INTERNATIONAL STANDARD

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Third edition
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Inhalational anaesthesia systems —

Part 2: Anaesthetic breathing systems

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes respiratoires d'anesthésie

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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 ± 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 × 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.

