

Specification for

Anaesthetic circle breathing systems

UDC 615.471:616-089.5:611.2

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/44, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- Department of Health
- Medical Sterile Products Association

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- Guild of Hospital Pharmacists
- Coopted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 February 1994

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The following BSI references relate to the work on this standard:
Committee reference HCC/44
Draft for comment 91/55198 DC

ISBN 0 580 22925 4

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 8835-2:1993 *Inhalational anaesthesia systems — Part 2: Anaesthetic circle breathing systems*, prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, of the International Organization for Standardization (ISO).

Parts 1 and 3 of ISO 8835 are currently in preparation by ISO/TC 121 and it is expected that, when published, they will be implemented as British Standards. Part 1 of ISO 8835 will specify requirements for the safety of anaesthetic workstations and Part 3 will give specifications for the transfer and receiving systems of anaesthetic gas scavenging systems.

Cross-references

International Standard	Corresponding British Standard
	BS 3849 <i>Conical connectors for anaesthetic and respiratory equipment</i>
ISO 5356-1:1987	Part 1:1988 <i>Specification for cones and sockets (excluding 8.5 mm size)</i> (Identical)
ISO 5356-2:1987	Part 2:1988 <i>Specification for screw-threaded weight-bearing connectors</i> (Identical)
ISO 5362:1986	BS 3353:1987 <i>Specification for anaesthetic reservoir bags</i> (Identical)
ISO 5367:1991	BS 6151:1992 <i>Specification for breathing tubes for use with anaesthetic apparatus and ventilators</i> (Identical)

The Technical Committee has reviewed the provisions of ISO 2878:1987, ISO 2882:1979 and ISO 4135, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard. ISO 4135 is being revised. ISO 4135:1979 is identical with BS 6015:1980. It is envisaged that the revision of ISO 4135 will be adopted without change as a revision of BS 6015.

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.

Introduction

A breathing system comprises an assembly of tubes and connectors, and may include valves, a reservoir bag and a carbon dioxide absorber. Its functions are to convey mixtures of gases to and from the patient. Other items of equipment may be incorporated into a breathing system, e.g. humidifiers, bacterial filters, spirometers, thermometers and gas analysers.

Annex A details test methods; Annex B describes a classification system for breathing systems.

1 Scope

This part of ISO 8835 specifies requirements in inhalational anaesthesia systems for circle absorption breathing systems which are supplied either complete by the manufacturer or for assembly by the user in accordance with the manufacturer's instructions. It also covers certain breathing attachments, in particular carbon dioxide absorbers, unidirectional valves and adjustable pressure-limiting (APL) valves.

This part of ISO 8835 excludes anaesthesia ventilators. It also excludes breathing systems and related components intended solely for use with dental analgesia machines. It does not cover the performance of breathing systems regarding the elimination of expired carbon dioxide, since this is complex and depends on the interaction of the patient, fresh-gas flow and the breathing system itself.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8835. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8835 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2878:1987, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance*.

ISO 2882:1979, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits*.

ISO 4135:—, *Anaesthesiology — Vocabulary*¹⁾.

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

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*.

ISO 5362:1986, *Anaesthetic reservoir bags*.

ISO 5367:1991, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*.

3 Definitions

For the purposes of this part of ISO 8835, the definitions in ISO 4135, together with the following apply.

The terms defined in 3.1 and 3.2 are also defined in ISO 4135, but the definitions in this part of ISO 8835 relate more particularly to anaesthetic breathing systems than do those in ISO 4135.

3.1 breathing system

those inspiratory and expiratory gas pathways, excluding the anaesthesia ventilator, between the common gas outlet and the patient connection port which contain gas at respiratory pressures

NOTE 1 Gas pathways exclusively concerned with gas scavenging systems are not regarded as part of a breathing system.

3.2 circle system

breathing system in which the direction of gas flow through separate inspiratory and expiratory pathways is determined by unidirectional valves and in which the two pathways form a circle

3.3 circle absorber assembly

that part of a circle system which comprises a carbon dioxide absorbent container, inspiratory and expiratory valves, two ports for connection to breathing tubes, a reservoir bag port and/or a ventilator port and a fresh-gas inlet. It may include an APL valve

3.4 fresh-gas inlet

that port on a breathing attachment through which fresh gas is supplied to the breathing system

3.5 fresh-gas supply tube

tube conveying fresh gas from the common gas outlet to the fresh-gas inlet

¹⁾ To be published. (Revision of ISO 4135:1979)

3.6**patient connection port**

that opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adaptor, or to a face mask or face mask angle piece

3.7**exhaust port**

that port through which excess and/or waste gas(es) are discharged to the atmosphere or to an anaesthetic gas scavenging system

3.8**Y-piece; 3-way breathing system connector**

3-way tubular connector for use within a breathing system having a patient connection port and two ports for connection to breathing tubes

4 General requirements**4.1 Connectors****4.1.1 Inspiratory port**

The inspiratory port shall be a 22 mm male conical connector complying with ISO 5356-1. It shall be marked with an arrow to indicate the direction of gas flow and the axis of the port shall be either horizontal or within 50° of the horizontal plane.

NOTE 2 The port may also incorporate a coaxial 15 mm female conical connector complying with ISO 5356-1.

4.1.2 Expiratory port

The expiratory port shall be a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2. It shall be marked with an arrow to indicate the direction of gas flow and the axis of the port shall be either horizontal or within 50° of the horizontal plane.

4.1.3 Connection port for reservoir bags

The connection port for a reservoir bag shall be a connector that mates with breathing tubes or reservoir bags complying with ISO 5367 or ISO 5362 respectively. This port shall be marked with the word “bag” or the equivalent in the national language, or with a symbol to denote “bag”. The port shall be either vertical or within 20° of the vertical axis with the port facing downwards.

4.1.4 Patient connection port

The patient connection port shall have a male 22 mm conical connector incorporating a coaxial female 15 mm conical connector, both complying with ISO 5356-1.

4.1.5 Y-piece

The machine ends of a Y-piece not permanently attached to breathing tubes shall be either 22 mm male conical connectors with a recess complying with ISO 5356-1 or other connectors which mate with a breathing tube complying with ISO 5367.

NOTE 3 The Y-piece may be designed so that the patient connection port swivels.

4.1.6 Exhaust port

Exhaust port(s) on a breathing attachment shall be one of the following:

- a) 30 mm male conical connector complying with ISO 5356-1;
- b) proprietary fitting incompatible with ISO 5356-1;
- c) a non-detachable connection to the transfer hose.

4.1.7 Ventilator port

If a ventilator port is provided, it shall be a 22 mm male conical connector complying with ISO 5356-1. This port shall be marked with the word “ventilator” and/or an appropriate symbol.

4.1.8 Other breathing attachments

4.1.8.1 If breathing attachments are fitted with conical connectors, they shall be either of 15 mm or 22 mm size complying with ISO 5356-1 or ISO 5356-2. Any port other than those for connection within a breathing system shall not be fitted with either 15 mm or 22 mm conical connectors complying with ISO 5356-1 or ISO 5356-2.

4.1.8.2 Circle absorber assemblies shall incorporate inspiratory and expiratory valves. If these valves can be detached from the absorber unit, the method of attachment to the latter shall be by means of connectors which are non-interchangeable with each other and which are not compatible with any of the connectors specified in ISO 5356-1 and ISO 5356-2.

4.2 Electrical conductivity

4.2.1 Breathing systems and breathing attachments intended for use with flammable anaesthetic agents shall comply with ISO 2882 when tested as specified in ISO 2878.

4.2.2 Breathing systems, breathing attachments and integrally attached non-metallic components made of antistatic (conductive) materials shall be clearly marked with the word “ANTISTATIC”.

They may also bear a continuous indelible yellow-coloured line throughout their length.

4.3 Recommendation on materials

All components of breathing systems should be made of materials that are compatible with the gases and anaesthetic agents with which they are intended to come into contact.

5 Breathing systems either supplied complete or assembled in accordance with manufacturer's instructions

5.1 Leakage

When tested as described in A.2, the leakage from complete breathing systems shall not exceed 150 ml/min (15,65 kPa l/min), in all the operational modes stated by the manufacturer [see clause 12 a) 2)].

5.2 Expiratory resistance

When tested as described in A.3, the pressure generated at the patient connection port shall not exceed 0,6 kPa (6 cmH₂O).

5.3 Inspiratory resistance

When tested as described in A.4, the sub-atmospheric pressure generated at the patient connection port shall not exceed 0,6 kPa (6 cmH₂O).

6 Adjustable pressure-limiting (APL) valves

6.1 Direction of movement

For APL valves with rotary controls, movement of the control in a clockwise direction shall progressively increase the limiting pressure.

NOTE 4 In some designs, movement of the control to a fully clockwise position will not close the valve.

6.2 Resistance to flow

For APL valves that are not an integral component of another medical device, when tested as described in A.5, the pressure drop across the APL valve, in the fully open position, shall be between 0,05 kPa and 0,3 kPa (0,5 cmH₂O and 3 cmH₂O) at an air flow of 3 l/min and between 0,1 kPa and 0,5 kPa (1 cmH₂O and 5 cmH₂O) at an air flow of 30 l/min.

For APL valves integrated into other medical devices, when tested as described in A.5, the pressure drop across that portion of the device incorporating the APL valve, in the fully open position, shall be between 0,05 kPa and 0,3 kPa (0,5 cmH₂O and 3 cmH₂O) at an air flow of 3 l/min and between 0,1 kPa and 0,6 kPa (1 cmH₂O and 6 cmH₂O) at an air flow of 30 l/min.

6.3 Leakage

If an APL valve can be fully closed, when tested as described in A.6, the leakage in the fully closed position shall not exceed 50 ml/min.

7 Circle absorber assemblies

7.1 Construction

7.1.1 The design of the carbon dioxide absorbent container shall enable any colour change of the absorbent to be clearly visible.

7.1.2 Carbon dioxide absorbent containers supplied prefilled by the manufacturer shall be packaged in a way that permits identification of the presence of the wrapper.

NOTE 5 This is to prevent inadvertent retention of the wrapper and to facilitate its removal by the operator prior to use.

7.2 Absorber bypass mechanism

7.2.1 If a means of excluding the absorbent from the gas pathway is provided, the operation of which is actuated automatically by removing the absorbent container(s), the circle absorber assembly shall meet the requirements of 7.3.1, 7.4 and 7.5 both with the container(s) in place and with it (them) removed.

