*)*—When tested by the method described in A1.5.18.2, 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 $cmH_2O$).

7.10.3 *Termination Pressure (See also* Annex A3*)*—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 A1.5.18.3.

## 8. Resistance to Environment

8.1 *Storage*—The resuscitator and the resuscitator kit (if provided) shall after storage at temperatures of − 40 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, that is operator-powered or gas-powered, etc., specified in Section 7.

8.2 *Operating Conditions (See also* Annex A3*)*—When tested by the method described in A1.5.19, the resuscitator shall meet the general requirements and the specific requirements for the category of resuscitator being tested, specified in Section 7, throughout the temperature range from −18 to + 50°C and a humidity range from 40 to 95 % relative humidity.

NOTE 14—Problems due to ice formation will occur during use at temperatures below − 4°C and may render the unit inoperable.

## 9. Gas Supply

9.1 *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 15—Small cylinders with special fittings are frequently used in special situations.

9.2 *Indication of Contents*—Each gas supplied at cylinder pressure shall be monitored by a cylinder pressure gage or contents indicator.

9.3 *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.

9.4 *Connections for Compressed Gas (See also* Annex A3*)*—Gas connections between different gas services shall be noninterchangeable 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 16—If provided, a press-fit connection should give an easy and reliable connection with 6 mm inside diameter elastomeric tubing.

9.5 *Supply Pressures (See also* Annex A3*)*—When supplied with gas at a pressure between 270 and 550 kPa (see 10.3.2.3(*n*)), the resuscitator shall meet the general requirements and any specific requirements for the type of resuscitator being tested, that is, automatically or manually cycled, specified in Section . Testing shall be as described in A1.5.20.

## 10. Information to be Supplied by Manufacturer

10.1 *Marking*:

10.1.1 *Manufacturer's Warning (See also* Annex A3*)*—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 shall be a warning that the unit is not designed to be used with closed-chest cardiac compression.

NOTE 17—Where possible, simple operating instructions should be provided on the resuscitator or the container.

10.1.2 *Range of Supply Pressures*—The range of supply pressures through which the resuscitator will operate shall be marked on the resuscitator.

10.1.3 *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.

10.1.4 *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.

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

10.3 *Information to be Provided by Manufacturer in Operating and Maintenance Instructions*:

10.3.1 *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.

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

10.3.2.1 A warning that the resuscitator must be used only by persons who have received adequate training.

10.3.2.2 Instructions on how to make the resuscitator operational in all intended modes of operation.

10.3.2.3 A specification detailing the following information:

*(a)* (*a*) The body mass range for which the resuscitator is suitable for use,

*(b)* (*b*) Range of ventilatory frequency,

*(c)* (*c*) Attainable delivery pressures,

*(d)* (*d*) Operating environmental limits,

*(e)* (*e*) Storage environmental limits,

*(f)* (*f*) Delivered oxygen concentrations under various test conditions,

*(g)* (*g*) Characteristics or dimensions, or both, of the gas inlet connection,

*(h)* (*h*) Stroke-volume range for operator-powered resuscitators,

*(i)* (*i*) Apparatus deadspace (backward leakage and forward leakage, where appropriate),

*(j)* (*j*) Expiratory resistance and inspiratory resistance, and any special fittings that impose such resistance,

*(k)* (*k*) The value of end-expiratory pressure generated by the resuscitator in normal use, if greater than 0,2 kPa (≃2 cm $H_2O$),

*(l)* (*l*) Details of the pressure-limiting system and override mechanism operation, if any,

*(m)* (*m*) External dimensions of the resuscitator and, if provided, the resuscitator case, and

*(n)* (*n*) Mass of the resuscitator and, if provided, the resuscitator case.

10.3.2.4 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,

10.3.2.5 Recommendations for the preferred methods of cleaning and disinfection or sterilization of the resuscitator and its components,

10.3.2.6 A recommended functional test for operation to be carried out immediately prior to use,

10.3.2.7 A list of operator-replaceable parts,

10.3.2.8 Recommendations for frequency of approved or factory service,

NOTE 18—If no service is required, this should also be stated in the manual.

10.3.2.9 Resuscitator flow capabilities (if gas-powered) at 2 and at 4 kPa (≃20 and at ≃40 cm$H_2O$) airway pressure,

10.3.2.10 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,

10.3.2.11 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,

10.3.2.12 Date of publication or revision of the manual, or both,

10.3.2.13 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 elected value less than 85 % (V/V) oxygen, if the resuscitator is so capable; and

10.3.2.14 The range of supply pressures with which the resuscitator meets the applicable requirements specified in Section 7 and details of any necessary adjustments for particular supply pressures.

## 11. Keywords

11.1 artificial breathing apparatus; intensive care equipment; medical equipment; resuscitators; specifications; tests

## ANNEXES

**(Mandatory Information)**

### A1. TEST METHODS

### A1.1 General Test Conditions

A1.1.1 The ambient temperature for the duration of the tests shall be between 20 and 25°C, except where otherwise stated. The relative humidity shall be within the range from 45 to 75 %, except where otherwise stated.

### A1.2 (A2) Apparatus

A1.2.1 Typical test apparatus is shown in Figs. A1.1-A1.6; alternative test apparatus of equivalent or greater accuracy may be used (see A1.3).

A1.2.2 (A2.1) *Test Lung* (see Figs. A1.4 and A1.5 for examples), with appropriate compliance and resistance characteristics (see Table 1).

A1.2.3 (A2.2) *Resistors*, if not provided with the test lung.

A1.2.4 (A2.3) *Pressure, Flow, and Volume-Measuring and Recording Apparatus*, including a pneumotachograph.

A1.2.5 (A2.4) *Temperature-Measurement Apparatus*.

A1.2.6 (A2.5) *Deadspace-Measurement Apparatus*, (see Fig. A1.3 for typical example).

A1.2.7 (A.2.6) *Negative Pressure Generator*, (see Fig. A1.6 for typical example).

A1.2.8 (A.2.7) *Graduated Cylinder*, of at least 200 mL capacity.

A1.2.9 (A.2.8) *Oxygen Analyzer*.

A1.2.10 (A.2.9) *Water Reservoir*, minimum 1 by 1 by 1 m.

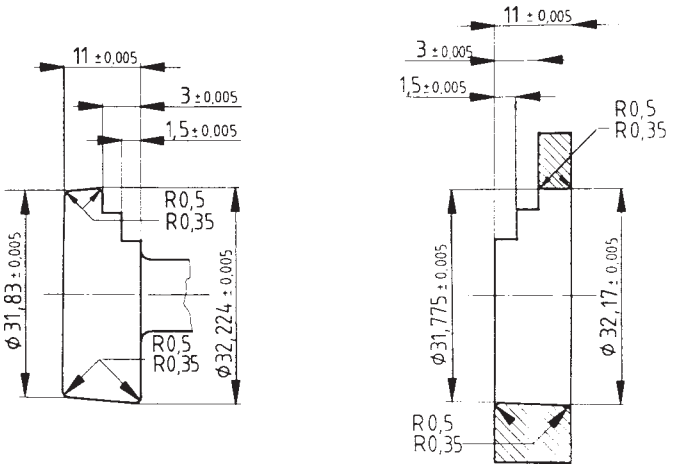
A1.2.11 (A.2.10) *Template*, 300 by 400 mm.

A1.2.12 (A.2.11) *Compressed Air Source*, capable of varying over the range from 270 to 550 kPa, and of producing a flow rate from 5 min to 60 L/min.

NOTE A1.1—This apparatus is only required if the resuscitator uses compressed air within the stated pressure ranges during normal operation.

NOTE A1.2—Flow rates exceeding 60 L/min may be required if the resuscitator is capable of flow rates exceeding 60 L/min (see A1.5.16).

A1.2.13 (A.2.12) *Environmental Chamber*, capable of maintaining temperatures from −40 ± 1°C to +60 ± 1°C and relative humidity from 40 to 95 % for periods of up to seven days.

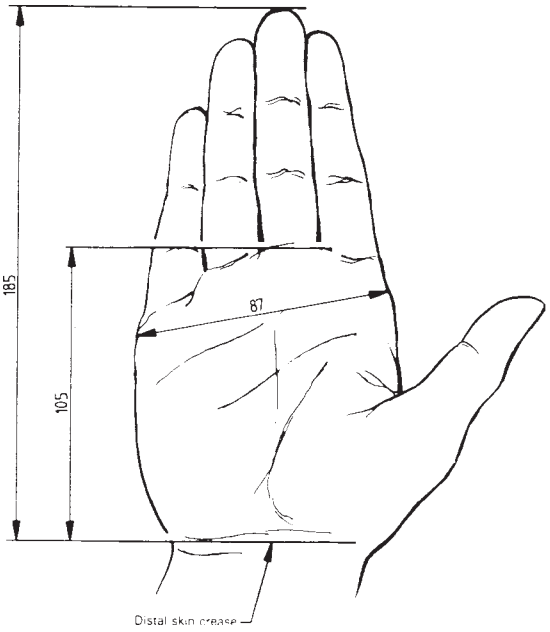



Dimensions in millimetres

NOTE 1—Basic taper is 1:28 on diameter.

NOTE 2—Engagement is 9.5 nom.

**FIG. A1.1 32-mm Ring and Plug Gages**




Dimensions in millimetres

**FIG. A1.2 Maximum Hand Dimensions**

A1.2.14 (A.2.13) *Oxygen Supply*, capable of varying over the range from 270 to 550 kPa and of producing a flow rate of at least 30 L/min.

A1.2.15 (A.2.14) *Vacuum Source*, capable of producing flow rates from 5 to 50 L/min.

A1.2.16 (A.2.15) *Gas Source*, capable of varying through the range of pressures from 270 to 550 kPa.

### A1.3 (A.3) Test Apparatus Tolerances

A1.3.1 Test apparatus shall have the following minimum tolerances:

A1.3.1.1 (A.3.1) *Oxygen Analyzer*—±1 % (V/V) of the concentration being measured with a response time of greater than 90 % in 10 s.

A1.3.1.2 (A.3.2) *Compliances*—±5 % of the required compliance value throughout a range of inspiratory phase times from 0.5 to 6 s (see Annex A3).

A1.3.1.3 (A.3.3) *Pressure, Flow, and Volume*—±2.5 % of the reading plus ±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.

A1.3.1.4 (A.3.4) *Resistances*—±20 % for linear resistances and ±10 % for parabolic resistances within the designated flow range (see Annex A2).

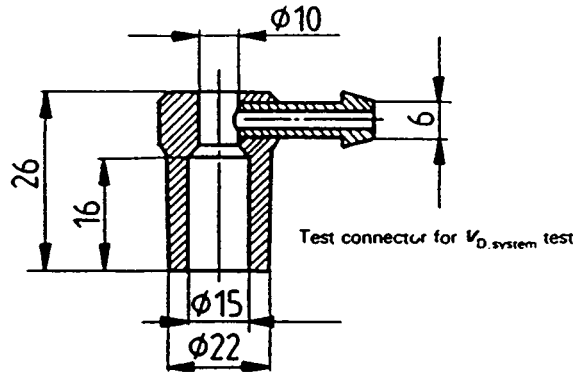
A1.3.1.5 (A.3.5) *Temperature Measurement*—±0.5°C.

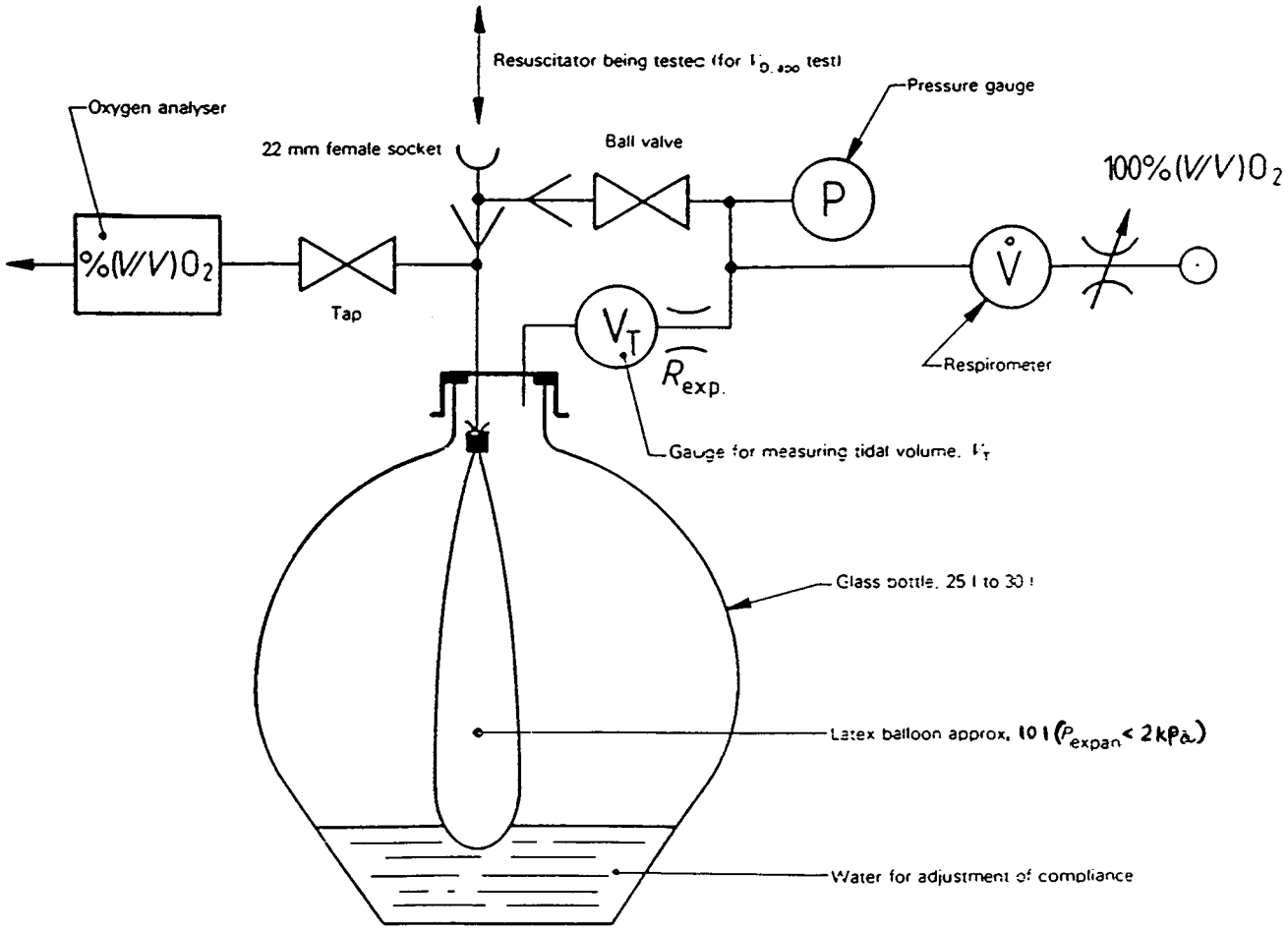
### A1.4 (A.4) Conditioning and Reference Conditions

A1.4.1 (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.

A1.4.2 (A.4.2) *Reference Conditions*—Correct all test readings to the reference conditions of ATPD (20°C, 1 atm, 0 % relative humidity).

Dimensions in millimetres




Dimensions in millimetres

**FIG. A1.3 Test Setup for Measuring Total Apparatus Deadspace**

### A1.5 (A.5) Procedures

A1.5.1 (A.5.1) *Bag Refill Valve Connectors*—Using a 32 mm gage (see Fig. A1.1), measure the internal and external diameters of the connector.

A1.5.2 (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.

A1.5.3 (A.5.3) *Valve Function After Contamination with Vomitus:*

A1.5.3.1 (A.5.3.1) *Test Material*—Simulated vomitus, prepared by mixing two parts of baby meal beef with vegetable meal and one part water.

A1.5.3.2 (A.5.3.2) *Procedure*—Warm the simulated vomitus to 37 ± 3°C and pour 175 mL into the patient connection port while cycling the resuscitator at a rate of 30 breaths per minute for resuscitators suitable for use with patients of a body mass up to 10 kg, and at a rate of 12 breaths per minute for all other models. Perform this test with the resuscitator connected to the test lung (see A1.2.2). Continue to cycle the resuscitator

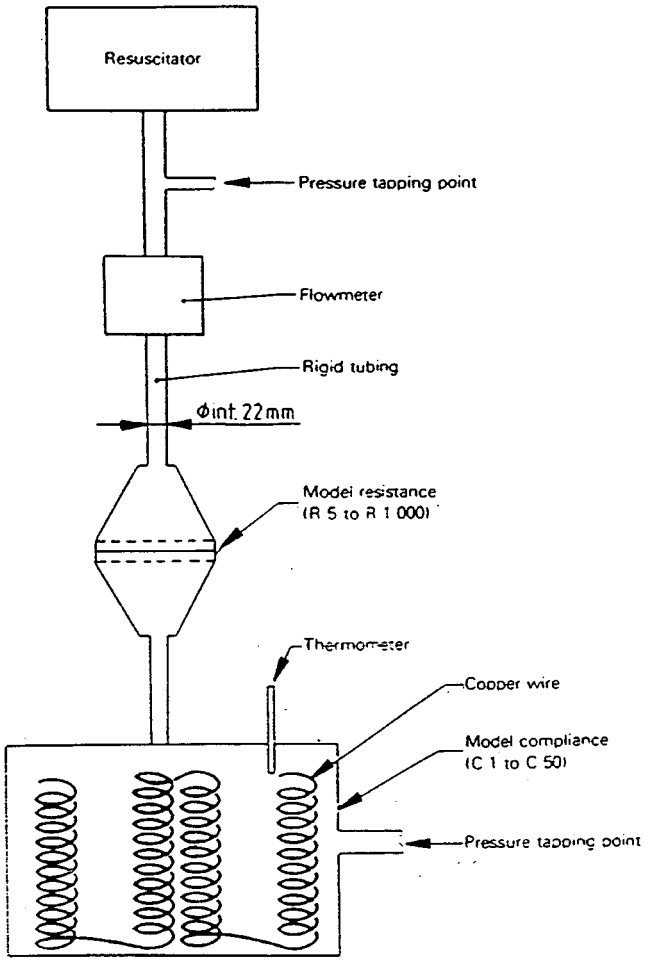



**FIG. A1.4 Representative Passive Test Lung System**

for 30 s. Clear the resuscitator of the mixture according to the manufacturer's instructions and verify the resuscitator's performance.

NOTE A1.3—Some of the test solution may spill over when poured into the patient connection port.

A1.5.4 (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.

A1.5.5 (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.

A1.5.6 (A.5.6) *Immersion in Water*—Arrange the resuscitator in its ready-for-use condition, that is, gas on, gas off, etc. and drop it from a height of 1 m into the water reservoir (see A1.2.10). Take the resuscitator out after 10 s and shake out the water for not more than 20 s. Begin ventilating the test lung (see A1.2.2) immediately.

A1.5.7 (A.5.7) *Supplementary Oxygen and Delivered Oxygen Concentration*—Connect the resuscitator to the test lung (see A1.2.2) set at C20 and R20 characteristics. Connect an oxygen analyzer (see A1.2.9) 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 per minute 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 Fig. A1.2 for maximum allowable hand dimensions).

A1.5.8 (A.5.8) *Delivered Oxygen Concentration for Gas-Powered Resuscitators:*

A1.5.8.1 Connect the resuscitator to the test lung (see A1.2.2) set at C20 and R20 characteristics. Connect the oxygen analyzer (see A1.2.9) 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 per minute 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.

A1.5.8.2 Repeat the whole procedure using the test lung set at C50 and R5 characteristics.

A1.5.8.3 Perform both tests at the maximum and minimum flow settings recommended for the resuscitator.

A1.5.9 (A.5.9) *Expiratory Resistance:*

A1.5.9.1 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.

A1.5.9.2 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.

A1.5.10 (A.5.10) *Inspiratory Resistance:*

A1.5.10.1 For resuscitators suitable for use with patients with a body mass of up to 10 kg, connect the patient connection port to a vacuum source producing an air flow rate of 5 L/min. Record the inspiratory pressure generated at the patient connection port.

A1.5.10.2 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.

A1.5.11 (A.5.11) *Patient Valve Malfunction*—Connect the resuscitator to the test lung (see A1.2.2) set at C20 and R20 characteristics. Ventilate the test lung at a frequency of 12 breaths per minute and a tidal volume of 600 mL. Using the oxygen supply (see A1.2.14), 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.

A1.5.12 (A.5.12) *Apparatus Deadspace:*

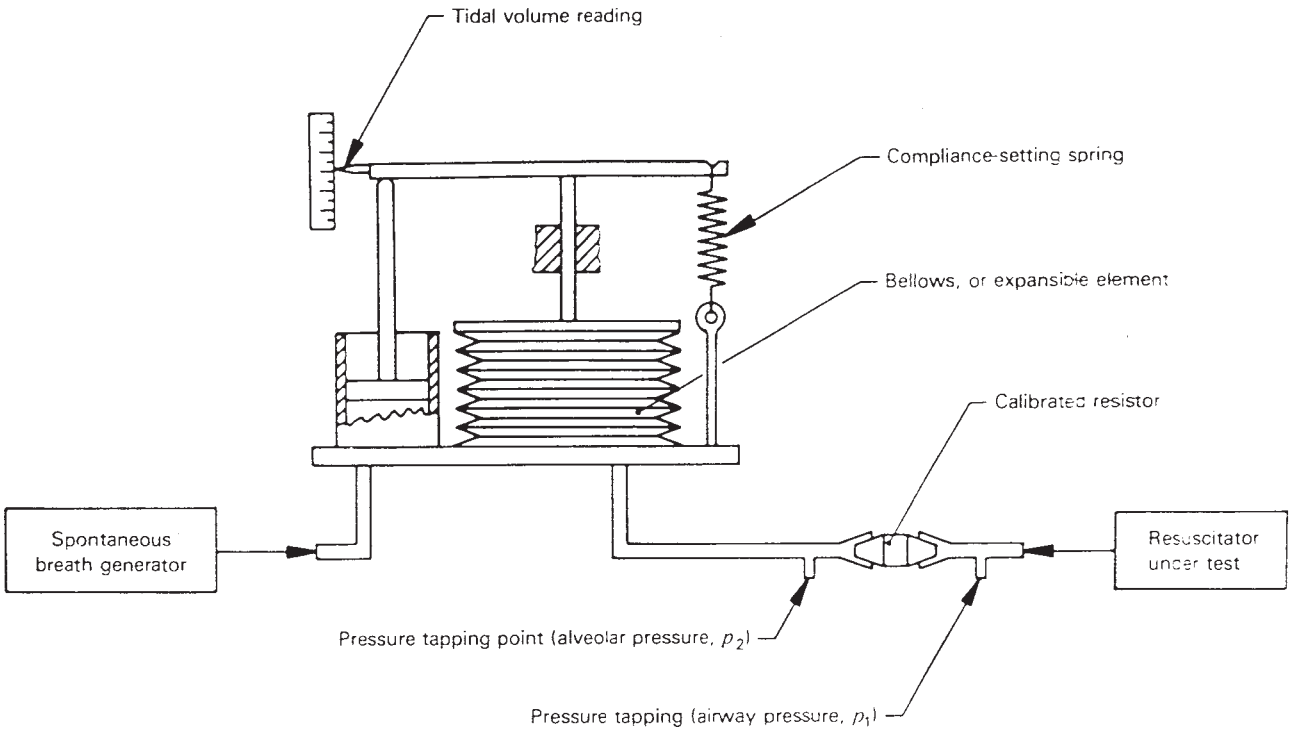



**FIG. A1.5 Example of Active Test Lung System**

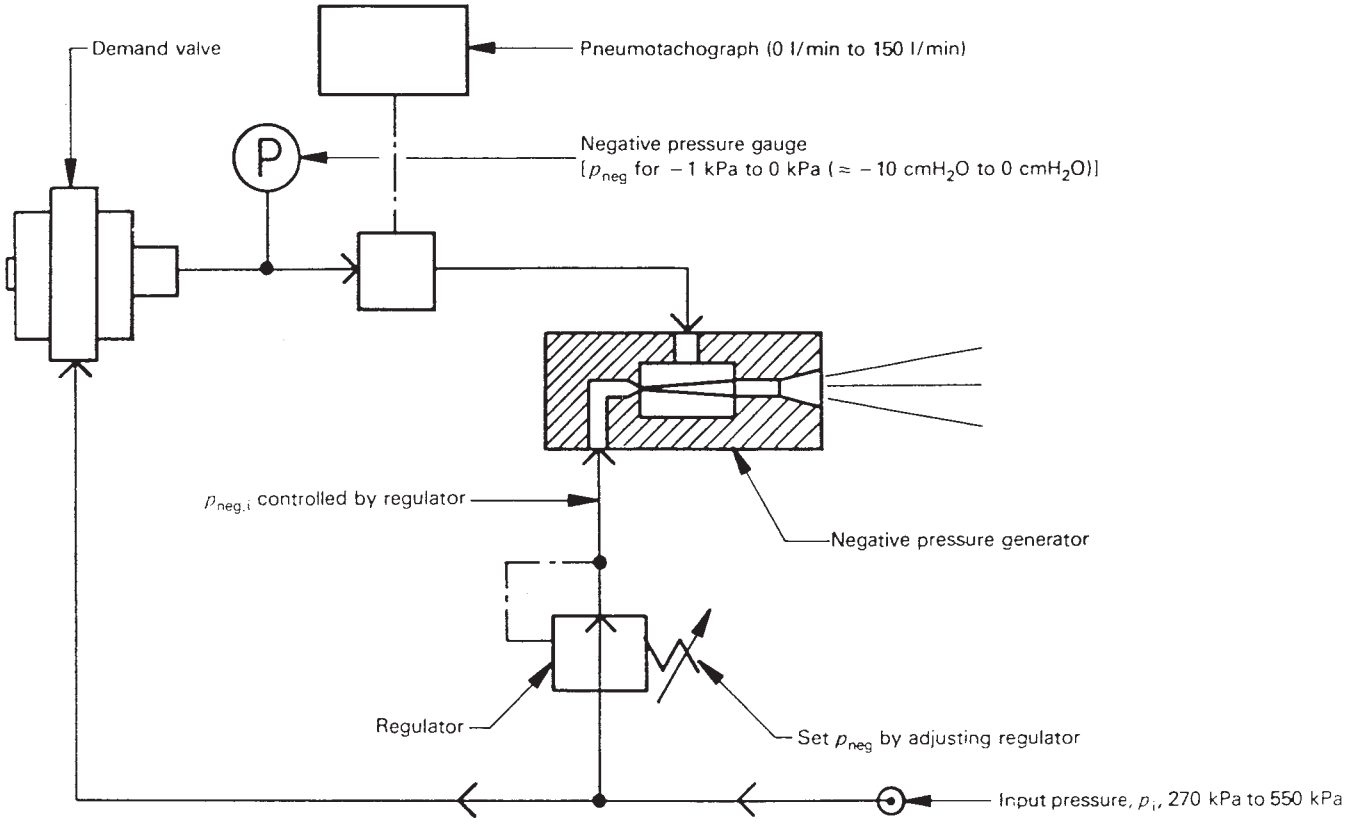



**FIG. A1.6 Example of Test Apparatus for Testing Demand Valves (Threshold and Peak Flows)**

A1.5.12.1 (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.

A1.5.12.2 (A.5.12.2) *Preparation of Apparatus Prior to Testing Resuscitator*—Set up the deadspace-measurement apparatus (see A1.2.6 and Fig. A1.3). Close the tap to the oxygen analyzer (see A1.2.9). 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 analyzer tap. Open the flowmeter and fill the bottle with 100 % (V/V) oxygen. Close the oxygen flowmeter when the pressure gage reads approximately 1 kPa (≃10 $cmH_2O$).

A1.5.12.3 Connect the 22/15 mm test connector to the 22 mm female socket and supply the appropriate flow of atmospheric air to the side nipple (see Table A1.1).

A1.5.12.4 Open the ball valve, whereby the expiratory flowpath is flushed with 100 % (V/V) oxygen.

A1.5.12.5 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 and pressure gage. The number of ventilating cycles is given in Table A1.1.

A1.5.12.6 Close the ball valve and open the analyzer 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 analyzer. Close off the oxygen flow when the pressure gage reads 1 kPa (≃10 cmH $_2$O) again.

A1.5.12.7 Determine the internal deadspace of the test apparatus for every combination of test parameters used.

A1.5.12.8 The apparatus is now ready for testing the resuscitator.

A1.5.12.9 (A.5.12.3) *Procedure*—Test the resuscitator using the same procedure as described for the test connector (see A1.5.12.2).

A1.5.12.10 (A.5.12.4) *Expression of Results*—Calculate the system deadspace (that is, with test connection) using the following equation:

$$V_{D,system} = \frac{F_{O2,bag}(test\ connection)^{-21}}{79} \times V_T$$

NOTE A1.4—The apparatus should be so designed that $V_{D,system}$ = 20 mL or less. The oxygen analyzer 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:

$$V_{D,system} = \frac{F_{O2,bag}^{-21}}{79} \times V_T - V_{D,system}$$

A1.5.13 (A.5.13) *Tidal Volumes*—Connect the resuscitator to the appropriate test lung (see A1.2.2 and Figs. A1.4 and A1.5) having the characteristics stated in Table 1. Measure the volume (see A1.2.4). Use only one hand to compress the compressible unit (see Fig. A1.2 for maximum allowable hand dimensions). Perform these tests without the use of an override mechanism if one is provided.

A1.5.14 (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 gage. Operate the resuscitator and adjust the flow regulator to give an output pressure of 2 kPa (≃20 $cmH_2O$). If appropriate, adjust the regulator flow setting to give 40 L/min ±10 % while maintaining the output pressure at 2 kPa (≃20 $cmH_2O$). Confirm that the required flow is achieved.

A1.5.15 (A.5.15) *Pressure Limitation (Operator-Powered Resuscitators):*

A1.5.15.1 For resuscitators classified for use with patients up to 10 kg body mass, occlude the patient connection port and, using the compressed air source (see A1.2.12), pass air at a flow rate of 15 L/min through the pressure-limiting system. Record the pressure at the patient connection port.

A1.5.15.2 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 (see A1.2.12), pass air at a flow rate of 60 L/min through the pressure-limiting system. Record the pressure at the patient connection port.

A1.5.16 (A.5.16) *Pressure-Limiting System (Gas-Powered Resuscitators*)—Follow the method described in A1.5.14, substituting flows of 60 L/min or the maximum flow delivered by the resuscitator, whichever is greater.

A1.5.17 (A.5.17) *Pressure-Cycling System (Automatic, Pressure-Cycled, Gas-Powered Resuscitators)*—Connect the resuscitator to the appropriate test lung (see A1.2.2 and Figs. A1.4 and A1.5) having the characteristics stated in Table 1. Operate the resuscitator and record the pressure at which the resuscitator cycles from inspiration to expiration.

A1.5.18 (A.5.18) *Peak Inspiratory Flow and Flow Threshold*—Connect the demand valve to be tested as shown in Fig. A1.6 and carry out the test procedure described in A1.5.18.1 and A1.5.18.2.

A1.5.18.1 (A.5.18.1) *Flow Threshold*—Adjust the regulator that controls the negative input pressure, $p_{neg,1}$ and note the reading on the negative pressure gage *P*, at which output flow is initiated.

A1.5.18.2 (A.5.18.2) *Peak Flow*—Set the negative pressure, $p_{neg}$to 0.8 kPa by adjusting the regulator that controls the negative input pressure, $p_{neg,i}$. Verify that the output flow, $q_{v,o}$, is 100 L/min for at least 10 s.

A1.5.18.3 (A.5.18.3) *Flow Termination*—Adjust the regulator that controls the negative input pressure, $p_{neg,i}$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 gage, *P*, at which this occurs.

**TABLE A1.1 Test Parameters**

| Tidal Volume ($V_T$), mL | Compliance, *C* | | Expiratory Resistance, $R_{exp}$ | | Test Flow for Internal Deadspace, L/min | Test Cycles |
|---|---|---|---|---|---|---|
| | mL/kPa | (mL/$cmH_2O$) | kPa/(L/s) | ($cmH_2O$/(L/s)) | | |
| 600 | 200 | (20) | 0,5 | (5) | 30 | >15 |
| 100 | 100 | (10) | 2 | (20) | 5 | >50 |

A1.5.19 (A.5.19) *Operating Conditions:*

A1.5.19.1 (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, that is, gas-powered volume-cycled, hand-powered, etc., specified in Section 7.

A1.5.19.2 (A.5.19.2) *Procedure:*

NOTE A1.5—In each of the operational tests given, the resuscitator should be operated continuously for a period of at least 10 min.

A1.5.19.3 (A.5.19.2.1) Prepare the resuscitator in accordance with the general requirements. Place the resuscitator system in the environmental chamber (see A1.2.13) set at 50°C and at least 95 % relative humidity. Maintain these conditions for no fewer than 4 h.

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

Once testing has been completed, return the resuscitator, within 5 min, to an ambient temperature between 18 and 22°C. Allow the resuscitator to stabilize for at least 4 h.

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

A1.5.19.4 (A.5.19.2.2) Place the resuscitator in the environmental chamber set at − 40°C for a period of at least seven days, or until the resuscitator stabilizes.

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

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 to 70 % relative humidity for a period of not less than seven days.

At the end of this period, return the resuscitator, within 5 min, to ambient conditions of 18 to 22°C and 40 to 70 % relative humidity. Allow the resuscitator to stabilize for at least seven days.

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

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 to 22°C.

Within 5 min, operate and test the resuscitator.

A1.5.20 (A5.20) *Supply Pressures*—Connect the resuscitator to the gas source (see A1.2.16) and test its performance at source pressures of 270 and 550 kPa using the test methods described for the general requirements and any specific requirements for the type of resuscitator being tested, that is, automatically or manually cycled, specified in Section 7.

## A2. COMPLIANCES AND RESISTANCES REQUIRED TO SET UP TEST LUNG

**TABLE A2.1 Required Compliances**

| Classification[A] | Compliance, *C* | |
|---|---|---|
| | mL/kPa | mL/cm$H_2O$ |
| C 50[B] | 500 | (50) |
| C 20 | 200 | (20) |
| C 10 | 100 | (10) |
| C 1 | 10 | (1) |

[A]The classification was originally based on conventional centimetres of water.
[B]Not used in test procedure.

**TABLE A2.2 Required Resistances**

| Classification[A] | Resistance | | | | Range of Air Flow[B] (for linear or parabolic resistances) is |
|---|---|---|---|---|---|
| | Linear, *R* | | Parabolic[C], *R*• | | |
| | kPa/(L/s) | [cm$H_2O$/(L/s)] | kPa/(L/s) | [cm$H_2O$/(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[D] | 5 | [50] | 0.39 | [3.9] | 0.25 to 0.5 |
| R 400 | 40 | [400] | 0.14 | [1.4] | 0.05 to 0.075 |

[A]The classification was originally based on conventional centimetres of water.
[B]The tolerances for the flow range values are ±20 % for linear resistances and = 0•• for parabolic resistances.
[C]The values for parabolic resistances refer to the nominal inside diameter in millimetres sharp-cornered orifices needed to achieve these resistance values. Other geometric shapes may be used, for example, thicker orifices with rounded corners, but nominal diameters would be different.
[D]Not used in test procedure.

## A3. RATIONALE STATEMENT

A3.1 This annex provides a concise rationale for the important requirements of this specification and is intended for those who are familiar with the subject of the specification but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the specification necessitated by those developments. The clauses in this annex have been so numbered to correspond to the clauses in the specification to which they refer. The numbering is, therefore, not consecutive.

A3.1.1 (5.1) *Patient Connection Port*—The patient connector dimensions permit connection to standard 15 mm tracheal tube connectors (see ISO 7228) and face masks having a 22 mm female connector or a 15 mm male connector.

A3.1.2 (5.2) *Expiratory Port for Breathing Gases*—The exhaust connection described is that used for connection to the transfer tubes of anesthetic gas scavenging systems. It is essential that breathing system conical connectors are not compatible with this port. It is also important that the exhaust port be designed such that it cannot be confused with the inspiratory port during use of the resuscitator.

A3.1.3 (5.3) *Face Mask Connectors*—It is important that resuscitator face masks should be generally interchangeable.

A3.1.4 (5.4) *Bag Refill Valve Connectors*—The size of this connector is chosen to prevent the accidental fitting of demand valves with manual controls.

A3.1.5 (6.2) *Dismantling and Reassembly*—Wrongly assembling a resuscitator so that it causes incorrect operation or complete malfunction is a serious hazard that may result in inadequate ventilation of the patient.

A3.1.6 (6.3) *Patient Valve Function After Contamination with Vomitus*—It is important that vomitus can be quickly and effectively cleared from a resuscitator so that resuscitation can be continued with a minimum of interruption.

A3.1.7 (6.4.1) *Drop Test*—It is important that resuscitators can withstand severe shock caused by falls from ambulances, hospital beds, etc.

A3.1.8 (6.4.2) *Mechanical Shock Test for Resuscitator Fixtures That are Mounted on Castors or on Wheels*—Castor-mounted or wheeled resuscitators may be tipped over either on the way to or during a resuscitation. This should not render the unit inoperative.

A3.1.9 (6.5) *Immersion in Water*—Resuscitators are often used in areas where the device may be inadvertently dropped into water during the resuscitation. If the unit is recovered quickly from the water, it should still function.

A3.1.10 (6.6) *Bag Refill Valves*—It is imperative that demand valves with manual controls are not accidentally substituted for bag refill valves. Demand valves are capable of high gas flows that may cause resuscitator patient valves to jam.

A3.1.11 (7.1) *Size* —Resuscitators may be required where access to patients is difficult, such as in crawl spaces and through manholes.

A3.1.12 (8.1.1) *Operator-Powered Resuscitators*—Although 40 % (V/V) oxygen concentration is adequate under some circumstances, 85 % (V/V) or higher oxygen concentrations are preferable for the treatment of severely hypoxemic patients during resuscitation. This concentration should be achievable at supplementary oxygen flows of 15 L/min or less because to specify greater than 15 L/min would exceed the normal calibration of standard, clinically used flowmeters for adult use and could potentially lead to inaccurate control of oxygen flows and jamming of the patient valve in the inspiratory position.

A3.1.13 (8.1.2) *Gas-Powered Resuscitators*—High oxygen concentrations are important in resuscitating patients who are extremely hypoxemic. Lower percentages of oxygen will lengthen the duration of oxygen supply. The performance of air-entrainment“ mixing” devices is influenced by the flow settings of the resuscitator and the compliance and resistance of the patient.

A3.1.14 (8.3) *Expiratory Resistance*—To facilitate exhalation, expiratory resistance should be minimized unless there are special clinical indications to impose such resistance.

A3.1.15 (8.4) *Inspiratory Resistance*—The design of a resuscitator should be such that it is possible for the patient to breathe spontaneously without excessive subatmospheric pressure when the resuscitator is applied to the patient’s airway but is not activated by the operator.

A3.1.16 (8.5) *Patient Valve Malfunction*—Valve malfunction or jamming in the inspiratory position at high supplementary oxygen flows may lead to failure of the resuscitator and transmission of excessive pressures to the patient. Resuscitators are commonly used at oxygen input flows of 15 L/min, but flowmeter valves are often capable of permitting flows of over 30 L/min. It is essential to follow the manufacturer’s instructions and to use only attachments recommended for use with the resuscitator.

A3.1.17 (8.6) *Patient Valve Leakage*—Forward leakage If forward leakage is a design feature of a resuscitator, it should be disclosed so that the user does not confuse this leakage with a malfunction.

A3.1.18 (8.7) *Apparatus Deadspace*—It is essential to minimize apparatus deadspace in order to limit rebreathing of expired gases.

A3.1.19 (8.8.1) *Tidal Volume*—For adult ventilation a typical tidal volume is approximately 600 mL. The compliances and resistances listed in Table 1 are representative of the possible compliances and resistances found in adults and children needing resuscitation. The tidal volume requirements of 15 mL/kg are higher than normal and are commonly used

during resuscitation to allow for mask leakage. The ventilatory frequencies are typical values used in pediatric and adult resuscitation.

A3.1.20 (8.8.2) *Pressure Limitation (Operator-Powered Resuscitators)*—Experience with infant resuscitation suggests that a maximum inspiratory pressure of 4.5 kPa (≃45 $cmH_2O$) will not produce lung damage and will permit adequate tidal volumes in most patients weighing under 10 kg.

A3.1.21 Pressure-limiting systems are not specified for operator-powered resuscitators designated for use with patients weighing over 10 kg. However, it is essential that resuscitators with such systems satisfy the tidal volume requirements specified in this specification (see Table 1) without the use of any override mechanism. When airway pressure is limited to below 6 kPa (≃60 $cmH_2O$), it was felt that an override mechanism is essential in order to ventilate those patients with low lung compliance or high airway resistance, or both.

A3.1.22 (8.9.1) *Pressure-Limiting System*—It is essential that maximum delivery pressure is limited on all gas-powered resuscitators. Airway pressure at 4.5 kPa (≃45 $cmH_2O$) was considered adequate for ventilation of the lungs, but unlikely to produce barotrauma. The selection of higher settings for difficult clinical problems necessitates risk of barotrauma.

A3.1.23 (8.9.2) *Inspiratory Flow*—To minimize the risk of gastric distension, 40 L/min is considered to be the maximum flow that should be used when resuscitating with a mask. This is in accordance with the recommendations of the American Heart Association,[5] and these recommendations are generally accepted worldwide. Higher flows may be used with intubated patients because of the decreased risk of gastric distension.

A3.1.24 (8.9.4) *Automatic Pressure-Cycled, Gas-Powered Resuscitators*—It is required that pressure-cycled resuscitators meet the performance requirements of this specification, but they are of limited use on patients with poor lung compliance or high airway resistance, or both, because the cycling pressure is achieved without adequate ventilation. A "negative" pressure phase should not be used as it is associated with a fall in functional residual capacity (FRC) and arterial oxygen partial pressure ($pO_2$).

A3.1.25 (8.10.1) *Pressure for Initiation*—It is important that the patient should not have to generate large amounts of negative pressure to initiate gas flow from the demand valve in order to minimize respiratory work. A negative pressure of − 0,2 kPa (≃−2 $cmH_2O$) is physiologically acceptable.

A3.1.26 (8.10.2) *Peak Inspiratory Flow*—Peak flows as outlined in A3.1.26 are necessary in order to satisfy the inspiratory needs of the typical patient; large amounts of negative pressure should not be required to generate these flows as it would cause fatigue in a spontaneously breathing patient.

A3.1.27 (8.10.3) *Termination Pressure*—Positive pressure indicates that adequate tidal volume has been delivered. When the pressure becomes slightly positive it indicates that the patient should be allowed to exhale and hence flow should stop.

A3.1.28 (9.2) *Operating Conditions*—Resuscitators can be expected to be exposed to the temperature extremes outlined in 8.2 since such temperatures frequently occur throughout the world in environments where resuscitators are used.

A3.1.29 (10.4) *Connections for Compressed Gas*—It is essential to be easily able to connect resuscitator oxygen tubing, for example, while the resuscitator is in use.

A3.1.30 (10.5) *Supply Pressures*—The range of supply pressures reflects the variety of pressures used internationally and the tolerances of pressure-regulating systems.

A3.1.31 (11.1.1) *Manufacturer's Warning*—These resuscitators are unacceptable for use during closed chest cardiopulmonary resuscitation because the increased intrathoracic pressure caused during chest compression causes the resuscitator to cycle from the inspiratory mode to the expiratory mode prior to adequate ventilation of the lungs.

A3.1.32 (11.3.2) *Duration of Gas Supply (See 10.3.2.3(m))*—Small, easily portable cylinders are commonly used with resuscitators. It is important that the operator have some idea of the duration of this size of oxygen supply under simulated conditions of use.

[5] "American Heart Association Standards for CPR and ECC," *Journal of American Medical Association*, Vol 25, No. 1, June 6, 1986.

## A4. MATERIALS

A4.1 *Cleaning and Disinfection or Sterilization (See also A4.5)* —Components that are subject to contamination should either withstand the methods of cleaning and disinfection or sterilization recommended by the manufacturer, or be labelled "for single use only" (disposable).

A4.2 *Oxygen Compatibility (See also A4.5)* —All resuscitator components should be compatible with and resistant to ignition with oxygen concentrations and pressures to which the component is exposed.

A4.3 *Resistance to Corrosion and Deterioration (See also A4.5)* —Resuscitator performance should not be degraded because of corrosion during a period of twelve months after being stored in accordance with the manufacturer's instructions.

A4.4 *Patient Valve Housing*—The valve housing should be constructed of materials such that the functioning mechanism is readily visible to the operator.

A4.5 *Rationale:*

A4.5.1 Cleaning and disinfection or sterilization Resuscitators are likely to become contaminated by bacteria and foreign matter during use. It is therefore essential that manufacturers recommend suitable methods of cleaning and disinfection or sterilization.

A4.5.2 For many applications, cleaning and disinfection alone is adequate. However, in certain situations, the user may require resuscitators that can withstand steam or ethylene oxide gas sterilization of the contaminated components. The user should appreciate that some methods of disinfection and sterilization may shorter the usable life of the resuscitator.

A4.6 *Oxygen Compatibility*—Selection of materials for use in high oxygen concentrations, especially at elevated supply pressures, involves consideration of both compatibility and ease of ignition. Materials that burn in air will burn violently in high concentrations of oxygen at atmospheric pressure and may explode at higher pressures. Many materials, including metals, will not burn in air but may do so in pure oxygen, particularly under pressure. Materials may be ignited by the friction of a valve seat or stem packing or by the adiabatic compression produced when oxygen at high pressure is suddenly introduced into a system at low pressure. Therefore, easily ignitable materials, such as some rubber and plastics, should be avoided in valves and fittings, especially in high-pressure oxygen systems, unless tested or experience-rated for such services. These conditions and requirement also apply to the use of nitrous oxide.

A4.7 *Resistance to Corrosion and Deterioration*—Since resuscitators are often stored and used in the proximity of sea water, it is important that resuscitators are capable of meeting the performance requirements of this specification after being used and stored in such an environment.

## A5. FACE MASKS

A5.1 A face mask provided with or recommended for use with a resuscitator should comprise a body, a face seal, and a port to receive the patient connector of the resuscitator.

A5.2 If the face mask is constructed of more than one part, then the parts should be easily assembled and securely held together in use.

A5.3 The face seal should be capable of providing a fit that minimizes leaks at the operating pressures and temperatures specified in this specification.

A5.4 The body of the mask should be transparent to allow the operator to observe the patient's nose and mouth for breath condensation as evidence of breathing and also for the possible appearance of vomitus. It is not intended that this specification should prohibit the use of nontransparent or translucent masks. Under certain circumstances, their use may be preferable.