

Gas powered ventilatory resuscitators

ICS 11.040.10

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/46, Lung ventilators and related equipment, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Northern Ireland
- Association of British Healthcare Industries
- Association of Paediatric Anaesthetists
- British Anaesthetic and Respiratory Equipment Manufacturers Association
- Department of Health (Medical Devices Agency)
- Institute of Physics and Engineering in Medicine
- Institution of Mechanical Engineers
- Intensive Care Society
- Personal Safety Manufacturers' Association
- Royal College of Paediatrics and Child Health

The following body was also represented in the drafting of the standard through a subcommittee:

- British Healthcare Trades Association

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Foreword

This British Standard has been prepared by Technical Committee CH/46. It supersedes BS 6850:1987 which is withdrawn.

This new edition of BS 6850 differs from the previous edition by addressing only gas-powered resuscitators. Requirements for operator-powered resuscitators previously given in BS 6850:1987 are now given in BS EN ISO 10651-4:2002. No technical changes to the requirements for gas-powered resuscitators have been made, and this edition of BS 6850 has been prepared by deleting from the previous edition material that has been superseded by BS EN ISO 10651-4:2002.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 19 and a back cover.

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1 Scope

This British Standard specifies performance and safety requirements for gas-powered ventilatory resuscitators (hereinafter referred to as resuscitators) intended for use with patients of any body mass. 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.

It applies to resuscitators 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.

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

Operator-powered resuscitators, 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.

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.

Ventilatory resuscitators complying with the requirements of this 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 dusty environment may occur.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 1752, *Specification for laboratory sintered or fritted filters including porosity grading.*

BS 5682, *Specification for probes (quick connectors) for use with medical gas pipeline systems.*

BS EN 285, *Sterilization — Steam sterilizers — Large sterilizers.*

BS EN 850, *Transportable gas cylinders — Pin-index, yoke-type valve outlet connections for medical use.*

BS EN 1281-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

3 Terms and definitions

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

3.1

resuscitator

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

3.2

gas-powered resuscitator

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

3.3

automatic resuscitator

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

3.4

compliance

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

3.5

resistance

pressure drop per unit of flow at a specified flow

3.6

tidal volume

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

3.7

minute volume

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

3.8

frequency

number of breaths per minute

3.9

airway pressure

pressure measured at the patient connection port

3.10

pressure-limiting system

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

3.11

patient connection port

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

3.12

exhaust port

opening through which exhaled gases pass to atmosphere

3.13

demand valve

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

3.14**patient demand valve**

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

3.15**patient valve**

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

3.16**delivered oxygen concentration**

average concentration of oxygen in the gas delivered from the resuscitator

3.17**apparatus deadspace (backward leak)**

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

3.18**intermediate hose**

hose that conducts gas between parts of the resuscitator

3.19**cylinder pressure regulator**

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

4 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 1 Resuscitators designed to deliver a tidal volume of 20 ml to 50 ml are usually suitable for use with neonates.

NOTE 2 Face masks should be in accordance with Annex A.

5 Cleaning, disinfection and sterilization

The resuscitator shall meet the requirements specified in **9.1**, **9.2**, **9.3**, **9.4** and **9.5** 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 Clause **13** item e)].

If the manufacturer recommends autoclaving as a method of sterilization, this shall be carried out using a sterilizer in accordance with BS EN 285.

NOTE Materials should be in accordance with Annex B.

6 Connectors**6.1 Patient connection port**

The patient connection port shall be a 15 mm female and a 22 mm male coaxial connector with dimensions in accordance with BS EN 1281-1 for the paediatric and adult size fittings respectively.

6.2 Exhaust port

If a tapered connector is provided at the exhaust port, it shall be a 30 mm male conical fitting as specified in BS EN 1281-1.

7 Operational requirements

7.1 Ease of operation

The position of the controls shall be such that during resuscitation the resuscitator can be operated by one person unaided.

7.2 Dismantling and reassembly

If it is intended that the resuscitator or part of the resuscitator be dismantled for cleaning or if it is possible to dismantle it without the use of tools, the resuscitator shall meet the requirements specified in **9.1, 9.2, 9.3, 9.4** and **9.5** when all components are reassembled. It shall not be possible to reassemble the components in any other way.

7.3 Patient valve function after contamination with vomitus

When the resuscitator is tested as described in Annex C, the time for cleaning and restoration to normal function shall not exceed 20 s.

7.4 Mechanical shock

7.4.1 After the resuscitator has been dropped in any orientation from a height of 1 m onto concrete, it shall meet the requirements specified in **9.1, 9.2, 9.3, 9.4** and **9.5**.

7.4.2 If the resuscitator is supplied with a gas cylinder and regulator in a carrying case or frame, it shall meet the requirement specified in **7.4.1** when dropped in the case or frame, in the ready-for-use condition and with the gas cylinder empty.

7.4.3 If the resuscitator can be operated outside its carrying case, it shall meet the requirements specified in **9.1, 9.2, 9.3, 9.4** and **9.5** after the individual parts of the resuscitator, excluding the cylinder and regulator, have been dropped as described in **7.4.1** and reassembled.

7.5 Immersion in water

After the resuscitator in the ready-for-use condition has been dropped from a height of 1 m into a full water reservoir having dimensions 1 m × 1 m × 1 m, has been left in the water for 10 s and the water has been expelled for 20 s, it shall meet the requirements specified in **9.1, 9.2, 9.3, 9.4** and **9.5**.

8 Physical requirements

8.1 Dimensions

The resuscitator including any carrying case or frame shall pass through a rectangular opening having dimensions of 400 mm × 300 mm.

8.2 Mass

The mass of the resuscitator, complete with its carrying case or frame and accessories including the gas cylinder in accordance with Clause **11**, shall not exceed 16 kg.