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Specification for

Ventilatory resuscitators

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- Association of Anaesthetists of Great Britain and Ireland
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Paediatric Association
- Department of Health and Social Security
- Electro Medical Trade Association Limited
- GAMBICA (BEAMA Ltd.)
- Industrial Safety (Protective Equipment) Manufacturers' Association
- Institution of Production Engineers
- Intensive Care Society
- Medical Sterile Products Association

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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
1 Scope	1
2 Definitions	1
3 Classification	2
4 Cleaning, disinfection and sterilization	2
5 Connectors	2
6 Operational requirements	4
7 Physical requirements	5
8 Performance requirements	5
9 Storage and operating conditions	6
10 Gas supply for gas-powered resuscitators	6
11 Marking	7
12 Information to be provided by the manufacturer	7
Appendix A Recommendations for face masks	9
Appendix B Recommendations for materials	9
Appendix C Method of test for patient valve function after contamination with vomitus	9
Appendix D Method of test for tidal volume	9
Appendix E Method of test for pressure limitation	10
Appendix F Method of test for delivered oxygen concentration	12
Appendix G Method of test for resistance to spontaneous breathing	12
Appendix H Method of test for patient valve malfunction	13
Appendix J Method of test for apparatus deadspace (backward leak)	13
Appendix K Method of test for flow through patient demand valves	13
Appendix L Method of test for storage and operating conditions	14
Appendix M Construction and testing of test lungs	14
Figure 1 — Conical fittings of 30 mm size	3
Figure 2 — Conical fittings of 32 mm size	4
Figure 3 — Schematic diagram of a test lung	10
Figure 4 — Schematic diagram of an instrumented test lung	11
Figure 5 — Apparatus for test for initiation of flow of patient demand valves	15
Table 1 — Resistance values of test lung	9
Table 2 — Compliance values of test lung	9
Table 3 — Test conditions for tidal volume test	11
Publications referred to	Inside back cover

Foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee. It applies to ventilatory resuscitators, i.e. small portable ventilators intended for use by paramedical and medical personnel and also for emergency use by personnel with very limited training. They may be used at the scene of emergencies both inside and outside hospitals or during patient transport.

The effective and safe use of a ventilatory resuscitator is determined not only by the performance of the resuscitator, but also by the skill of the operator. This 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.

The committee responsible for this British Standard considers that ventilatory resuscitators complying with the requirements of the standard are suitable for use with closed-chest cardiac compression. Currently available automatic pressure-cycled gas-powered resuscitators are not considered suitable for such use because the increased intrathoracic pressure occurring during chest compression causes the resuscitator to cycle from the inspiratory mode to the expiratory mode prior to adequate ventilation of the lungs. These resuscitators have therefore been excluded from the scope of this standard.

Ventilatory resuscitators are used in widely varying environments and additional requirements may be necessary in certain situations, e.g. in mine rescue work, where a flammable or toxic atmosphere may be present, or where a dust environment may occur. In these instances, the purchaser is recommended to agree additional requirements with the manufacturer.

Attention is drawn to the requirements for respirators and breathing apparatus given in BS 2091, BS 4555, BS 4558, BS 4667-1 to BS 4667-4 and BS 6016.

NOTE Throughout this standard the unit of pressure used is the kilopascal (kPa). It should be noted that 1 kPa = 10.1972 cmH₂O.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This British Standard specifies performance and safety requirements for ventilatory resuscitators (hereinafter referred to as resuscitators) intended for use with patients of any body mass. It covers both operator-powered and gas-powered resuscitators. Requirements are also included for equipment essential for the use of a resuscitator as a self-contained piece of portable equipment, e.g. a gas supply system and carrying case.

No requirements are included for face masks although recommendations for these are given in Appendix A.

Electrically-powered resuscitators, automatic pressure-cycled gas-powered resuscitators, devices which have been designed only to deliver gases to a patient breathing adequately, or devices which are designed to assist or provide for the ventilation of a patient for an extended period of time are outside the scope of this standard.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

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

2.1 resuscitator

a self-contained portable device, intended for use in emergency situations to provide lung ventilation to individuals whose breathing appears to be inadequate

2.2 gas-powered resuscitator

a resuscitator which produces inflation of the lungs by the energy of compressed gas

2.3 automatic resuscitator

a resuscitator from which the flow of gas for repeated inflations of the lungs is independent of any repetitive action by the operator

2.4 operator-powered resuscitator

a resuscitator which produces inflation of the lungs by the operator compressing the compressible unit

2.5 compliance

the volume of gas at ambient atmospheric pressure that has to be added to an enclosed space to produce a unit increase in pressure

2.6 resistance

the pressure drop per unit of flow at a specified flow

2.7 tidal volume

the volume of gas, entering or leaving a patient or test lung during the inspiratory or expiratory phase

2.8 minute volume

the volume of gas entering or leaving the patient or test lung in 1 min

2.9 frequency

the number of breaths per minute

2.10 airway pressure

the pressure measured at the patient connection port

2.11 pressure-limiting system

a mechanism for limiting the maximum pressure that can be generated by the resuscitator at its patient connection port

2.12 patient connection port

the opening at the patient end of the resuscitator which is connected either to a face mask or to a tracheal tube connector

2.13 exhaust port

the opening through which exhaled gases pass to atmosphere

2.14 bag inlet valve

a valve which permits the compressible unit to refill with gas at ambient pressure

2.15 bag refill valve

a demand valve which permits refilling of the compressible unit from a compressed gas source

2.16 demand valve

a device that delivers a flow of gas which is related to a reduction in downstream pressure and that terminates flow when that pressure equals atmospheric pressure or a preset pressure

2.17**patient demand valve**

a demand valve in which the reduction in downstream pressure is created by the inspiratory efforts of the patient

2.18**patient valve**

a valve that directs gas from the resuscitator into the lungs during the inspiratory phase and from the lungs to atmosphere during the expiratory phase

2.19**compressible unit**

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

2.20**delivered oxygen concentration**

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

2.21**apparatus deadspace (backward leak)**

that volume of previously exhaled gas which is delivered from the resuscitator in the succeeding inspiratory phase

2.22**intermediate hose**

hose that conducts gas between parts of the resuscitator

2.23**cylinder pressure regulator**

a device for reducing the gas supplied at cylinder pressure to the working pressure required by the resuscitator

3 Classification

Resuscitators for use with patients up to 40 kg body mass shall be classified by the body mass range for which they are suitable. This range shall be derived on the basis that resuscitators shall deliver a tidal volume of 15 mL/kg body mass.

Resuscitators delivering a tidal volume of 600 mL and above, i.e. suitable for patients over 40 kg body mass, shall be classified as adult resuscitators.

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

4 Cleaning, disinfection and sterilization

NOTE Recommendations for materials are given in Appendix B.

The resuscitator shall meet the requirements specified in 8.1 to 8.6 after those components which are in contact with the patient's expired gases or are subject to contamination have been submitted to 30 cycles of cleaning and disinfection or sterilization, whichever is recommended by the manufacturer in the manual [see 12.1 e)].

If the manufacturer recommends autoclaving as a method of sterilization, this shall be by using a sterilizer complying with BS 3970-1.

5 Connectors**5.1 Patient connection port**

The patient connection port shall be a 15 mm female and a 22 mm male coaxial connector dimensioned as specified in BS 3849 for the paediatric and adult size fittings respectively.

5.2 Exhaust port

If a tapered connector is provided at the exhaust port, it shall be a 30 mm male conical fitting dimensioned as shown in Figure 1.

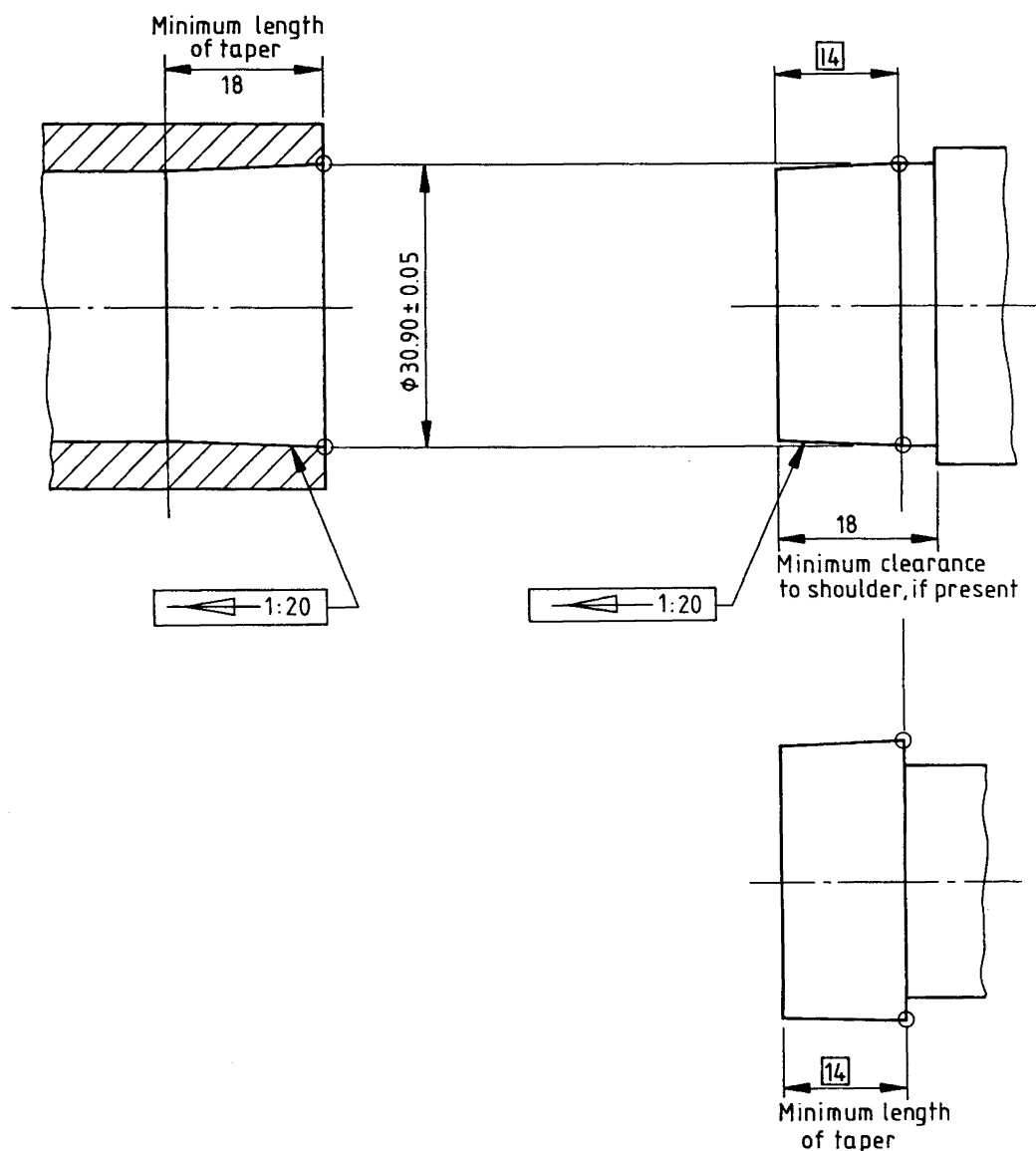
5.3 Bag inlet valve connector

The bag inlet valve connector shall not be compatible with the following:

- a) connectors dimensioned in accordance with BS 3849;
- b) the 30 mm connector dimensioned as shown in Figure 1;
- c) the 32 mm connector dimensioned as shown in Figure 2.

5.4 Bag refill valve connector

The bag refill valve connector shall not be compatible with connectors dimensioned in accordance with BS 3849 or with the 30 mm connector dimensioned as shown in Figure 1. 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 connector dimensioned as shown in Figure 2.



All dimensions are in millimetres.

NOTE Maximum radius on the entrance to the female fitting and the leading edge of the male cone should not exceed 0.5 mm.

Figure 1 — Conical fittings of 30 mm size