
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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Contents

Page

Foreword.....	iv
Introduction	v
* 1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and alternative test methods	4
4.1 Materials	4
4.2 Means of pressure relief	4
4.3 Alternative test methods	4
* 5 Patient and environmental protection	4
5.1 Normal operating conditions	4
5.2 Single fault conditions	5
* 6 Connectors	5
* 7 Transfer systems	5
7.1 Inlet of transfer systems	5
7.2 Outlet of transfer systems	6
* 8 Receiving systems	6
8.1 General	6
8.2 Inlet of receiving systems	6
8.3 Outlet of receiving systems	7
8.4 Visual indicator	7
8.5 Particle filter	7
8.6 Receiving hoses	7
9 Extract flow resistance	7
9.1 Low-flow transfer and receiving systems	7
9.2 High-flow transfer and receiving systems	7
10 Electrical requirements	8
* 11 Information to be supplied by the manufacturer	8
12 Marking	8
* 13 Colour coding	8
Annex A (informative) Typical test arrangement and method for pressure measurement at inlet to AGSS	9
Annex B (informative) Typical test arrangement and method for sub-atmospheric pressure limitation	13
Annex C (informative) Typical test arrangement and method for testing of induced flow	14
Annex D (informative) Typical test arrangement and method for resistance to extract flow	15
Annex E (informative) Typical test arrangement and method for spillage	17
Annex F (informative) Rationale	20
Annex G (informative) Environmental aspects	22
Bibliography	23

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 asterisk (*) before their number have corresponding rationale contained in Annex F, included to provide additional insight into the reasoning that led to the requirements and recommendations 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)**