INTERNATIONAL STANDARD

ISO 8835-3

First edition
1997-01-15

Inhalational anaesthesia systems —

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

Système d'anesthésie par inhalation —
Partie 3: Systèmes d'évacuation des gaz d'anesthésie — Systèmes de transfert et de réception

Reference number
ISO 8835-3:1997(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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 8835-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee 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*

NOTE — ISO 8835-1 will be published as IEC 601-2-13.

Annexes A to D form an integral part of this part of ISO 8835. Annex E is for information only.

Introduction

It is recognized that there are many factors affecting conditions within the operator's working environment which are outside the control of manufacturers of anaesthetic gas scavenging systems (AGSS). 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.

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

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

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

The devices for limiting the extent of pressure changes in breathing systems resulting from the use of AGSS should be as close as possible to, or within, the breathing system.

Protection against sub-atmospheric pressure and induced flow is less straightforward, experience having shown that any negative pressure at the patient end of an AGSS can induce a flow of gas from the breathing system under certain conditions. Such gas loss can be hazardous, for example, by reducing the fresh gas flowrate below the minimum required by the patient, by altering the composition of the inspired gas mixture, by affecting the proper functioning of disconnection alarms or other ventilatory measuring equipment, or by a combination of these factors.

As it is difficult to design the receiving system to prevent it inducing any flow from the breathing system to the inlet of the AGSS under all conditions, it has been decided to specify the limits of this flow. Requirements are included in this part of ISO 8835 for information concerning induced flow and warning statements, if applicable, to be supplied by the manufacturer [(see 11 b)].

Nonactive (passive) AGSS, i.e. those in which the air flow in the disposal system does not result from a powered device, have been excluded from

this part of ISO 8835 because they cannot meet the specified safety requirements under all conditions of use. Proximity gas extraction systems (i.e. systems not directly connected to the breathing system) are also excluded from this part of ISO 8835. Therefore this part of ISO 8835 is restricted to the transfer and receiving systems of active AGSS and to AGSS in which the receiving system and the disposal system are integrated.

Examples of typical arrangements of AGSS are shown in figure 1.

This page intentionally left blank

Inhalational anaesthesia systems —

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

1 Scope

This part of ISO 8835 specifies requirements for transfer and receiving systems of active anaesthetic gas scavenging systems (AGSS) intended to reduce the exposure of hospital personnel to anaesthetic gases and vapours. It does not apply to nonactive AGSS (passive AGSS) or to proximity gas extraction systems. This part of ISO 8835 also specifies requirements for AGSS in which the receiving system is integrated with the disposal system.

This part of ISO 8835 does not specify requirements for:

a) discrete disposal systems;

b) permanent disposal system installations.

This part of ISO 8835 does not specify connectors for purposes such as the connection of the exhaust outlet of gas monitors to the AGSS; a specification for such connectors is under consideration.

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 5356-1:1996, *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 connections.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 8835-1:— [1], *Inhalational anaesthetic systems — Part 1: Anaesthesia workstations and their components — Particular requirements.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

Munsell Book of Color [2].

3 Definitions

For the purposes of this part of ISO 8835, the following definitions apply.

3.1 active anaesthetic gas scavenging system (AGSS): AGSS in which the gas flow in the disposal system results from a power device.

3.2 anaesthetic gas: Gas and/or vapour of a volatile agent used in anaesthesia.

3.3 anaesthetic gas scavenging system (AGSS)**:** Complete system which is connected to the exhaust port of a breathing system or to other equipment for the purpose of conveying expired and/or excess anaesthetic gases to an appropriate place of discharge.

NOTE — Functionally, a complete system comprises three parts: a transfer system, a receiving system and a disposal system. These three functionally discrete parts may be either separate or sequentially combined in part or in total. In addition, one or more parts of an AGSS may be sequentially combined with a breathing system, e.g. as in a ventilator, to include the transfer system, or transfer and receiving systems.

3.4 breathing system: Those gas pathways continuously or intermittently in communication with the patient's respiratory tract during any form of ventilation.

NOTES

1) In practice a breathing system usually extends from:

   a) the point of supply of a controlled gas mixture, for example the fresh-gas outlet of an anaesthetic machine. In some situations, particularly in lung ventilators, this point may be inside a piece of equipment and should not be confused with a connection port fitted elsewhere, for example on the casing of a ventilator.

   b) the fresh-gas inlet of a circle system, lung ventilator, T-piece, etc.

   c) the fresh-gas inlet of a manually operated resuscitator.

2) The breathing system usually extends to the point at which the gas mixture escapes to atmosphere or to a gas scavenging system, for example from an APL valve, the open end of a T-piece, etc.

3) The exact arrangement of any system and the method of use influences and may affect the composition of a gas mixture.

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

5) It is not possible to eliminate all ambiguity in defining the term "breathing system". When this term is used in any standard or document, or other scientific publication, in which it could affect the precise interpretation thereof, the limits and configuration of any "breathing system" referred to therein should be clearly defined.

3.5 disposal system: That part of an AGSS by means of which the expired and/or excess anaesthetic gases are conveyed from a receiving system to a point of discharge.

NOTE — The disposal system contains a power device which may either form part of a permanent disposal system installation or be installed within the operator's working environment, either as a discrete device or integrated with the receiving system.

3.6 extract flow: Flow of gas from the transfer and receiving systems of an AGSS at the entry to the disposal system.

---

1) To be published.

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, MD, 21218 USA.

3.7 high-flow disposal system: Disposal system which, when connected to a high-flow transfer and receiving system complying with this part of ISO 8835, is able to generate an extract of flowrate of 75 l/min.

3.8 induced flow: Flow at the inlet of the transfer system which is caused by the subatmospheric pressure generated in the AGSS.

3.9 low-flow disposal system: Disposal system which, when connected to a low-flow transfer and receiving system complying with this part of ISO 8835, is able to generate extract flowrates of not more than 50 l/min.

3.10 maximum extract flowrate: Highest flowrate of gas at the entry to the disposal system which can be accommodated without exceeding the specified limitations for induced flow.

3.11 minimum extract flowrate: Lowest flowrate of gas at the entry to the disposal system which ensures that the specified limit of spillage to atmosphere is not exceeded.

3.12 non-operator-detachable equipment: Equipment that is connected by means of a permanent connection or a connection that can be detached only by the use of a tool.

3.13 power device: That part of the disposal system of an active AGSS which generates the extract flow.

3.14 receiving hose: That part of an AGSS which transfers expired and/or excess gases from the receiving system to the disposal system.

3.15 receiving system: That part of AGSS which provides an interface between a transfer system and a disposal system.

3.16 spillage: Volume of expired and/or excess anaesthetic gas which cannot be accommodated by the AGSS over a specified period.

3.17 transfer tube: That part of the AGSS transfer system which transfers gases from the breathing system to the receiving system.

3.18 transfer system: That part of an AGSS which transfers expired and/or excess anaesthetic gases from the exhaust port of a breathing system to a receiving system.

4 Patient and environmental protection

4.1 Normal operating conditions

4.1.1 Pressure

When tested by the method described in annex A, with continuous flowrates of 30 l/min and 75 l/min of air into the inlet of the AGSS, the pressure rise at this inlet shall not exceed 50 Pa (0,5 cmH_2O) and 350 Pa (3,5 cmH_2O) respectively. 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).

4.1.2 Induced flow

The effect of operating the AGSS at the maximum extract flow specified for the transfer and receiving systems shall be such that, when tested by the method described in annex B, the induced flowrate at the inlet to the AGSS shall not exceed 50 ml/min.

4.1.3 Spillage

When tested by the method described in annex C, the spillage to atmosphere shall not exceed 100 ml/min.

4.2 Single fault condition

4.2.1 Pressure

The pressure rise at the inlet of the AGSS shall not exceed 1,5 kPa (15 cmH_2O) when the procedure described in 4.1.1 is repeated at a flowrate of 75 l/min, having introduced single faults one at a time.

NOTE — An example of a single fault is occlusion of the transfer tubing.

4.2.2 Induced flow

The induced flowrate at the inlet to the AGSS shall not exceed 500 ml/min when the procedure described in 4.1.2 is repeated, having introduced single faults one at a time.

NOTE — An example of a single fault is occlusion of any air-entrainment inlet.

4.2.3 Spillage

Under single fault condition, gases may be spilled into the atmosphere at a rate in excess of 100 ml/min.

4.3 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.

5 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 may be spilled into the atmosphere.

6 Transfer systems

6.1 Inlet to interchangeable systems

The inlet to an interchangeable transfer system that incorporates a means of pressure relief shall be a 30 mm diameter female connector complying with 8.1 and 8.2.

6.2 Inlet to noninterchangeable systems

The inlet to a transfer system that does not incorporate a means of pressure relief shall be either:

a) a proprietary fitting complying with 8.1 and 8.3; or

b) non-operator-detachable. If the transfer system can be separated from the breathing system with the use of a tool, e.g. for servicing or repair, the connector shall comply with 8.1 and 8.3.

6.3 Outlet of transfer system

6.3.1 For interchangeable transfer and receiving systems, the outlet of the transfer system shall be a 30 mm diameter male conical connector complying with 8.1 and 8.2.

6.3.2 For noninterchangeable transfer and receiving systems which are operator-detachable, the outlet connector of the transfer system shall comply with 8.1 and 8.3.

7 Receiving systems

7.1 The inlet of an interchangeable receiving system shall be a 30 mm diameter female conical connector complying with 8.1 and 8.2.

7.2 The inlet of an operator-detachable, noninterchangeable receiving system shall have a connector complying with 8.1 and 8.3.

7.3 A visual indicator shall be provided to indicate that the AGSS is working below the maximum extract flowrate, if any, specified by the manufacturer and above the minimum extract flowrate specified by the manufacturer.

7.4 A particle filter, if provided, shall be located on the disposal side of the receiving system. It shall be removable without the use of a tool and its functional characteristics shall be disclosed by the manufacturer.

NOTE — If provided, the particle filter should be visible.

7.5 Hoses used in the receiving system shall comply with the requirements for hoses for vacuum services given in clauses 5, 6.5 and C.2 of ISO 5359:1989, and shall have connectors complying with 8.1 and 8.3.

7.6 The receiving system shall be provided, if required, with a means to reduce the extract flowrate to within the range specified by the manufacturer.

8 Connectors

8.1 If connectors are fitted to hoses, the connectors shall not be operator-detachable from the hose.

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

8.3 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, hose assemblies, breathing systems and other AGSS components. If conical, connectors shall not be compatible with any connector complying with ISO 5356-1 or ISO 5356-2.