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Inhalational anaesthesia systems —

Part 2:
Anaesthetic circle breathing systems

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes de respirateurs circulaires d'anesthésie

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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*, Sub-Committee SC 1, *Breathing attachments and anaesthetic machines*.

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

— *Part 1: Anaesthetic workstations and their components — Particular requirements*

— *Part 2: Anaesthetic circle breathing systems*

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

Annex A forms an integral part of this part of ISO 8835. Annex B is for information only.

Introduction

A breathing system comprises an assembly of tubes and connectors, and may include valves, a reservoir bag and a carbon dioxide absorber. Its functions are to convey mixtures of gases to and from the patient.

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

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

Inhalational anaesthesia systems —

Part 2:
Anaesthetic circle breathing systems

1 Scope

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

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

2 Normative references

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

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

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

ISO 4135:—[1], *Anaesthesiology — Vocabulary.*

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

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

ISO 5362:1986, *Anaesthetic reservoir bags.*

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

3 Definitions

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

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

3.1 breathing system: Those inspiratory and expiratory gas pathways, excluding the anaesthesia ventilator, between the common gas outlet and the patient connection port which contain gas at respiratory pressures.

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

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

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

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

3.4 fresh-gas inlet: That port on a breathing attachment through which fresh gas is supplied to the breathing system.

3.5 fresh-gas supply tube: Tube conveying fresh gas from the common gas outlet to the fresh-gas inlet.

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

3.7 exhaust port: That port through which excess and/or waste gas(es) are discharged to the atmosphere or to an anaesthetic gas scavenging system.

3.8 Y-piece; 3-way breathing system connector: 3-way tubular connector for use within a breathing system having a patient connection port and two ports for connection to breathing tubes.

4 General requirements

4.1 Connectors

4.1.1 Inspiratory port

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

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

4.1.2 Expiratory port

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

4.1.3 Connection port for reservoir bags

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

4.1.4 Patient connection port

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

4.1.5 Y-piece

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

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

4.1.6 Exhaust port

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

a) 30 mm male conical connector complying with ISO 5356-1;

b) proprietary fitting incompatible with ISO 5356-1;

c) a non-detachable connection to the transfer hose.

4.1.7 Ventilator port

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

4.1.8 Other breathing attachments

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

4.1.8.2 Circle absorber assemblies shall incorporate inspiratory and expiratory valves. If these valves can be detached from the absorber unit, the method of attachment to the latter shall be by means of con-

nectors which are non-interchangeable with each other and which are not compatible with any of the connectors specified in ISO 5356-1 and ISO 5356-2.

4.2 Electrical conductivity

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

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

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

4.3 Recommendation on materials

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

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

5.1 Leakage

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

5.2 Expiratory resistance

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

5.3 Inspiratory resistance

When tested as described in A.4, the sub-atmospheric pressure generated at the patient connection port shall not exceed 0,6 kPa (6 cmH_2O).

6 Adjustable pressure-limiting (APL) valves

6.1 Direction of movement

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

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

6.2 Resistance to flow

For APL valves that are not an integral component of another medical device, when tested as described in A.5, the pressure drop across the APL valve, in the fully open position, shall be between 0,05 kPa and 0,3 kPa (0,5 cmH_2O and 3 cmH_2O) at an air flow of 3 l/min and between 0,1 kPa and 0,5 kPa (1 cmH_2O and 5 cmH_2O) at an air flow of 30 l/min.

For APL valves integrated into other medical devices, when tested as described in A.5, the pressure drop across that portion of the device incorporating the APL valve, in the fully open position, shall be between 0,05 kPa and 0,3 kPa (0,5 cmH_2O and 3 cmH_2O) at an air flow of 3 l/min and between 0,1 kPa and 0,6 kPa (1 cmH_2O and 6 cmH_2O) at an air flow of 30 l/min.

6.3 Leakage

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

7 Circle absorber assemblies

7.1 Construction

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

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

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

7.2 Absorber bypass mechanism

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

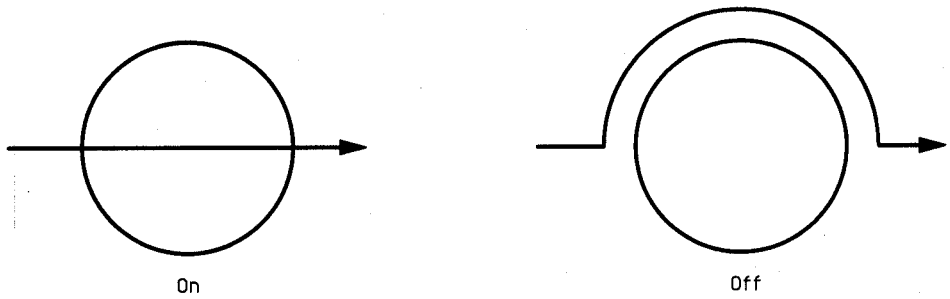

Figure 1 — Markings for carbon dioxide absorbers and circle absorber assemblies

7.2.2 When the mechanism for excluding the absorbent is operator-controlled, the control shall have detents to prevent accidental movement and shall be marked "on" and "off", and/or with the symbols shown in figure 1. The "off" indicator shall be visible to the operator from his/her normal operating position.

The words "on" and "off" may be preceded by the word "absorber".

NOTE 6 The "off" position means that gas does not pass through the absorbent.

7.2.3 Unless the absorber bypass mechanism is intended to function at an intermediate setting(s), the control shall have detents in only the "on" and "off" positions, and shall be bi-stable. The circle absorber assembly shall meet the requirements of 7.3, 7.4 and 7.5 with the control in the "on" and "off" positions.

7.2.4 For a bypass mechanism intended to function at an intermediate setting(s), the control shall so indicate, and the circle absorber assembly shall meet the requirements of 7.3, 7.4 and 7.5 in the "on" and "off" positions, and at any intermediate setting of the control.

7.3 Leakage

7.3.1 Circle absorber assemblies shall be tested by the method described in A.7 and the leakage shall be disclosed by the manufacturer [see clause 12 d) 9)].

7.3.2 For assemblies with an operator-controlled absorber bypass mechanism, when the control is in the "off" position, the absorbent container(s) shall be removable without opening the gas pathway to the atmosphere and the leakage with the container(s) removed shall be disclosed by the manufacturer [see clause 12 d) 9)].

7.4 Expiratory resistance of circle absorber assembly

When tested as described in A.8, the pressure generated at the expiratory port shall not exceed 0,6 kPa (6 cmH_2O).

7.5 Inspiratory resistance of circle absorber assembly

When tested as described in A.9, the subatmospheric pressure generated at the inspiratory port shall not exceed 0,6 kPa (6 cmH_2O).

8 Unidirectional valves

It should be possible to see the movement of a valve.

8.1 Resistance to flow

When tested as described in A.10, the pressure generated by a dry valve shall not exceed 0,15 kPa (1,5 cmH_2O) [see also clause 12 c) 4)].

8.2 Reverse flow and dislocation

When tested as described in A.11, the pressure shall rise to at least 0,5 kPa (5 cmH_2O) within 5 min and the valve shall not become dislocated on application of a reverse pressure of 5 kPa (50 cmH_2O).

NOTES

7 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 up to 0,5 kPa (see also note 11 to A.11.2.1).

8 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 may be at a higher pressure.

8.3 Opening pressure

When tested as described in A.12, the pressure to open a dry valve shall not exceed 0,12 kPa (1,2 cmH_2O) [see also clause 12 c) 5)].

8.4 Inspiratory/expiratory valves

Inspiratory/expiratory valves shall comply with 8.1, 8.2, 8.3 and clause 12 c).

9 Pressure-monitoring

9.1 A means shall be provided to allow the breathing system pressure to be measured on the patient side of the unidirectional valve(s).

9.2 If a pressure-monitoring 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 -1 kPa to $+6$ kPa, as appropriate, and shall be detachable to permit sterilization or disinfection of the components of the breathing system or shall itself be capable of sterilization or disinfection.

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

10 Location of breathing system components

The carbon dioxide absorber should not be placed between the patient and the unidirectional valve(s).

10.1 APL valves

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

If an APL valve is permanently located on a circle absorber assembly, it shall not be on the patient side of the inspiratory valve.

10.2 Port for connection to reservoir bag

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

10.3 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 reservoir bag and the inspiratory valve.

10.4 Unidirectional valve(s)

The unidirectional valve(s) shall not be located in a Y-piece.

11 Marking

NOTE 9 See also 4.1.1, 4.1.2, 4.1.3, 4.1.7, 4.2.2, 7.2.2 and clause 9.

11.1 Marking of breathing attachments

11.1.1 Complete anaesthetic breathing systems and operator-detachable breathing attachments (e.g. APL valves and unidirectional valves) shall be permanently and legibly marked with the following:

a) the name and/or trademark of the manufacturer and/or supplier (except for breathing attachments supplied as an integral part of a breathing system);

b) an identification reference to the lot or date of manufacture;

c) the maximum limiting pressure, if any valve has a designed limited pressure.

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

The words "inlet" and "outlet" may additionally be marked.

The safe and correct functioning of certain breathing attachments is dependent on the direction of gas flow through them. Care should be taken to ensure that any such flow-direction-sensitive component is fitted in the correct limb of the breathing system.

11.2 Marking of complete breathing systems intended for re-use

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

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

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

11.3 Marking of packages

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

a) a description of the contents;

b) the words "FOR SINGLE USE";

NOTE 10 Symbol No. 1051 ("Do not re-use") given in ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis* may additionally be used.

c) the word "STERILE" if appropriate;

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

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

11.3.2 Packages containing breathing attachments or complete breathing systems intended for re-use shall be clearly 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 sterilization or disinfection, including the maximum number of cycles recommended.

11.3.3 Packages containing breathing attachments or complete breathing systems made of antistatic (conductive) material shall be clearly marked with the word "ANTISTATIC".

12 Information to be provided by manufacturer

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

a) for complete breathing systems:

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) a diagram of the circle absorber assembly,

4) a diagram of the absorber bypass mechanism, if present,

5) 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) shall be disclosed,

6) the typical pressure drops due to expiratory and inspiratory gas flow in the breathing system (see 7.4 and 7.5), at a flow of 60 l/min,

7) the internal compliance of the breathing system, expressed as a volume in millilitres at 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,

8) the leakage from the breathing system in all operational modes stated by the manufacturer [see clause 12 a) 2)], measured as described in A.2,

9) a statement to inform the operator that accidental hypercapnia or hypocapnia can occur with the use of the system;

b) for APL valves:

1) details of the use of the valve control and the pressure-flow characteristics of the valve, including the pressure drop, with the valve fully open, at a dry air flow of 30 l/min,

2) except if the valve is permanently mounted, the recommended orientation of the valve and details of the effects of other orientations on its peformance,

3) details of any additional system 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),

4) recommended service intervals;

c) for unidirectional valves:

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

2) the recommended orientation of the valve and details of the effects of other orientations on its performance,

3) recommended service intervals,

4) the pressure generated by a wet valve when tested as described in A.10,

5) the pressure to open a wet valve when tested as described in A.12;

d) for circle absorber assemblies:

1) a diagram of the circle absorber assembly,

2) a diagram of the absorber 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) shall 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 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 and maintaining the leaktightness of the absorber,

8) instructions for draining water from the circle absorber assembly,

9) the leakage from the circle absorber assembly, measured as described in A.7 with and without the carbon dioxide absorbent container(s) removed,

10) the expiratory and inspiratory resistances of a freshly filled circle absorber assembly at a flow of 60 l/min, together with details of the absorbent used during the determination;

e) for breathing systems intended to be assembled by the operator, instructions for assembling the breathing attachments, including a statement that the APL valve is not to be placed between the inspiratory valve and the Y-piece.

f) for breathing attachments and complete breathing systems intended for re-use, recommended methods of sterilization or disinfection, including the maximum number of cycles recommended, together with a method by which the operator can determine whether or not a sterilized or disinfected device remains safe for clinical re-use.