INTERNATIONAL STANDARD

ISO 8835-2

Third edition
2007-08-15

Inhalational anaesthesia systems —

Part 2: Anaesthetic breathing systems

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes respiratoires d'anesthésie

Reference number
ISO 8835-2:2007(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition (ISO 8835-2:1999), which has been technically revised.

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

— *Part 2: Anaesthetic breathing systems*

— *Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

Introduction

An anaesthetic breathing system comprises an assembly of tubes and connectors and may include valves, a reservoir bag and a circle absorber assembly. Other items of equipment (e.g. humidifiers, filters, spirometers, thermometers, gas analysers) may be incorporated into an anaesthetic breathing system.

Its function is to convey mixtures of gases to and from the patient.

Annex A gives typical test arrangements and methods. Annex B gives the rationale for some of the requirements found within this part of ISO 8835.

Annex B contains rationale statements for some of the requirements of this part of ISO 8835. The clauses and subclauses marked with an asterix (*) before their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard.

Annex C lists the clauses of this part of ISO 8835 that address the environmental aspects of the device.

Inhalational anaesthesia systems —

Part 2:
Anaesthetic breathing systems

* 1 Scope

This part of ISO 8835 specifies requirements for anaesthetic breathing systems that 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 inhalation anaesthetic system, including the expiratory gas pathway of an anaesthetic ventilator.

This part of ISO 8835 does not cover the performance of anaesthetic 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 anaesthetic breathing system itself.

This part of ISO 8835 does not apply to anaesthetic breathing systems intended for use with flammable anaesthetic agents/gases as determined by Annex DD of IEC 60601-2-13:2003.

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.

ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 4135, *Anaesthetic and respiratory equipment — 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 reservoir bags*

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

ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and IEC 60601-2-13 and the following apply.

3.1
anaesthetic breathing system
ABS
those inspiratory and expiratory pathways through which gas flows at respiratory pressure between the **fresh gas inlet (3.6)**, the **patient connection port (3.9**) and the **exhaust valve (3.5)** or **exhaust port (3.4)**

3.2
circle absorber assembly
that part of a **circle breathing system (3.3)** 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 (3.6)**, a reservoir bag port and/or an anaesthetic ventilator port

3.3
circle breathing system
anaesthetic breathing system (3.1) in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a circle

3.4
exhaust port
that port through which waste gas(es) are discharged to the atmosphere or to an anaesthetic gas scavenging system (AGSS)

3.5
exhaust valve
valve through which waste gas(es) are discharged to the atmosphere or to an AGSS

NOTE Such a valve can or might not be an adjustable pressure-limiting (APL) valve.

3.6
fresh gas inlet
that port through which fresh gas is supplied to the **anaesthetic breathing system (3.1)**

3.7
interchangeable component
operator-detachable anaesthetic breathing system component designed to be used with specified equipment from different manufacturers

3.8
non-rebreathing exhaust valve
exhaust valve (3.5) with three ports, namely an inlet port for connection to a breathing tube or ABS component, a **patient connection port (3.9)** and an **exhaust port (3.4)**, the function of the valve being to prevent exhaled gas from re-entering the **anaesthetic breathing system (3.1)**

3.9
patient connection port
that port at the patient end of an **anaesthetic breathing system (3.1)** intended for connection to devices such as a tracheal or tracheostomy tube connector, or the connector to a face mask or supraglottic device

3.10
Y-piece
three-way connector with a **patient connection port (3.9)** and two ports for connection to breathing tubes

4 General

4.1 Materials

All components of an anaesthetic breathing system shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaching from them.

When selecting materials for components of anaesthetic 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.

4.2 Anaesthetic breathing system component packaging

Anaesthetic breathing system components shall be packaged in such a way as to minimize the risk of incomplete removal of the packaging before use.

NOTE 1 This is to prevent accidental retention of the packaging (e.g. transparent wrapper, caps, lids, covers, etc.) and to ensure its removal by the operator prior to use.

NOTE 2 Attention is drawn to IEC 60601-1-6 which requires a usability engineering process. Completion of this process will ensure that such risks are minimized to an acceptable level.

4.3 Electrical requirements

* 4.3.1 General

If the anaesthetic breathing system incorporates electrically powered components, the system shall comply with applicable parts of IEC 60601-1 and IEC 60601-1-2.

Anaesthetic breathing systems and anaesthetic breathing system components which incorporate RF wireless technology should be assessed for the following risks:

— electromagnetic compatibility (EMC);

— performance of wireless functions;

— wireless coexistence;

— wireless quality of service;

— integrity of data transmitted wirelessly;

— security of data transmitted wirelessly;

— wireless network access.

4.3.2 Electrical conductivity

Anaesthetic breathing systems and anaesthetic breathing system components marked as “antistatic” or “conductive” shall comply with Annex D when tested as described in ISO 2878.

NOTE See 12.1 h) for marking requirements.

4.4 Alternative test methods

The manufacturer may use type tests different from those described in this part of ISO 8835 if an equivalent degree of compliance can be demonstrated. However, in the event of dispute, the test arrangements and methods described in this part of ISO 8835 should be used as the reference methods.

5 Connection ports

5.1 Patient connection port

The patient connection port shall be a coaxial male 22 mm/female 15 mm conical connector complying with ISO 5356-1.

NOTE The patient connection port can be designed so that it will swivel.

5.2 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 compatible with breathing tubes complying with ISO 5367.

5.3 Exhaust connection port

The exhaust connection port shall be one of the following:

a) a 30 mm male conical connector complying with ISO 5356-1, for connection to an interchangeable AGS transfer and receiving system and with means of preventing connection of the orifice to any anaesthetic breathing system component;

b) a proprietary fitting incompatible with connectors complying with ISO 5356-1 and breathing tubes complying with ISO 5367, for connection to a non-interchangeable anaesthetic gas scavenging (AGS) transfer and receiving system;

c) non-operator-detachable from the anaesthetic gas scavenging transfer system.

NOTE See 12.1 c) for marking requirements.

5.4 Interchangeable non-rebreathing exhaust valves

The inlet connection port shall be a female 22 mm conical connection complying with ISO 5356-1.

The patient connection port shall comply with 5.1

The exhaust connection port shall comply with 5.3

* 5.5 Reservoir bag connection port

The reservoir bag connection port shall be compatible with a reservoir bag complying with ISO 5362 and a breathing tube complying with ISO 5367.

This connection shall be within 20° of the vertical axis.

NOTE See 12.1 d) for marking requirements.

5.6 Anaesthetic ventilator connection port

If a connection port for an interchangeable anaesthetic ventilator is provided, it shall be a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2

If a connection port for a manufacturer-specific anaesthetic ventilator is provided, it shall be a proprietary fitting incompatible with connectors complying with ISO 5356-1 and breathing tubes complying with ISO 5367.

NOTE See 12.1 e) for marking requirements.

5.7 Connection ports of interchangeable anaesthetic breathing system components

Interchangeable anaesthetic breathing system components shall have connection ports with conical connectors of either 15 mm or 22 mm complying with ISO 5356-1 or ISO 5356-2.

NOTE To prevent unintended disengagement of conical connection, 22 mm latching connectors complying with ISO 5356-1 can be used.

* 5.8 Inspiratory and expiratory connection ports of an interchangeable circle absorber assembly

If these connection ports are operator-detachable, the inspiratory and the expiratory ports of a circle absorber assembly shall have 22 mm male conical connectors with or without coaxial 15 mm female conical connectors, both complying with ISO 5356-1 or ISO 5356-2. The axis of these ports shall be either horizontal or within $\pm$ 50° of the horizontal plane.

5.9 Other connection ports

Connection ports used for specific purposes (e.g. pressure measurement, gas sample return, etc.) shall not be compatible with ISO 5356-1, ISO 5356-2 or ISO 594-2 connectors. The connection ports shall be provided with a means of securing closure when not in use. The means of closure shall be non-detachable from the component.

NOTE 1 Particular device standards (e.g. ISO 8185 for humidifiers) might contain requirements for specific ports (e.g. temperature probe) when such equipment is added to the anaesthetic breathing system.

NOTE 2 For gas sample return port, see 12.1 g) for marking requirements.

6 Reservoir bag/anaesthetic ventilator selector switch

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

NOTE See 12.1 i) for marking requirements.

7 Complete anaesthetic breathing system either supplied assembled or assembled in accordance with the manufacturer's instructions

* 7.1 Leakage

The leakage from an anaesthetic breathing system shall not exceed 150 ml/min (15,2 kPa $\times$ l/min) at 3,0 kPa (30 cm H_2O) internal pressure.

NOTE 1 For some uses the leakage limit of 150 ml/min might not be appropriate.

NOTE 2 See Annex A for typical test arrangement and method.

* 7.2 Inspiratory and expiratory pressure/flow characteristics

The pressure (positive/sub-atmospheric) generated at the patient connection port shall not exceed 0,6 kPa (6 cm H_2O) at the peak flow of 60 l/min when connected to the anaesthesia system or suitable test rig supplying a fresh gas flow of 10 l/min (± 1 l/min) or the maximum fresh gas inlet flow specified by the manufacturer.

The manufacturer shall disclose the pressure/flow characteristics of the anaesthetic breathing system, including the pressure at 60 l/min [see 13.2 b)].

NOTE See Annex A for typical test arrangement and method.

8 Interchangeable anaesthetic breathing system components — Exhaust valves

8.1 Direction of movement of controls

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

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

8.2 Pressure/flow characteristics

For exhaust valves supplied separately, the manufacturer shall disclose the pressure-flow characteristics of the valve, including the opening pressure and the pressure drop with any valve control fully open at a flow of 30 l/min [see 13.3.2 b)].

8.3 Opening pressure

For exhaust valves supplied separately, the manufacturer shall disclose the opening pressure of the valve under wet conditions [see 13.3.2 c)].

8.4 Leakage

For exhaust valves supplied separately, which can be fully closed, the manufacturer shall disclose the leakage to atmosphere in the fully closed position at a pressure of 3 kPa (30 cm H_2O).

9 Circle absorber assemblies

9.1 Construction

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 circle absorber assembly, 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.

NOTE See 12.1 l) for marking requirements.

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

It should be possible to change the absorbent without opening the gas pathway to the atmosphere.

9.2 Absorbent bypass mechanism

9.2.1 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 7.1 and the pressure/flow requirements of 7.2, both with the container(s) in place and with them removed.

9.2.2 When the mechanism for excluding the absorbent is operator-controlled, the control shall have a means of preventing accidental movement and shall be marked in accordance with 12.1 j). The “off” indicator shall mean that the gas does not pass through the absorbent and the indicator shall be visible to the operator from the normal operating position.

9.2.3 Unless the absorber 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 7.1 and the pressure/flow requirements of 7.2 with the control in the “on” and “off” positions.

9.2.4 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 7.1 and the pressure/flow requirements of 7.2 in the “on” and “off” positions and at any intermediate setting of the control.

9.2.5 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.

9.3 Pressure/flow characteristics

Circle absorber assemblies supplied separately, when assembled with other components according to the manufacturer's instructions to form a complete anaesthetic breathing system, shall meet the leakage and pressure/flow requirements of Clause 7.

NOTE See Annex A for typical test arrangement and method.

9.4 Inspiratory and expiratory valves

9.4.1 General

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

9.4.2 Pressure/flow characteristics

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 13.3.4 a)].

At a flow of 20 ml/min the pressure to open a dry valve shall not exceed 0,12 kPa (1,2 cm H_2O).

NOTE See Annex A for typical test arrangement and method.

* 9.4.3 Reverse flow and dislocation

The reverse flow through the valve shall not exceed 60 ml/min at a pressure of up to 0,5 kPa (5,0 cm H_2O)

NOTE 1 Typically the most significant reverse flow with disc-type valves is at pressures of less than 0,05 kPa (0,5 cm H_2O), whereas with flap valves it can be at a higher pressure.

The valve disc or flap shall not become dislocated on application of a reverse pressure of 5 kPa (50 cm H_2O) and the reverse flow through the valve shall not exceed 60 ml/min at a pressure of up to 0,5 kPa (5,0 cm H_2O)

NOTE 2 See Annex A for typical test arrangement and method.

10 Pressure monitoring and limitation

10.1 Pressure monitoring

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

10.1.2 If a pressure-measuring device is provided, it shall be marked in kilopascals.

NOTE Additional units (e.g. cm H_2O) can be used.

The pressure-measuring device shall have a minimum range from -1 kPa (-10 cm H_2O) to $+6$ kPa ($+60$ cm H_2O).

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

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

10.2 Pressure-limiting device

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

NOTE A reservoir bag complying with ISO 5362 may be considered as a maximum pressure-limiting device for an anaesthetic system without an anaesthetic ventilator or when the anaesthetic ventilator is in the manual or spontaneous ventilation mode.

* 11 Location of components in an anaesthetic breathing system containing a circle absorber assembly (as defined in 3.3)

NOTE For circle absorber assemblies integrated within an anaesthesia system these restrictions on the location of components might not apply.

11.1 Exhaust valve

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

11.2 Reservoir bag connection port

The port for connection to a reservoir bag shall not be on the patient side of the inspiratory or expiratory valve(s).

11.3 Fresh gas inlet

The fresh gas inlet shall not be on the patient side of the inspiratory or expiratory valve.

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

11.4 Inspiratory and expiratory valves

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

12 Marking

12.1 Marking of complete anaesthetic breathing systems and anaesthetic breathing system components

Complete anaesthetic breathing systems and components shall be marked with the following as appropriate:

a) the name and/or trademark of the manufacturer or supplier;

b) the production identifier (e.g. batch or lot);

c) for an exhaust connection port complying with 5.3, the word “EXHAUST” and/or “AGS” or the equivalent in the national language or an appropriate symbol;

d) for a reservoir bag connection port complying with 5.5, the word “BAG” or the equivalent in the national language or an appropriate symbol;

e) for an anaesthetic ventilator connection port complying with 5.6, the word “VENTILATOR” or the equivalent in the national language or an appropriate symbol;

f) for operator-interchangeable flow-direction sensitive components, an indication of the direction of gas flow;

g) for a gas sampling return connection port complying with 5.9, the words “GAS SAMPLE RETURN” or the equivalent in the national language or symbol from ISO 7000;

h) the word “ANTISTATIC” or “CONDUCTIVE” for anaesthetic breathing systems and integrally attached non-metallic components made of antistatic or conductive materials;

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

i) for a switch provided to change from reservoir bag to anaesthetic ventilator and vice versa, complying with Clause 6, the words “BAG” and “VENTILATOR” or the equivalent in the national language and/or appropriate symbols;

j) for an operator-controlled mechanism for excluding the absorbent from the gas pathway, the control shall be marked with the words “on” and “off”, or the equivalent in the national language, and/or with symbols shown in Figure 1;

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

k) for single use devices, the words “FOR SINGLE USE” or the equivalent in the national language or symbol No. 1051 of ISO 7000:2004 (indicating “do not re-use”);

l) inspiratory and expiratory ports of a circle absorber assembly, with an arrow to indicate the direction of gas flow.

a) Symbol for “absorber on” **b) Symbol for “absorber off”**

Figure 1 — Absorbent bypass control markings

12.2 Marking of packages

Packages containing complete anaesthetic breathing system or anaesthetic breathing system components shall be marked with the following as appropriate:

a) the name and/or trademark of the manufacturer or supplier;

b) the production identifier (e.g. batch or lot);

c) a description of the contents;

d) the words “FOR SINGLE USE” or the equivalent in the national language or symbol No. 1051 of ISO 7000:2004 (indicating “do not re-use”);

e) the word “STERILE” or a symbol;

f) the word “ANTISTATIC” or “CONDUCTIVE”.

13 Information to be provided by the manufacturer or supplier

13.1 General

The following information shall be provided as appropriate by the manufacturer for complete anaesthetic breathing systems and for anaesthetic breathing system components supplied separately:

a) installation instructions;

b) warnings, cautions and safety notices;

c) the meaning or a description of all symbols, abbreviations and figures;

d) explanation of the function of controls;

e) a description of all the operational modes in which the anaesthetic breathing system or anaesthetic breathing system component is intended to be used;

f) a statement of known compatibility with gases and anaesthetic agents, and a statement regarding suitability for use with flammable anaesthetic agents;

g) where appropriate, an indication of the date by which the anaesthetic breathing system or ABS component can be used in safety, expressed as the year and month;

h) where appropriate, the recommended methods of cleaning and disinfection or sterilization, including the number of cycles;

i) where appropriate, information as to how the operator can check for correct performance of the system/component and recommended frequency of such checks;

j) the recommended service intervals;

k) a statement about the presence and where applicable location of latex.

13.2 For anaesthetic breathing systems supplied complete

a) a diagram of the complete anaesthetic breathing system identifying its components and their recommended location(s);

b) the pressure/flow characteristics of the anaesthetic breathing system;

NOTE See typical test setups in Annex A.

c) the leakage from the anaesthetic breathing system in all operational modes stated by the manufacturer when tested at a pressure of 3,0 kPa (30 cm H_2O) (see 7.1);

d) the internal compliance of the anaesthetic breathing system, expressed as a volume, in millilitres, at a pressure of 3 kPa (30 cm H_2O) and measured with any carbon dioxide absorbent container(s) filled with fresh absorbent of any type recommended by the manufacturer and any reservoir bag excluded;

e) if the anaesthetic breathing system is intended to be used with an anaesthetic system complying with IEC 60601-2-13, a statement relating to pressure monitoring, pressure limitation and the requirements for other relevant monitoring, alarm and protection devices;

f) the inspiratory and expiratory pressure/flow characteristics with a fresh gas flow of 10 l/min or the maximum specified by the manufacturer.

13.3 For anaesthetic breathing system components

13.3.1 General

a) a diagram showing their recommended location(s) within the anaesthetic breathing system;

b) a statement to the effect that the user-assembled complete anaesthetic breathing system leakage at 30 cm H_2O shall be less than 150 ml/min.

13.3.2 Exhaust valves

a) instructions for use of the exhaust valve control, if any;

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

c) the information given in 13.3.2 b) obtained under wet conditions specified by the manufacturer;

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

d) unless the exhaust valve is permanently mounted, the recommended orientation of the exhaust valve and details of the effects of other orientations on its performance;

e) information on any other means of pressure relief, including pressure-flow characteristics, covering a range of pressures from 0,5 kPa (5 cm H_2O) to 6 kPa (60 cm H_2O);

f) for an exhaust valve supplied separately, which can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 3 kPa (30 cm H_2O).

13.3.3 Circle absorber assemblies

a) a diagram of the circle absorber assembly;

b) a diagram of the circle absorber assembly bypass mechanism, if present;

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

d) the volume of the carbon dioxide absorbent container(s) expressed in millilitres;

e) 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 cm H_2O);

f) the carbon dioxide absorbent recommended for use in the circle absorber assembly;

g) instructions for changing the carbon dioxide absorbent, cleaning the absorber and maintaining the leaktightness of the assembly, if appropriate;

h) instructions for draining water from the circle absorber assembly;

i) the leakage from the circle absorber assembly with and without the carbon dioxide absorbent container(s) fitted and at all the intended settings of the circle absorber assembly bypass control, if fitted, expressed as a volume in millilitres at a pressure of 3 kPa (30 cm H_2O);

j) the pressure/flow characteristics of the circle absorber assembly;

NOTE See typical test setups in Annex A.

k) information as to how the operator can check the performance of the unidirectional valves.

13.3.4 Inspiratory and expiratory valves

a) the pressure-flow characteristics of the inspiratory and/or expiratory valve, including the opening pressure and the pressure drop across the valve at an air flow of 60 l/min at ATPD;

b) the information given in 13.3.4 a) obtained under wet conditions specified by the manufacturer;

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

c) the recommended orientation of the inspiratory and/or expiratory valve and details of the effects of other orientations on its/their performance;

d) information as to how the operator can check the performance of the inspiratory and/or expiratory valves.

Annex A
(normative)

Typical test arrangements and methods

A.1 General

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

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

A.2 Leakage from complete anaesthetic breathing systems

A.2.1 Apparatus

A.2.1.1 Pressure-compensated flow-measuring device, of accuracy specified in A.1 at flows between 25 ml/min and 200 ml/min.

A.2.1.2 Pressure-measuring device, of similar accuracy at a pressure of 3 kPa (30 cm H_2O).

A.2.2 Procedure

Connect the pressure-measuring device (A.2.1.2) to an appropriate port and seal all other ports. Seal any valve in the anaesthetic breathing system that is designed to allow gas to leak to atmosphere at or below pressures of 3 kPa (30 cm H_2O). Introduce air into the fresh gas inlet until a pressure of 3 kPa (30 cm H_2O) is indicated.

Adjust the flow of air to stabilize the pressure at 3 kPa (30 cm H_2O) and record the leakage flow. If the anaesthetic breathing system contains a circle absorber assembly fitted with an absorbent bypass mechanism, test the anaesthetic breathing system at the intended settings of the absorbent bypass control both with the carbon dioxide absorbent container(s) fitted and with them removed (see 9.3).

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

A.3 Pressure/flow characteristics of complete anaesthetic breathing systems

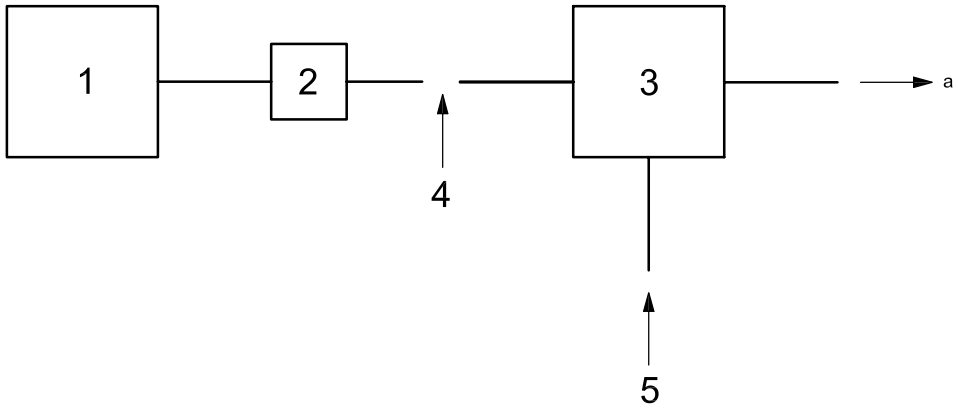
A.3.1 Apparatus

A.3.1.1 Flow- and pressure-measuring devices, of accuracy specified in A.1.

A.3.2 Procedure

Set up the anaesthetic breathing system with the reservoir bag fitted, any ventilator connection port sealed or switched to “bag” mode, and any exhaust valve, if adjustable, fully open. Connect the anaesthetic breathing system to the fresh-gas outlet of an anaesthetic system or to an appropriate 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 anaesthetic breathing system. Set the test apparatus to generate bidirectional 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/flow curves derived therefrom.

If the anaesthetic breathing system contains a circle absorber assembly, carry out this test 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 when fitted and when removed and at all the intended settings of the absorbent bypass control.



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

[a] To anaesthetic gas scavenging system.

Figure A.1 — Typical test arrangement for measuring pressure/flow characteristics of complete anaesthetic breathing systems

A.3.3 Procedure for anaesthetic breathing system partly incorporated within an anaesthetic system

Test the anaesthetic breathing system as described in A.3.2, having connected the breathing tubes to the inspiratory and expiratory ports of the anaesthetic system. If the anaesthetic system is fitted with an anaesthetic ventilator, repeat the test procedure with the reservoir bag/anaesthetic ventilator selector switch set to “ventilator” and the test apparatus set to generate a half-sine wave flow into the patient connection port of the anaesthetic 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/flow curves derived therefrom. Carry out the test in accordance with the manufacturer’s instructions.

A.4 Circle absorber assemblies supplied separately

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

Test the completed anaesthetic breathing system for leakage as described in Clause A.2 and for pressure/flow characteristics as described in Clause A.3.

A.5 Resistance to flow of unidirectional valves

A.5.1 Apparatus

A.5.1.1 **Flow-measuring device**, accurate to within ± 5 % at an indicated flow of 5 l/min, 30 l/min or 60 l/min

A.5.1.2 **Pressure-measuring device**, accurate to within ± 5 % at a pressure of 0,15 kPa (1,5 cm H_2O).

A.5.2 Procedure

If testing a dry unidirectional valve, connect a pressure source on the input side of the valve, connect the pressure-measuring device (A.5.1.2) in order to record the pressure generated at the input side of the valve, and connect the flow-measuring device (A.5.1.1) between the pressure source and the pressure-measuring device. Adjust the flow to 5 l/min, 30 l/min or 60 l/min. Record the pressure generated.

A.6 Reverse flow through and dislocation of unidirectional valves

A.6.1 Apparatus

A.6.1.1 **Flow-measuring device**, accurate to within ± 5 % at an indicated flow of 63 ml/min.

A.6.1.2 **Pressure-measuring device**, accurate to within ± 5 % at a pressure of 0,5 kPa (5 cm H_2O) and at a pressure of 5 kPa (50 cm H_2O).

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

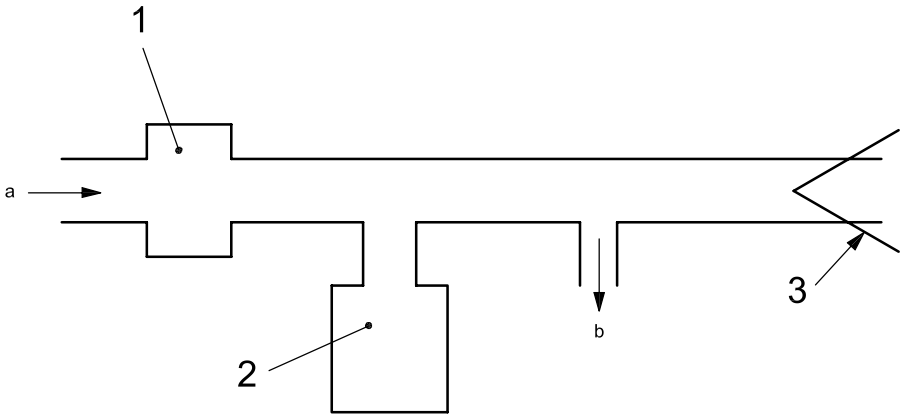
A.6.1.4 **Stopwatch**.

A.6.2 Procedure

A.6.2.1 Connect the unidirectional valve to the pressure source, pressure-measuring device (A.6.1.2), flow-measuring device (A.6.1.1) and rigid container (A.6.1.3) as shown in Figure A.2. Adjust the flow to a constant 63 ml/min and start the stopwatch (A.6.1.4). Observe the pressure-measuring device and record the time taken for the pressure to reach at least 0,5 kPa (5 cm H_2O).

NOTE Within the tolerance of the test apparatus, using a flow of 63 ml/min will mean that valves having a reverse flow of less than 60 ml/min will meet the requirement and those having a reverse flow of more than 70 ml/min will fail to meet the requirement.

A.6.2.2 Adjust the flow to give a pressure of 5 kPa (50 cm H_2O) and hold this pressure for 1 min. Release the pressure and check that the valve has not become dislocated by repeating the procedure described in A.6.2.1 and verifying that the pressure rises to at least 0,5 kPa within 5 min.



Key

1 flowmeter
2 rigid container
3 inspiratory or expiratory valve

a From pressure source.
b To pressure-measuring device.

Figure A.2 — Arrangement for test — Reverse flow through unidirectional valves

A.7 Opening pressure of unidirectional valves

A.7.1 Apparatus

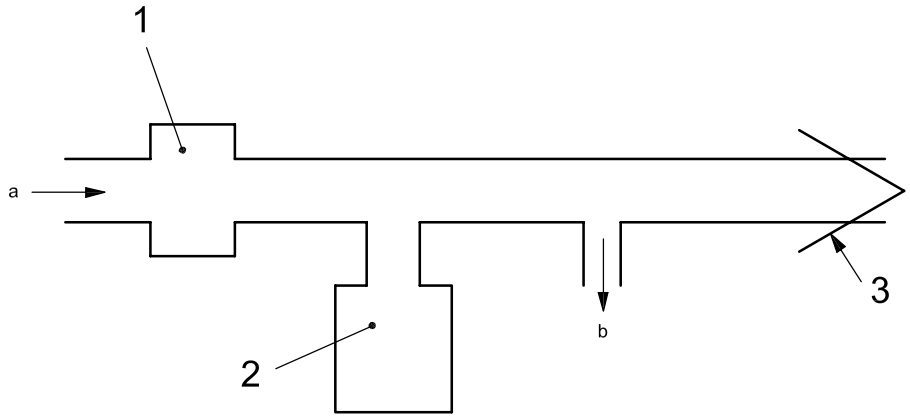
A.7.1.1 **Flow-measuring device**, accurate to within ± 5 % at an indicated flow of 20 ml/min.

A.7.1.2 **Pressure-measuring device**, accurate to within ± 5 % at a pressure of 0,15 kPa (1,5 cm H_2O).

A.7.2 Procedure

A.7.2.1 Connect a pressure source on the upstream side of the unidirectional valve and connect the pressure-measuring device (A.7.1.2) to record the pressure generated at the input side of the valve, as shown in Figure A.3.

A.7.2.2 If testing a dry unidirectional valve, 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 flowmeter
2 rigid container
3 inspiratory or expiratory valve

a From pressure source.
b To pressure-measuring device.

Figure A.3 — Arrangement of components for test of opening pressure of unidirectional valves

Annex B
(informative)

Rationale

This annex provides a rationale for some requirements of this part of ISO 8835 and is intended for those who are familiar with the subject of this part of ISO 8835 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 8835 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 8835. The numbering is, therefore, not consecutive.

B.1 Scope

The use of flammable anaesthetics has diminished to a point where it was agreed not to consider adding specific requirements to this part of ISO 8835 to address hazards associated with the use of flammable anaesthetics.

B.4.3.1 Electrical

RF wireless technology is increasingly being incorporated into medical devices and systems. There are concerns that should be addressed about the potential effects of the use of this technology on the ability of inhalation devices to function properly and the resultant safety of patients and operators.

B.5.5 Reservoir bag connection port

During development of this part of ISO 8835, the requirement for the reservoir bag connection port to be "within 20° of the vertical axis" was questioned. Some of the working group members felt the requirement was unnecessarily design-restrictive. In the end, the majority of the working group members believed this requirement was an important and effective deterrent against accidental misconnections.

B.5.8 Inspiratory and expiratory ports of circle absorber assembly

During development of this part of ISO 8835, the requirement that the "axis of these ports be either horizontal or within 50° of the horizontal plane" was questioned. Some of the working group members felt the requirement was unnecessarily design-restrictive. In the end, the majority of the working group members believed this requirement was an important and effective deterrent against accidental misconnections.

B.7.1 Leakage of the anaesthetic breathing system

The limit of 150 ml/min for an entire anaesthetic breathing system was established for two reasons: (1) to restrict the loss of gas volume intended to be delivered to the patient; (2) to limit anaesthetic gas pollution in the anesthetizing locations. This limit was considered to be the maximum acceptable in view of all the other potential sources of gas leaks. Individual component limits were not established to allow flexibility in design; for example, a design can include a swivel adapter on the Y-piece, a potential source of increased leakage, provided the rest of the components or connections of the anaesthetic breathing system leak minimally.

B.7.2 Resistance of the anaesthetic breathing system

Total expiratory and total inspiratory resistance were established at a maximum of 0,6 kPa (6,0 cm H_2O) each in order to limit the work of breathing for the spontaneously breathing patient and to restrict positive end-expiratory pressure. In setting the maximum, the committee considered the resistances of commercially available devices and selected a value between those considered and the ideal of zero resistance. A resistance of 0,6 kPa (6,0 cm H_2O) was considered by clinicians to be a generally acceptable physiological

maximum. Since there are cases where one would require a system with resistance much more than the maximum or require the use of components that would increase the resistance above the maximum, the requirement for disclosure of the anaesthetic breathing system pressure/flow characteristics was included.

B.9.4.3 Reverse flow and dislocation of inspiratory and expiratory valves

Reverse flow, dislocation or incompetence of inspiratory or expiratory valves could result in rebreathing of end-expiratory gases and a reduction of CO_2 elimination. The most significant leak with disc-type valves may be at low pressures, whereas with flapper valves, the most significant leak may be closer to a pressure of 0,5 kPa (5,0 cm H_2O). A 60 ml/min reverse flow was considered clinically acceptable and attainable using current manufacturing techniques.

The pressure needed to open moist/wet unidirectional valves may be higher than that to open dry unidirectional valves. However, because wet testing of these valves is difficult to repeat, this part of ISO 8835 does not require a type test for the opening pressure of wet valves. Instead this part of ISO 8835 requires the manufacturer to disclose the opening pressure of these valves under wet conditions as specified.

B.11 Location of components in a circle absorber anaesthetic breathing system

An open exhaust valve between the inspiratory valve and the Y-piece permits free return of exhaled gas into the inspiratory pathway with subsequent re-breathing.

A reservoir bag on the patient side of either unidirectional valve will fill with exhaled gas which will be re-breathed on subsequent inhalation.

If the fresh gas inlet is placed on the patient side of the expiratory valve, loss of fresh gas through the exhaust valve will occur. If the fresh gas inlet is placed between the expiratory valve and the absorber, the humidification of the fresh gas mixture will be enhanced; however, with this arrangement loss of fresh gas through the exhaust valve may occur if the exhaust valve is not placed at a sufficient distance from the fresh gas inlet. Placement of the fresh gas inlet on the patient side of the inspiratory valve vents that fresh gas flow which passes by the Y-piece during exhalation. This prevents the use of a spirometer in the expiratory limb of the anaesthetic breathing system.

A Y-piece with valves could be placed in reverse orientation to another set of unidirectional valves on a circle absorber assembly, making ventilation impossible.

Annex C
(informative)

Environmental aspects

Planning and design of products applying to this part of ISO 8835 should consider the environmental impact of the product during its life cycle. The environmental impact generated by an anaesthetic breathing system or anaesthetic breathing system component is mainly restricted to the following occurrences:

— impact on local environment during normal use;

— use, cleaning and disposal of consumables during testing and normal use;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this part of ISO 8835 addresses requirements or recommendations intended to decrease the environmental impact caused by those aspects.

See Table C.1 for a mapping of the life cycle of an anaesthetic breathing system or anaesthetic breathing system component to aspects of the environment.

Table C.1 — Environmental aspects addressed by clauses of this part of ISO 8835

Environmental aspects (inputs and outputs)		**Product life cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in clause/subclause:			
1	Resource use	1	—	4.1 12 13	4.1
2	Energy consumption	1	—	4.3.1	—
3	Emissions to air	1	—	7.1	4.1
4	Emissions to water	1	—	13	4.1
5	Waste	1	1 4.1	13	4.1
6	Noise	1	—	—	—
7	Migration of hazardous substances	1	—	—	4.1
8	Impacts on soil	1	—	13	—
9	Risks to the environment from accidents or misuse	1	—	—	—

Annex D
(normative)

Antistatic requirements

The electrical resistance of the product as manufactured, shall comply with the requirements given in Table D.1.

Table D.1 — Electrical resistances

Product	Electrical resistance Ω		Method of test (Reference to subclause in ISO 2878:2005)
	min	max	
Anaesthetic airways	—	10^6	7.4.1
Anaesthetic bellows	—	10^6	7.2
Anaesthetic face pieces	—	10^6	7.2 or 7.3.1
Anaesthetic tubing	3×10^4/m	10^6/m	7.3.2 or 7.4.1
Hose	3×10^3/m	10^6/m	7.4.1 or 7.4.2
Non-wire reinforced hose with permanently attached metal end fittings	3×10^3/m	10^6/m	7.4.5
Mouldings, small	—	10^6	7.2
NOTE The electrical resistance of antistatic products for use in anaesthetic areas of hospitals should not exceed 10^8 Ω at any time during their useful life, subject to local codes and regulations. **CAUTION — Procucts which achieve their antistatic properties by a thin conductive surface coating can lose these properties during use as a result of wear or solvent action.**			

Bibliography

[1] ISO 8185, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

[2] ISO/TS 18835, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment*

[3] IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

ICS 11.040.10

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