INTERNATIONAL STANDARD

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Inhalational anaesthesia systems —

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

Systèmes d'anesthésie par inhalation —

Partie 3: Systèmes de transfert et de réception des systèmes d'évacuation des gaz 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 8835-3 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 8835-3:1997), 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

This part of ISO 8835 is intended to ensure that, for all practical purposes, an active AGSS will remove essentially all gases delivered to it and thereby reduce atmospheric pollution to a small fraction of the uncontrolled level.

It is recognized that there are many factors affecting conditions within the operator's working environment, which are outside the control of manufacturers of active AGSSs. These include room ventilation, leakage from equipment and the choice of anaesthetic technique, all of which are variable. Furthermore, the amount of pollutant taken up by personnel will be affected by other factors, such as the duration of exposure, their position in relation to any source of pollution, etc.

Atmospheric pollution by anaesthetic gases is the subject of considerable discussion, and opinions differ as to the limits that should be allowed in the working environment. Recommendations on permissible levels are therefore not included in this part of ISO 8835 but can be specified in national standards.

The committee responsible for this part of ISO 8835 has been primarily concerned with limiting the risks to the patient, which the transfer and receiving systems of AGSS can introduce by altering the function of breathing systems. The wide range of anaesthetic machines, ventilators and related equipment in general use today has been taken into account.

Annex F 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 F, included to provide additional insight into the reasoning that led to the requirements and recommandations that have been incorporated in this International Standard.

Inhalational anaesthesia systems —

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

* 1 Scope

This part of ISO 8835 specifies requirements for transfer and receiving systems of active anaesthetic gas scavenging systems (active AGSSs) intended to reduce exposure of healthcare personnel to anaesthetic gases and vapours while providing patient protection (e.g. against excessive flow and pressure). This part of ISO 8835 also specifies requirements for transfer and receiving systems of active anaesthetic gas scavenging systems in which the power device is integral with the transfer and receiving system.

This part of ISO 8835 does not specify requirements for

— disposal systems which are covered by ISO 7396-2,

— non-active AGSSs (passive AGSSs),

— proximity gas extraction systems (i.e. systems not directly connected to the breathing system or associated equipment),

— transfer and receiving systems intended for use with flammable anaesthetic 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 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 connections*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 8835-2, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2:—[1)], *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 21647, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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, IEC 60601-2-13 and the following apply.

3.1
anaesthetic gas scavenging system
AGSS
system that is connected to the exhaust port of an anaesthetic breathing system, or to associated equipment, or which is integrated into an anaesthetic system (workstation) for the purpose of conveying expired and excess **anaesthetic gases (3.3)** to an appropriate place of discharge

NOTE Functionally, an anaesthetic gas scavenging system comprises three different parts: a transfer system, a receiving system and a disposal system. These three functionally discrete parts can be either separate or sequentially combined in part or in total. In addition, one or more parts of an anaesthetic gas scavenging system can be sequentially combined with an anaesthetic breathing system (e.g. as in an anaesthetic ventilator) to include the transfer system or transfer and receiving system.

3.2
active anaesthetic gas scavenging system
active AGSS
anaesthetic gas scavenging system (3.1) in which the gas flow in the **disposal system (3.4)** results from a powered device

3.3
anaesthetic gas
gas and/or vapour of a volatile agent used in anaesthesia

3.4
disposal system
that part of an **active AGSS (3.2)** by means of which the expired or excess **anaesthetic gases (3.3)** are conveyed from the **receiving system (3.14)** to the point of discharge by a **power device (3.13)**

NOTE The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.

1) To be published. (Revision of 9170-2:1999)

3.5
disposal hose
that part of a **disposal system (3.4)** which conveys expired and/or excess **anaesthetic gases (3.3)** and vapours from the **power device (3.13)** to the probe of an AGSS type 2 terminal unit

3.6
extract flow
flow of gas from the **transfer system (3.16)** and **receiving system (3.14)** of an **AGSS (3.1)** at the entry to the **disposal system (3.4)**

3.7
high-flow transfer and receiving system
transfer system (3.16) and **receiving system (3.14)** complying with this part of ISO 8835, which connects through a 1L **AGSS (3.1)** terminal unit as specified in ISO 9170-2 to a high-flow **disposal system (3.4)** complying with ISO 7396-2

3.8
induced flow
flow at the inlet of the **transfer system (3.16)**, which is generated by the **power device (3.13)** in the **disposal system (3.4)**

3.9
low-flow transfer and receiving system
transfer system (3.16) and **receiving system (3.14)** complying with this part of ISO 8835, which connects through a 1L **AGSS (3.1)** terminal unit as specified in ISO 9170-2 to a low-flow **disposal system (3.4)** complying with ISO 7396-2

3.10
maximum extract flow
highest flow of gas at the entry to the **disposal system (3.4)** that can be accommodated without exceeding the specified limitations for **induced flow (3.8)**

3.11
minimum extract flow
lowest flow of gas at the entry to the **disposal system (3.4)** that ensures that the specified limit of **spillage (3.15)** to atmosphere is not exceeded

3.12
non-operator-detachable connector
connector that is either permanent or can be separated only with the use of a tool

3.13
power device
that part of the **disposal system (3.4)** of an **active AGSS (3.2)** which generates the **extract flow (3.6)**

3.14
receiving system
that part of an **AGSS (3.1)** which provides an interface between the **transfer system (3.16)** and the **disposal system (3.4)**

3.15
spillage
volume of expired and/or excess **anaesthetic gas (3.3)** which cannot be accommodated by the **AGSS (3.1)** over a specified period

3.16
transfer system
that part of an **AGSS (3.1)** which transfers expired and/or excess **anaesthetic gases (3.3)** from the exhaust port of a breathing system, or associated equipment, to the **receiving system (3.14)**

3.17
transfer tube
that part of an AGSS **transfer system (3.16)** which transfers expired and/or excess **anaesthetic gases (3.3)** from the exhaust port of a breathing system, or associated equipment, to the **receiving system (3.14)**

4 General requirements and alternative test methods

4.1 Materials

All components of the AGSS shall be made of materials that are compatible with the gases and anaesthetic agents with which these components are designed to come into contact. These components shall also be designed and manufactured from materials that minimize the leaching of substances during normal use.

4.2 Means of pressure relief

The means of pressure relief, if provided, shall be accessible for cleaning and/or servicing.

NOTE When the means of pressure relief is actuated, gases might be spilled into the atmosphere.

4.3 Alternative test methods

The manufacturer may use type tests different from those described within 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 shall be used as the reference methods.

* 5 Patient and environmental protection

5.1 Normal operating conditions

* 5.1.1 Pressure

With a flow of 75 l/min of test gas into the inlet of the AGSS, the pressure at the inlet shall not exceed 350 Pa (3,5 cm H_2O). This requirement shall also be met when there is no extract flow at the outlet of the receiving system (e.g. when the power device is inoperative or disconnected from the receiving system).

NOTE If this requirement is met by means of pressure relief, the spillage requirements might not be met.

* 5.1.2 Induced flow

The effect of operating the AGSS at the maximum extract flow specified for the transfer and receiving system shall be such that the induced flow at the inlet to the AGSS shall not exceed 50 ml/min.

* 5.1.3 Sub-atmospheric pressure

The effect of operating the AGSS at the maximum extract flow specified for the transfer and receiving system shall be such that the sub-atmospheric pressure at the inlet of the receiving system shall not exceed 50 Pa (0,5 cm H_2O).

5.1.4 Spillage to atmosphere

With an input of test gas to the inlet of the transfer and receiving system at a frequency of 20 cycles/min, an I to E ratio 1:1 and a tidal volume of 1 l, spillage to atmosphere shall not exceed 100 ml/min.

NOTE See Annex E for possible test arrangements.

5.1.5 Leakage

The leakage rate of gas from the transfer and receiving system shall be less than 100 ml/min at a test gas flow of 10 ± 0,5 l/min.

Test methods used by the manufacturer shall be made available upon request.

Test procedures used by the manufacturer should be presented in the instruction manual. The test should include all components of the entire transfer and receiving system.

NOTE Leakage might be increased under single fault conditions.

5.2 Single fault conditions

5.2.1 Pressure

With a flow of 75 l/min of test gas into the inlet of the AGSS, the pressure at the inlet shall not exceed 2,0 kPa (20 cm H_2O).

5.2.2 Induced flow

The effect of operating the AGSS at the maximum extract flow specified for the transfer and receiving system shall be that the induced flowrate at the inlet to the AGSS shall not exceed 500 ml/min under single fault conditions.

5.2.3 Sub-atmospheric pressure

The sub-atmospheric pressure generated at the inlet of the receiving system shall not exceed 50 Pa (0,5 cm H_2O) at the maximum extract flows specified for the transfer and receiving system.

* 6 Connectors

6.1 Connectors fitted to hoses shall not be operator-detachable from the hose.

6.2 Conical connectors of size 30 mm shall comply with ISO 5356-1.

6.3 Connectors between subassemblies of AGSS transfer and receiving systems shall be designed to prevent misassembly. Such connections shall be incompatible with those used for medical gas pipeline systems (as specified in ISO 9170-1 and ISO 9170-2), hose assemblies (as specified in ISO 5359), breathing systems (as specified in ISO 8835-2) and other AGSS components. If conical connectors other than 30 mm are used they shall not be compatible with any connector complying with ISO 5356-1 or ISO 5356-2.

6.4 If provided, connectors into the AGSS for the scavenging of sample gas from a diverting respiratory gas monitor shall not be compatible with ISO 594-2.

* 7 Transfer systems

7.1 Inlet of transfer systems

7.1.1 The inlet to an interchangeable transfer system shall be a 30 mm diameter female connector complying with ISO 5356-1.

7.1.2 Interchangeable transfer systems shall either

a) include a means of pressure relief at the inlet

or

b) the transfer tube shall be so constructed (e.g. of wire-reinforced tubing) that the transfer system complies with 5.2.1.

7.1.3 The inlet to transfer systems that are not interchangeable shall comply with 6.1 and 6.3 and shall be either

— a proprietary fitting

or

— non-operator-detachable (permanent).

7.2 Outlet of transfer systems

7.2.1 The outlet of interchangeable transfer systems shall be a 30 mm diameter male conical connector complying with 6.1 and 6.2.

7.2.2 The outlet of transfer systems that are not interchangeable shall comply with 6.1 and 6.3 and shall be either

— a proprietary fitting

or

— non-operator-detachable (permanent).

* 8 Receiving systems

8.1 General

The receiving system intended for use with low-flow disposal systems shall meet the requirements of this part of ISO 8835 for spillage and induced flow throughout the entire flow range given in 9.1

The receiving system intended for use with high-flow disposal systems shall meet the requirements of this part of ISO 8835 for spillage and induced flow throughout the entire flow range given in 9.2

NOTE An operator-adjustable flow adjustment device can be used.

8.2 Inlet of receiving systems

8.2.1 The inlet of an interchangeable receiving system shall be a 30 mm diameter female conical connector complying with 6.2.

8.2.2 The inlet of a receiving system that is not interchangeable shall comply with 6.3 and shall be either

— a proprietary fitting

or

— non-operator-detachable (permanent).