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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

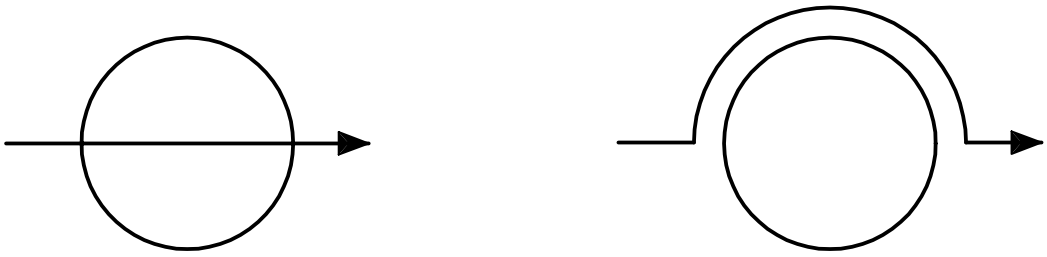
7.2.1 If a means of excluding the absorbent from the gas pathway is provided, the operation of which is actuated automatically by removing the absorbent container(s), the circle absorber assembly shall meet the leakage requirements of 7.3.1 and the resistance to flow requirement of 7.4 with the container(s)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