INTERNATIONAL STANDARD

ISO 8835-2

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Inhalational anaesthesia systems —

Part 2:
Anaesthetic breathing systems for adults

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes respiratoires d'anesthésie pour adultes

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft international Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 8835-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment,* Subcommittee SC 1, *Breathing attachments and anaesthetic machines.*

This second edition cancels and replaces the first edition (ISO 8835-2:1993), which has been technically revised. The major difference between this revision and the first edition is the broadening of the scope to include all types of breathing system.

ISO 8835 consists of the following parts, under the general title *Inhalational anaesthesia systems*:

— *Part 1:* Published as IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety of anaesthetic workstations*

— *Part 2: Anaesthetic breathing systems for adults*

— *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

Annex A forms an integral part of this part of ISO 8835. Annexes B and C are for information only.

Introduction

A breathing system comprises an assembly of tubes and connectors and may include valves, a reservoir bag and a circle absorber assembly. Its function is to convey mixtures of gases to and from the patient.

Other items of equipment may be incorporated into a breathing system, e.g. humidifiers, filters, spirometers, thermometers and gas analysers.

Annex A (normative) gives test methods. Annex B (informative) describes a standardized set of graphical symbols for breathing attachments and gives some examples of their use in a schematic representation of a circle absorber system, and annex C (informative) gives the rationale for some of the requirements.

Inhalational anaesthesia systems —

Part 2:
Anaesthetic breathing systems for adults

1 Scope

This part of ISO 8835 specifies requirements for inhalational anaesthetic breathing systems for adults which are supplied either assembled by the manufacturer or for assembly by the user in accordance with the manufacturer's instructions. It also covers circle absorber assemblies, exhaust valves, inspiratory and expiratory valves and, in some designs, those parts of an anaesthetic breathing system that are incorporated within an anaesthetic workstation, including the expiratory gas pathway of an anaesthetic ventilator and any parts of a non-operator-detachable anaesthetic-gas scavenging system (AGSS).

This part of ISO 8835 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, the fresh-gas flow, the carbon dioxide absorbent and the breathing system itself.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8835. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8835 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4135:1995, *Anaesthesiology — Vocabulary.*

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

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

ISO 5362, *Anaesthetic gas reservoir bags*.

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

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

3 Definitions

For the purposes of this part of ISO 8835 the definitions in ISO 4135:1995, together with the following, apply. Terms 3.1, 3.2 and 3.9 are also defined in ISO 4135:1995 but the definitions in this part of ISO 8835 relate more particularly to anaesthetic breathing systems than do those in ISO 4135:1995.

3.1
breathing system
those inspiratory and expiratory pathways through which gas flows at respiratory pressure between the fresh-gas inlet, the patient-connection port and the exhaust valve or port

3.2
circle breathing system
breathing system in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a circle

3.3
circle absorber assembly
that part of a circle system which comprises one or more carbon-dioxide-absorbent containers, inspiratory and expiratory valves or other means of ensuring unidirectional gas flow, two ports for connection to breathing tubes, a fresh-gas inlet, a reservoir bag port and/or a ventilator port

3.4
fresh-gas inlet
that port through which fresh gas is supplied to the breathing system

3.5
fresh-gas tube
tube conveying fresh gas to the fresh-gas inlet

3.6
patient-connection port
that port at the patient end of a breathing system intended for connection to devices such as a tracheal or tracheostomy tube connector, or to a face mask

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 (AGSS)

3.8
exhaust valve
a valve through which excess and/or waste gas(es) are discharged to the atmosphere or to an AGSS

NOTE Such a valve may or may not be an adjustable pressure-limiting (APL) valve

3.9
Y-piece
3-way breathing-system connector
3-way connector with a patient-connection port and two ports for connection to breathing tubes

3.10
non-rebreathing exhaust valve
exhaust valve with three ports, namely an inlet port for connection to a breathing tube or attachment, a patient-connection port and an exhaust port, the function of the valve being to prevent exhaled gas from entering the breathing system

NOTE Such a valve may or may not allow intermittent positive-pressure ventilation.

4 Breathing-system connections and materials

4.1 Connectors

4.1.1 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.

4.1.2 Y-piece

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

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

4.1.3 Exhaust port

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

a) 30 mm male conical connector(s) complying with ISO 5356-1 and with means to prevent connection of the orifice to any breathing attachment;

b) proprietary fitting(s) incompatible with connectors complying with ISO 5356-1 and breathing tubes complying with ISO 5367;

c) non-operator-detachable connection(s) to the transfer hose(s) of a non-interchangeable AGSS.

NOTE See 10.1.and 10.2 for marking requirements.

4.1.4 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.

NOTE See10.1 and 10.2 for marking requirements.

4.1.5 Ventilator port

If an operator-accessible ventilator port is provided, it shall be a 22 mm male conical connector complying with ISO 5356-1.

NOTE See 10.1 and 10.2 for marking requirements.

4.1.6 Ports on operator-interchangeable breathing attachments

Interchangeable breathing attachments intended for use within a breathing system shall have conical connectors of either 15 mm or 22 mm size complying with ISO 5356-1 or ISO 5356-2.

4.1.7 Other ports

Ports used for purposes such as sampling, monitoring and pressure measurement shall not have connectors complying with ISO 5356-1 or ISO 5356-2 and shall be provided with a means to secure engagement and closure of the ports when not in use.

4.2 Bag/ventilator selector switch

If a switch is provided to change from bag to ventilator and *vice versa*, it shall be bi-stable.

NOTE See 10.1 and 10.2 for marking requirements.

4.3 Electrical conductivity

Breathing systems and breathing attachments marked as "antistatic" shall comply with the requirements for prevention of electrostatic charges specified in 39.3 b) of IEC 60601-1:1988.

4.4 Recommendations on materials

When selecting materials for components of breathing systems, manufacturers should take particular care to ensure compatibility of the materials with the gases and anaesthetic agents with which they are intended to come into contact.

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

5.1 Leakage

The leakage to atmosphere from a complete breathing system when tested as described in clause A.2 in all the operational modes stated by the manufacturer [see 11 b) 2)] should preferably not exceed 50 ml/min but shall not exceed 150 ml/min (15,21 kPa·l/min). The manufacturer shall disclose the leakage rate if it is between 51 ml/min and 150 ml/min.

5.2 Resistance to flow

When tested as described in clause A.3, the pressure generated at the patient-connection port shall not exceed ± 0,6 kPa (± 6 cmH_2O).

5.3 Cleaning and disinfection or sterilization

Unless the breathing system is intended and marked as being for single use, the manufacturer shall recommend methods of cleaning and disinfection or sterilization [see 11 g)].

6 Exhaust valves

6.1 Direction of movement of controls

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

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

6.2 Resistance to flow

6.2.1 Opening pressure

The manufacturer shall disclose the minimum opening pressure of the valve [see 11 c) 2) and 11 c) 3)].

6.2.2 Pressure-flow characteristics

For exhaust valves supplied separately, the manufacturer shall disclose the pressure-flow characteristics of the valve, including the pressure drop with any valve control fully open at a flow of 30 l/min [see 11 c) 2) and 11 c) 3)].

6.3 Leakage

For an exhaust valve supplied separately that can be fully closed, the manufacturer shall disclose the leakage to atmosphere in the closed position at a pressure of 3 kPa (30 cmH_2O) [see 11 c) 6)].

6.4 Non-rebreathing exhaust valves supplied separately

6.4.1 Ports

The inlet port shall have a male 22 mm conical connector complying with ISO 5356-1 and shall not be a 22 mm/15 mm co-axial connector [see also 10.2.2 h)].

The patient-connection port shall comply with 4.1.1.

The exhaust port shall comply with 4.1.3.

6.4.2 Resistance to flow

6.4.2.1 Opening pressure

The manufacturer shall disclose the minimum opening pressure of the valve [see 11 c) 2) and 11 c) 3)].

6.4.2.2 Pressure-flow characteristics

The manufacturer shall disclose the pressure-flow characteristics of the valve, including the pressure drop with any valve control fully open at a flow of 30 l/min [see 11 c) 2) and 11 c) 3)].

7 Circle absorber assemblies

7.1 Construction

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

7.1.2 Circle absorber assemblies supplied separately shall incorporate inspiratory and expiratory valves or other means of ensuring unidirectional gas flow. If these valves or means 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.

7.2 Absorbent-bypass mechanism

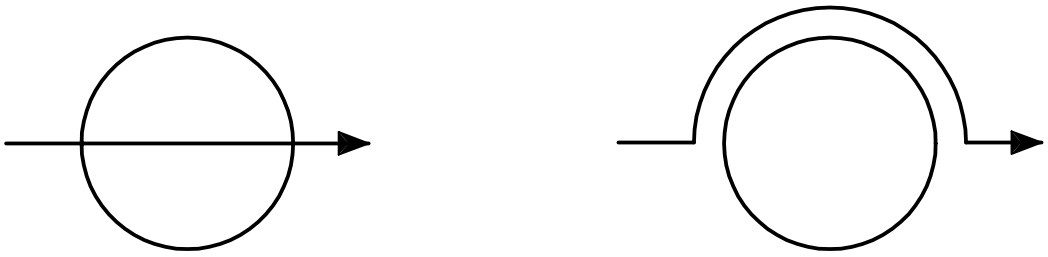
7.2.1 If a means of excluding the absorbent from the gas pathway is provided, the operation of which is actuated automatically by removing the absorbent container(s), the circle absorber assembly shall meet the leakage requirements of 7.3.1 and the resistance to flow requirement of 7.4 with the container(s)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

7.2.2 When the mechanism for excluding the absorbent is operator-controlled, the control shall have means to prevent accidental movement and shall be durably marked with the clearly legible words “on” and “off” or the equivalent in the national language, and/or with the symbols shown in figure 1. The “off” indication shall mean that gas does not pass through the absorbent and the indication shall be visible to the operator from his/her normal operating position.

NOTE The words “on” and “off” may be preceded by the word “absorber”.

7.2.3 Unless the absorbent-bypass mechanism is intended to function at one or more intermediate setting(s), the control shall have only “on” and “off” positions and shall be bi-stable. The circle absorber assembly shall meet the leakage requirements of 7.3 and the resistance to flow requirements of 7.4 with the control in the “on” and “off” positions.

7.2.4 For a bypass mechanism intended to function at one or more intermediate setting(s), the control shall so indicate and the circle absorber assembly shall meet the leakage requirements of 7.3 and the resistance to flow requirements of 7.4 in the “on” and “off” positions and at any intermediate setting of the control.



a) Symbol for "absorber on" b) Symbol for "absorber off"

Figure 1 — Markings for operator-controlled absorbent-bypass mechanism

7.3 Leakage

7.3.1 For a circle absorber assembly with an operator-controlled absorbent-bypass mechanism, when the control is in the “off” position it shall be possible to change the absorbent without opening the gas pathway to the atmosphere.

7.3.2 For an assembly supplied separately, the manufacturer shall disclose the leakage to atmosphere when tested as described in clause A.4.

7.4 Resistance to flow

For a circle absorber assembly supplied separately, the pressure generated at the patient-connection port shall not exceed ± 0,6 kPa (± 6 cmH_2O) when tested as described in clause A.4.

7.5 Inspiratory and expiratory ports

Inspiratory and expiratory ports shall be either 22 mm male conical connectors or coaxial 22/15 mm conical connectors complying with ISO 5356-1 or ISO 5356-2. The inspiratory and expiratory ports shall be differentiated from the reservoir bag port.

NOTE 1 See 10.1 and 10.2 for marking requirements.

NOTE 2 Differentiation of the ports can be achieved by, e.g., different orientation.

7.6 Inspiratory and expiratory valves

7.6.1 General

Unless a means of indicating valve malfunction is provided, the valves shall be designed and located such that their action is visible to the operator.

7.6.2 Reverse flow and dislocation

When tested as described in clause A.6, the pressure shall rise to at least 0,5 kPa (5 cmH_2O) within 5 min and the valve disc or flap shall not become dislocated on application of a reverse pressure of 5 kPa (50 cmH_2O).

NOTE 1 Requiring the pressure to rise to at least 0,5 kPa within 5 min is equivalent to requiring that the reverse flow does not exceed 60 ml/min at a pressure of up to 0,5 kPa (see also the note to A.6.2.1).

NOTE 2 Typically, the most significant reverse flow with disc-type valves is at pressures of less than 0,05 kPa (0,5 cmH_2O), whereas with flap valves it can be at a higher pressure.

7.6.3 Resistance to flow

For inspiratory and expiratory valves supplied as separate components, the manufacturer shall disclose the pressure-flow characteristics of the valves under both wet and dry conditions, including the pressure drop at a flow of 60 l/min [see 11 e) 1) and 11 e) 2)].

7.6.4 Opening pressure

For inspiratory and expiratory valves supplied as separate components, the manufacturer shall disclose the pressure required to open the valves under both wet and dry conditions [see 11 e) 1) and 11 e) 2)].

8 Pressure monitoring and limitation

8.1 Pressure monitoring

8.1.1 The anaesthetic breathing system shall incorporate either a pressure-measuring device or a means for connection to a pressure-measuring device.

8.1.2 If a pressure-measuring device is provided, it shall be marked in units of cmH_2O and/or kPa and shall have a minimum range from either –10 cmH_2O to +60 cmH_2O or from –1 kPa to +6 kPa, as appropriate.

Under conditions of dynamic testing, readings shall be within a tolerance of ± (4 % of the full scale reading + 4 % of the reading).

8.1.3 To permit cleaning and disinfection or sterilization of the components of the breathing system , the pressure-measuring device shall either be detachable or itself capable of being cleaned and disinfected or sterilized.

8.2 Pressure limitation

If a pressure-limiting device is provided, then both during normal conditions and under a single-fault condition the pressure at the patient-connection port shall not exceed 12,5 kPa (125 cmH_2O).

9 Location of components in circle absorber breathing systems

9.1 Exhaust valve

An exhaust valve shall not be located between the inspiratory valve and the Y-piece.

9.2 Port for connection to a reservoir bag

On a circle absorber assembly, the port for connection to a reservoir bag shall not be on the patient side of the inspiratory or expiratory valve(s).

9.3 Fresh-gas inlet

If a fresh-gas inlet is permanently located on an absorber assembly, it shall not be on the patient side of the expiratory valve.

The fresh-gas inlet should preferably be between the carbon-dioxide-absorbent container and the inspiratory valve.

9.4 Inspiratory valves and expiratory valves

Inspiratory valves and expiratory valves shall not be located in the Y-piece.

10 Marking

10.1 Marking of breathing systems supplied complete

10.1.1 Marking of breathing systems intended for single use

Breathing systems supplied complete and intended for single use shall be legibly marked with the following:

NOTE See also 7.2.2, 7.2.4 and 7.5.

a) The name and/or trademark of the manufacturer and/or supplier.

b) An identification reference to the lot or date of manufacture.

c) The maximum limiting pressure, if the system has a designed limiting pressure.

d) For exhaust ports complying with 4.1.3, the word “EXHAUST” and/or “AGS” or the equivalent in the national language or an appropriate symbol.

e) For ventilator ports complying with 4.1.5, the word “VENTILATOR” or the equivalent in the national language or an appropriate symbol.

f) The word “ANTISTATIC” for breathing systems and integrally attached non-metallic components made of antistatic materials.

NOTE They may also bear an indelible yellow-coloured mark.

g) If a switch is provided to change from bag to ventilator and *vice versa*, it shall be marked with the words “BAG” and “VENTILATOR” or the equivalent in the national language and/or appropriate symbols.

10.1.2 Marking of breathing systems intended for re-use

Complete breathing systems intended for re-use shall be durably and legibly marked with the following:

NOTE See also 7.2.2, 7.2.4 and 7.5.

a) The name and/or trademark of the manufacturer and/or supplier.

b) An identification reference to the lot or date of manufacture.

c) The maximum limiting pressure, if the system has a designed limiting pressure.

d) For exhaust ports complying with 4.1.3, the word “EXHAUST” and/or “AGS” or the equivalent in the national language or an appropriate symbol.

e) For reservoir bag ports complying with 4.1.4, the word “BAG” or the equivalent in the national language and/or an appropriate symbol.

f) For ventilator ports complying with 4.1.5, the word “VENTILATOR” or the equivalent in the national language or an appropriate symbol.

g) The word “ANTISTATIC” for breathing systems and integrally attached non-metallic components made of antistatic materials.

NOTE They may also bear an indelible yellow-coloured mark.

h) If a switch is provided to change from bag to ventilator and *vice versa*, it shall be marked with the words “BAG” and “VENTILATOR” or the equivalent in the national language and/or appropriate symbols.

10.2 Marking of breathing attachments

10.2.1 Marking of breathing attachments intended for single use

Operator-detachable breathing attachments (e.g. exhaust valves, inspiratory and expiratory valves) intended for single use shall be legibly marked with the following:

NOTE See also 7.2.2, 7.2.4, 7.5 and clause 8.

a) The name and/or trademark of the manufacturer and/or supplier.

b) An identification reference to the lot or date of manufacture.

c) The maximum limiting pressure, if the component has a designed limiting pressure.

d) For exhaust ports complying with 4.1.3, the word “EXHAUST” and/or “AGS” or the equivalent in the national language or an appropriate symbol.

e) For connection ports for reservoir bags complying with 4.1.4, the word “BAG” or the equivalent in the national language or an appropriate symbol.

f) For ventilator ports complying with 4.1.5, the word “VENTILATOR” or the equivalent in the national language or an appropriate symbol.

g) The word “ANTISTATIC” for breathing attachments and integrally attached non-metallic components made of antistatic materials.

NOTE They may also bear an indelible yellow-coloured mark.

h) Flow-direction-sensitive components shall be marked with at least one arrow to indicate the direction of gas flow.

NOTE 1 The words “INLET” and “OUTLET” or the equivalent in the national language may be marked in addition.

NOTE 2 The safe and correct functioning of certain breathing attachments is dependent upon the direction of gas flow through them.

i) If a switch is provided to change from bag to ventilator and *vice versa*, it shall be marked with the words “BAG” and “VENTILATOR” or the equivalent in the national language and/or appropriate symbols.

10.2.2 Marking of breathing attachments intended for re-use

Operator-detachable breathing attachments (e.g. exhaust valves, inspiratory and expiratory valves) intended for re-use shall be durably and legibly marked with the following:

NOTE See also 7.2.2, 7.2.4, 7.5 and clause 8.

a) The name and/or trademark of the manufacturer and/or supplier.

b) An identification reference to the lot or date of manufacture.

c) The maximum limiting pressure, if the component has a designed limiting pressure.

d) For exhaust ports complying with 4.1.3, the word “EXHAUST” and/or “AGS” or the equivalent in the national language or an appropriate symbol.

e) For reservoir bag ports complying with 4.1.4, the word “BAG” or the equivalent in the national language and/or an appropriate symbol.

f) For ventilator ports complying with 4.1.5, the word “VENTILATOR” or the equivalent in the national language and/or an appropriate symbol.

g) The word “ANTISTATIC” for breathing attachments and integrally attached non-metallic components made of antistatic materials.

NOTE They may also bear an indelible yellow-coloured mark.

h) Flow-direction-sensitive components shall be marked with at least one arrow to indicate the direction of gas flow.

NOTE 1 The words “INLET” and “OUTLET” or the equivalent in the national language may be marked in addition.

NOTE 2 The safe and correct functioning of certain breathing attachments is dependent upon the direction of gas flow through them.

i) If a switch is provided to change from bag to ventilator and *vice versa*, it shall be marked with the words “BAG” and “VENTILATOR” or the equivalent in the national language and/or appropriate symbols.

10.3 Marking of packages

10.3.1 Packages containing breathing attachments or complete breathing systems intended for single use shall be legibly marked with the following:

a) A description of the contents.

b) The words “FOR SINGLE USE” or symbol No. 1051 (indicating “do not re-use”) given in ISO 7000:1989.

c) If appropriate, the word “STERILE” or a symbol.

d) The name and/or trademark of the manufacturer and/or supplier.

e) An identification reference to the lot or date of manufacture.

10.3.2 Packages containing breathing attachments or complete breathing systems intended for re-use shall be legibly marked with the following:

a) A description of the contents.

b) The name and/or trademark of the manufacturer and/or supplier.

c) Recommended methods of cleaning and sterilization or disinfection, including the maximum number of cycles recommended.

d) An identification reference to the lot or date of manufacture.

10.3.3 Packages containing breathing attachments or complete breathing systems made of antistatic material shall be legibly marked with the word “ANTISTATIC” or the equivalent in the national language.

11 Information to be provided by the manufacturer

The following information shall be provided by the manufacturer for complete breathing systems and for breathing attachments supplied separately:

a) for all breathing systems and breathing attachments

A statement of known compatibility with gases and anaesthetic agents, including suitability for use with flammable anaesthetic agents.

b) for breathing systems supplied complete

1) A diagram of the breathing system identifying its components and their recommended locations.

2) A description of all the operational modes in which the breathing system is intended to be used.

3) The typical pressure drops at the peak flows developed in the breathing system when tested as described in clause A.3 (see 5.2).

4) The internal compliance of the breathing system, expressed as a volume in millilitres at a pressure of 3 kPa (30 cmH_2O) and measured with any carbon-dioxide-absorbent container(s) filled with fresh absorbent of the type recommended by the manufacturer and any reservoir bag excluded.

5) The leakage from the breathing system in all the operational modes stated by the manufacturer [see 11 b) 2)], measured as described in clause A.2, if the leakage is between 51 ml/min and 150 ml/min.

6) A statement that care should be taken to ensure that any flow-direction-sensitive component is fitted in the correct limb of the breathing system.

7) If the anaesthetic breathing system is intended to be used with an anaesthetic workstation complying with ISO 8835-1, a statement relating to pressure monitoring, pressure limitation and the requirements for other relevant monitoring, alarm and protection devices.

c) for exhaust valves

1) Details of the use of the valve control, if any.

2) The pressure-flow characteristics of the valve, including the opening pressure and the pressure drop at a flow of 30 l/min at atmospheric temperature and pressure, dry (ATPD).

3) The information given in 11 c) 2) obtained under wet conditions specified by the manufacturer.

NOTE Wet conditions are intended to simulate actual breathing-system conditions, including elevated temperature and increased humidity.

4) Unless the valve is permanently mounted, the recommended orientation of the valve and details of the effects of other orientations on its performance.

5) Details of any other means of pressure relief, including pressure-flow characteristics, covering a range of pressures from 0,5 kPa (5 cmH_2O) to 6 kPa (60 cmH_2O).

6) For a valve supplied separately that can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 3 kPa (30 cmH_2O).

7) Recommended service intervals.

d) for circle absorber assemblies

1) A diagram of the circle absorber assembly.

2) A diagram of the absorbent-bypass mechanism, if present.

3) The proportion of gas which does not pass through the absorbent with the bypass control, if fitted, in the “on” position (the operating conditions and the test method(s) used shall also be disclosed).

4) The volume of the carbon-dioxide-absorbent container(s), expressed in millilitres.

5) The internal compliance of the circle absorber assembly, measured with the carbon-dioxide-absorbent container(s) filled with fresh absorbent of the type recommended by the manufacturer, and expressed as a volume in millilitres at a pressure of 3 kPa (30 cmH_2O).

6) The carbon dioxide absorbent recommended for use in the absorber.

7) Instructions for changing the carbon dioxide absorbent, cleaning the absorber assembly and maintaining the leak-tightness of the assembly, if appropriate.

8) Instructions for draining water from the circle absorber assembly, if appropriate.

9) The leakage from the circle absorber assembly, measured as described in clause A.4 with and without the carbon-dioxide-absorbent container(s) fitted and at all the intended settings of the absorber-bypass control, if fitted.

10) The resistance to flow of a freshly filled circle absorber assembly, when tested as described in clause A.4, together with details of the absorbent used during the determination.

11) Information as to how the operator can check the performance of the unidirectional valves.

e) for inspiratory and expiratory valves supplied as separate components

1) The pressure-flow characteristics of the valve, including the opening pressure and the pressure drop across the valve at an air flow of 60 l/min at ATPD.

2) The information given in 11 e) 1) obtained under wet conditions specified by the manufacturer.

NOTE Wet conditions are intended to simulate actual breathing-system conditions, including elevated temperature and increased humidity.

3) The recommended orientation of the valve and details of the effects of other orientations on its performance.

4) Recommended service intervals.

5) Information as to how the operator can check the performance of the valves.

f) for breathing systems intended to be assembled by the operator

Instructions for assembling the breathing system.

g) for breathing attachments and complete breathing systems intended for re-use

The recommended methods of cleaning and disinfection or sterilization, including the maximum number of cycles.

Annex A
(normative)

Type test methods

A.1 General

A.1.1 The ambient temperature for the duration of each test shall be between 20 °C and 25 °C, except where otherwise stated.

A.1.2 The accuracy of the equipment used to carry out measurements shall be ± 5 % of the variable to be measured, except where otherwise stated. Dry air shall be used as the test gas, except where otherwise stated.

A.2 Leakage from complete breathing systems

A.2.1 Apparatus

A.2.1.1 Flow-measuring device, of accuracy specified in A.1.2 at flows of 25 ml/min, 75 ml/min, 100 ml/min, 150 ml/min and 200 ml/min.

A.2.1.2 Pressure-measuring device, of accuracy ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 3 kPa (30 cmH_2O).

A.2.2 Procedure

Set up the breathing system and seal the reservoir-bag port and/or ventilator port and the patient-connection port. Seal any valve in the breathing system that is designed to allow gas to leak to atmosphere at pressures of 3 kPa (30 cmH_2O) or below. Connect the pressure-measuring device at the patient-connection port and introduce air into the fresh-gas inlet until a pressure of 3 kPa (30 cmH_2O) is indicated. Adjust the flow of air to stabilize the pressure at 3 kPa (30 cmH_2O) and record the leakage flow.

If the breathing system contains a circle absorber assembly fitted with an absorbent-bypass mechanism, test the system at the intended settings of the absorbent-bypass control and with the carbon-dioxide-absorbent container(s) both fitted and removed (see 7.3.1).

For breathing systems of which part is contained within the anaesthetic workstation, carry out the test in accordance with the manufacturer's instructions.

A.3 Resistance to flow of complete breathing systems

A.3.1 Apparatus

A.3.1.1 Flow-measuring device, of accuracy specified in A.1.2 at flows between 3 l/min and 75 l/min.

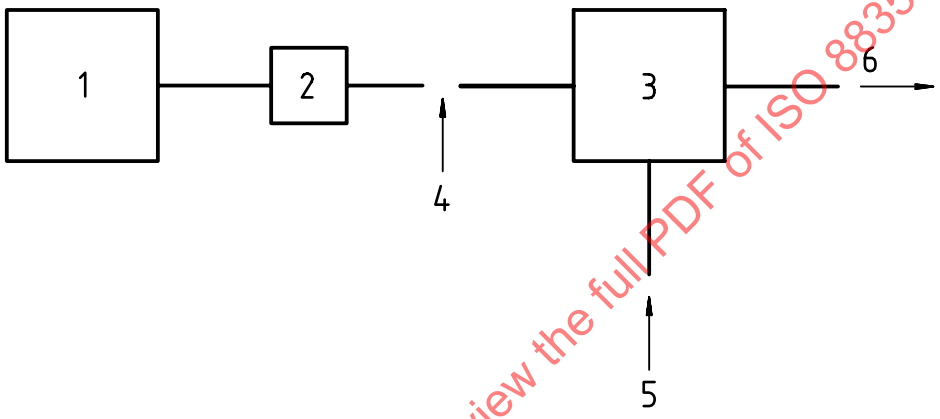
A.3.1.2 Pressure-measuring device, of accuracy ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 3 kPa (30 cmH_2O).

A.3.1.3 Recording device(s), capable of continuous recording of pressure and flow and of displaying the values both numerically and graphically.

A.3.2 Procedure for breathing systems supplied complete

A.3.2.1 Set up the breathing system with the reservoir bag fitted, any ventilator port sealed or switched to “bag” mode and any exhaust valve, if adjustable, fully open. Connect the breathing tube(s) to the fresh-gas outlet or to the inspiratory and expiratory ports of an appropriate anaesthetic workstation or test rig. Connect the test apparatus to the patient-connection port as shown in figure A.1 and introduce air or oxygen into the fresh-gas inlet at 10 l/min or the maximum flow if such a flow is stated by the manufacturer of the breathing system. Set the test apparatus to generate bi-directional sine wave flows at a frequency of 20 cycles/min and with a tidal volume of 1 l, and test the system in all the operational modes stated by the manufacturer. Record the resulting pressures and flows, and the pressure/volume curves derived therefrom.

A.3.2.2 If the breathing system contains a circle absorber assembly, carry out the test in A.3.2.1 with the absorbent container(s) filled with fresh absorbent of the type recommended by the manufacturer. For circle absorber assemblies with an operator-controlled absorbent-bypass mechanism, test the system with the absorbent container(s) both fitted and removed.



Key

1 Sine wave pattern flow generator
2 Flow- and pressure-measuring devices
3 Anaesthetic breathing system
4 Patient-connection port
5 Fresh-gas inlet
6 To anaesthetic-gas scavenging system

Figure A.1 — Arrangement of apparatus to test resistance to flow of complete breathing systems

A.3.3 Procedure for breathing systems supplied as part of an anaesthetic workstation

A.3.3.1 Test the breathing system as described in A.3.2.1.

A.3.3.2 If the anaesthetic workstation is fitted with an anaesthetic ventilator, repeat the test procedure with the ventilator-mode selector set to "ventilator" and the test apparatus set to generate a half-sine wave flow into the patient-connection port of the breathing system at a frequency of 20 cycles/min and a tidal volume of 1 l. Record the resulting flow and pressure, and the pressure/volume curves derived therefrom. Carry out the test in accordance with the manufacturer’s instructions.

A.3.3.3 For a breathing system integrated with an anaesthetic-gas scavenging system or parts thereof, perform the tests described in A.3.3.1 and A.3.3.2.

A.4 Circle absorber assemblies supplied separately

Perform the tests using the other breathing attachments necessary to complete the breathing system as provided or stated by the manufacturer.

Test the completed breathing system for leakage as described in clause A.2 and for resistance to flow as described in clause A.3. [See 11 d) 9) and 11 d) 10).]

A.5 Resistance to flow of inspiratory and expiratory valves supplied as separate components

A.5.1 Apparatus

A.5.1.1 Flow-measuring device, of accuracy specified in A.1.2 at an indicated flow of 60 l/min.

A.5.1.2 Pressure-measuring device, of accuracy ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 0,5 kPa.

A.5.2 Procedure

Connect a pressure source on the upstream side of the valve, connect the pressure-measuring device to record the pressure generated at the upstream side of the valve and connect the flow-measuring device between the pressure source and the pressure-measuring device. Adjust the flow to 60 l/min. Record the pressure generated.

A.6 Reverse flow through, and dislocation of, inspiratory and expiratory valves

A.6.1 Apparatus

A.6.1.1 Flow-measuring device, of accuracy specified in A.1.2 at an indicated flow of 65 ml/min.

A.6.1.2 Pressure-measuring device, of accuracies ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 0,5 kPa (5 cmH_2O) and ± 0,03 kPa (± 0,3 cmH_2O) at a pressure of 5 kPa (50 cmH_2O).

A.6.1.3 Rigid container, having a capacity of (5 ± 0,25) l.

A.6.2 Procedure

A.6.2.1 Connect the downstream side of the inspiratory or expiratory valve to a pressure source, the flow-measuring device, the rigid container and the pressure-measuring device as shown in figure A.2. Adjust the flow to a constant 65 ml/min and record the time taken for the pressure to reach 0,5 kPa (5 cmH_2O).

NOTE Within the tolerances of the test apparatus, using a flow of 65 ml/min will mean that valves having a reverse flow of less than 60 ml/min will meet the requirement (see 7.6.2) and those having a reverse flow of more than 70 ml/min will fail.

A.6.2.2 Adjust the flow to give a pressure of 5 kPa (50 cmH_2O) and hold this pressure for 1 min. Release the pressure and check that the valve disc or flap has not become dislocated by repeating the procedure described in A.6.2.1 and verifying that the pressure rises to 0,5 kPa (5 cmH_2O) within 5 min.

A.7 Opening pressure of inspiratory and expiratory valves supplied as separate components

A.7.1 Apparatus

A.7.1.1 Flow-measuring device, of accuracy specified in A.1.2 at an indicated flow of 20 ml/min.

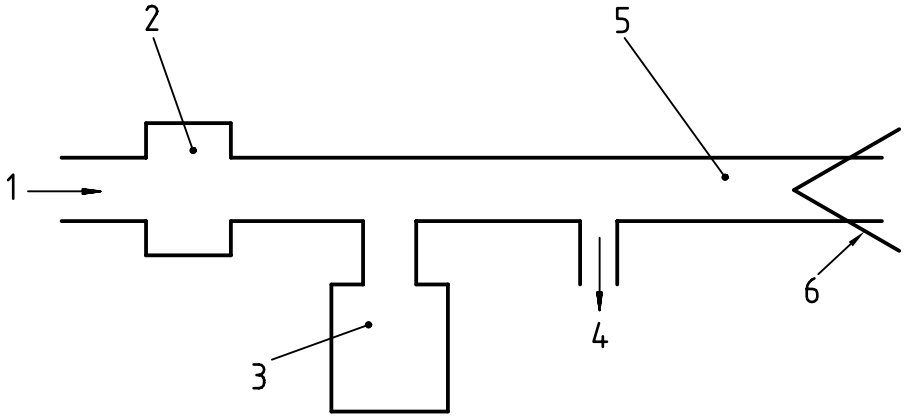
A.7.1.2 Pressure-measuring device, of accuracy ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 0,15 kPa (1,5 cmH_2O).

A.7.1.3 Rigid container, having a capacity of (5 ± 0,25) l.

A.7.2 Procedure

A.7.2.1 Connect the upstream side of the inspiratory or expiratory valve to a pressure source, the flow-measuring device, the rigid container and the pressure-measuring device as shown in figure A.3.

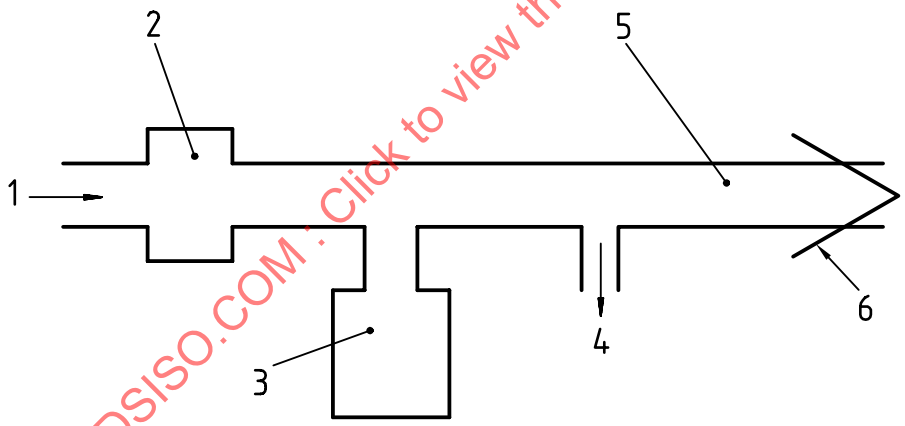
A.7.2.2 Allow the valve to close and determine the opening pressure by adjusting the flow of gas to 20 ml/min and recording the peak pressure obtained on the upstream side of the valve.



Key

1 From pressure source
2 Flowmeter
3 Rigid container
4 To pressure-measuring device
5 Thermometer
6 Inspiratory or expiratory valve

Figure A.2 — Arrangement of apparatus to test for reverse flow through inspiratory and expiratory valves supplied as separate components



Key

1 From pressure source
2 Flowmeter
3 Rigid container
4 To pressure-measuring device
5 Thermometer
6 Inspiratory or expiratory valve

Figure A.3 — Arrangement of apparatus to test for opening pressure of inspiratory and expiratory valves supplied as separate components

Annex B
(informative)

Breathing-system notation

B.1 General

To assist in defining and describing breathing systems, it is helpful to use a standardized method of notation, including a set of symbols and principles for diagrams. The purpose of this annex is to describe the commonly used notation and to give examples of its use.

B.2 System notation

The method of notation consists of two parts, i.e. graphical representation of breathing attachments with numerical representation of functional segments of a circle absorber system and principles for diagrams.

B.2.1 Graphical representation

The symbols shown in figure B.1 are used to depict the various breathing attachments.

B.2.2 Numerical notation

A circle absorber system may be divided into four segments as follows:

a) from the patient to the expiratory valve (segment 1);

b) from the expiratory valve to the reservoir bag (segment 2);

c) from the reservoir bag to the inspiratory valve (segment 3);

d) from the inspiratory valve to the patient (segment 4).

A typical circle absorber system with the segments marked is shown in figure B.2.

B.3 Principles for diagrams

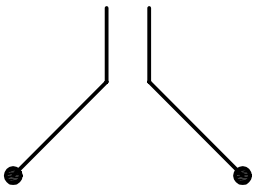
The following principles are used when depicting circle absorber breathing systems:

a) the gas flow in the circuit is anti-clockwise;

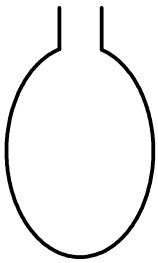
b) the patient end is shown on the right-hand side of a circle system;

c) the reservoir bag is shown on the left-hand side of a circle system opposite the patient end.

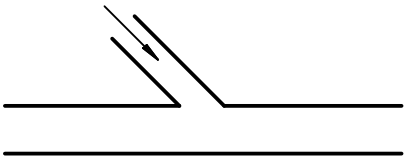
A typical circle absorber system with the components marked is shown in figure B.3.



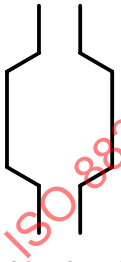
a) Patient end



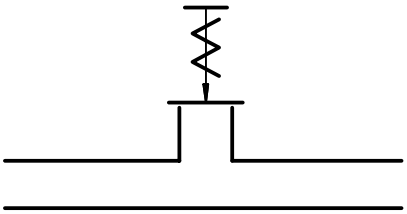
f) Reservoir bag



b) Fresh-gas inlet

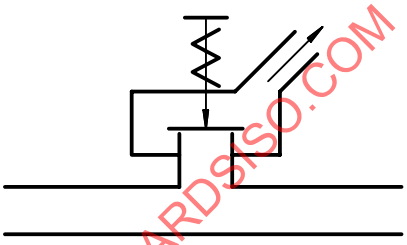


g) Carbon-dioxide-absorbent container

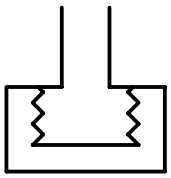


c) Adjustable exhaust valve (not scavenged)

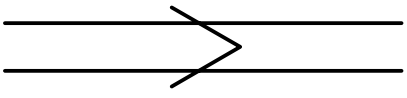
h) Breathing tube



d) Adjustable exhaust valve with gas-capturing assembly



i) Ventilator



e) Unidirectional valve
(indicating controlled flow going from left to right)

j) Thermometer

Figure B.1 — Symbols for breathing attachments used in figures B.2 and B.3 *(continued on next page)*